CERTIFICAT UE DE SYSTEME DE GESTION DE LA QUALITE
Règlement (UE) 2017/746, Annexe IX chapitres I et III

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/746, Annex IX chapters I and III

Certificat/*Certificate:* N° 38817 rev. 21

Délivré le/*Issued on:* September 30th, 2026

Certificat délivré à/*Certificate issued to:* **BIOMERIEUX S.A.**

376, Chemin de l'Orme

69280 MARCY L ETOILE FRANCE

SRN: FR-MF-000004436

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) d'audit du système de gestion de la qualité et le(s) rapport(s) d'évaluation de la documentation technique associé(s), le cas échéant, référencé(s) P602831 - P604661 - P604659 - P608204, le système de gestion de la qualité est conforme aux dispositions pertinentes du règlement (UE) 2017/746 pour les produits suivants :

GMED certifies that, on the basis of the results listed in the quality management system audit report(s) and the associated technical documentation assessment report, where appropriate, referenced P602831 - P604661 - P604659 - P608204, the quality management system complies with the relevant provisions of the regulation (EU) 2017/746 for the following products:

Dispositifs médicaux de diagnostic in vitro (trousses d'essai, réactifs, matériaux de contrôle, analyseurs et logiciels) destinés à être utilisés pour la culture, l'identification, la caractérisation des agents infectieux et les tests de sensibilité des agents antimicrobiens.

In vitro diagnostic medical devices (test kits, reagents, control materials, analyzers and software) intended to be used for culture, identification, characterization of infectious agents and susceptibility testing of antimicrobial agents.

Voir détails sur addendum / See addendum for additional information

Aux fins de la mise sur le marché de dispositifs de diagnostic in vitro de classe D, de diagnostics compagnons de classe C et de dispositifs de diagnostic in vitro d'autodiagnostic et de diagnostic près du patient de classe B et C, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/746 est requis. La validité du présent certificat est conditionnée au respect des obligations qui découlent du système de gestion de la qualité approuvé et de la surveillance effectuée par l'organisme notifié prévue par le règlement. Ce certificat est lié par les conditions du contrat.

For the purpose of placing on the market class D in vitro diagnostic devices, class C companion diagnostics and class B and C in vitro diagnostic devices for self-testing and near-patient testing, another certificate issued in accordance with the provisions of Regulation (EU) 2017/746 is required. The validity of this certificate is subject to compliance with the obligations arising from the approved quality management system and the surveillance carried out by the notified body as required by the regulation. This certificate is bound by the conditions of the contract.

Début de validité /*Effective date:* September 30th, 2026 (included)

Valable jusqu'au /*Expiry date:* April 5th, 2027 (included)

Signé par :
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On behalf of the President
Béatrice LYS
Technical Director

GMED - 38817 rev. 21
Modifie le certificat 38817-20

720 RDM 07/01-98 rev 3 du 29/JAN/2024

1. **Le cas échéant, le nom et l'adresse du mandataire /** *If applicable, the name and address of the authorised representative:*
   Non applicable / *Non applicable*

2. **Identification des sites /** *Identification of sites:*
   BIOMERIEUX S.A. - 376 Chemin de l'Orme - 69280 MARCY L'ETOILE - FRANCE
   BIOMERIEUX S.A. - Avenue des Bergeries - 01150 SAINT VULBAS - FRANCE
   BIOMERIEUX S.A. - 5 rue des Aqueducs - 69290 CRAPONNE - FRANCE
   BIOMERIEUX S.A. - 3 route de Port Michaud - 38390 LA BALME LES GROTTES - FRANCE
   BIOMERIEUX S.A. - 4 bis, rue des Coutures - 35270 COMBOURG - FRANCE
   BIOMERIEUX España S.A. - C/Isaac Newton n°6 - Parque Técnologico de Madrid Tres Cantos 28760 - ESPAGNE
   BIOMERIEUX Inc. Saint-Louis - 595 Anglum Road - Hazelwood - MO 63042 - ETATS-UNIS

3. **Identification des dispositifs /** *Identification of devices:*

Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
API® 10 S	10100	API® 10 S is a qualitative standardized system for the identification of Enterobacteriaceae and other non-fastidious Gram-negative rods. It uses miniaturized tests as well as a specially adapted database. Inoculation and reading of the strip are performed manually d the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure - Information for Identification Software.	B
API® 20 A	20300	API® 20 A is a qualitative standardized system for the identification of anaerobes. It uses miniaturized tests as well as a specially adapted database. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure -Information for Identification Software.	B

Signé par :
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On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • RCS Paris 839 022 522 • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • lne-gmed.com

Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
API® 20 C AUX	20210	API® 20 C AUX is a qualitative standardized system for the precise identification of the most frequently encountered yeasts. It uses miniaturized tests as well as a specially adapted database. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure - Information for Identification Software.	B
API® 20 E	20100 20160	API® 20 E is a qualitative standardized system for the identification of Enterobacteriaceae and other non-fastidious Gram-negative rods. It uses miniaturized tests as well as a specially adapted database. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure - Information for Identification Software.	B
API® 20 NE	20050	API® 20 NE is a qualitative standardized system for the identification of non-fastidious, non-enteric Gram-negative rods (for example, Pseudomonas, Acinetobacter, Moraxella, Vibrio, Aeromonas). It uses miniaturized tests as well as a specially adapted database. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure - Information for Identification Software.	B
API® 20 Strep	20600	API® 20 STREP is a qualitative standardized system for the group or species identification of most streptococci and enterococci, and those most common related organisms. It uses miniaturized tests as well as a specially adapted database. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure -Information for Identification Software.	B
API® Campy	20800	API® CAMPY is a qualitative standardized system for the identification of Campylobacter. It uses miniaturized tests as well as a specially adapted database. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure -Information for Identification Software.	B

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API® Candida	10500	API® CANDIDA is a qualitative standardized system for the identification in 18-24 hours of yeasts, notably those most frequently encountered in clinical microbiology. It uses miniaturized tests as well as a specially adapted database. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure - Information for Identification Software.	B
API® Coryne	20900	API® CORYNE is a qualitative standardized system for the identification of coryneform bacteria in 24 hours. It uses miniaturized tests as well as a specially adapted database. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure -Information for Identification Software.	B
API® Listeria	10300	API® LISTERIA is a qualitative standardized system for the identification of Listeria. It uses miniaturized tests as well as a specially adapted database. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure - Information for Identification Software.	B
API® NH	10400	API® NH is a qualitative standardized system for the identification of Neisseria, Haemophilus (and related genera) and Moraxella catarrhalis (Branhamella catarrhalis). It uses miniaturized tests as well as a specially adapted database. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure - Information for Identification Software. API® NH also enables the biotyping of Haemophilus influenzae and Haemophilus parainfluenzae, as well as the detection of a penicillinase.	B
API® Staph	20500	API® STAPH is a qualitative standardized system for the identification of the genera Staphylococcus, Micrococcus and Kocuria. It uses miniaturized tests as well as a specially adapted database. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure -Information for Identification Software.	B
BCP	70510	Reagent kit to be used with API® 20 A (20300), RAPID ID 32 E (32700) => refer to related Intended Use	B
EHR	70520	Reagent kit to be used with API® 20 A (20300) => refer to related Intended Use	B

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FB	70562	Reagent kit to be used with API® CAMPY (20800), ID 32 STAPH (32500), RAPID ID 32 A (32300), RAPID ID 32 STREP (32600) => refer to related Intended Use	B
ID 32 C	32200	ID 32 C is a qualitative standardized system for the identification of yeasts. It uses miniaturized tests as well as a specially adapted database. After manual inoculation of the strip, reading can be performed either automatically or manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure -Information for Identification Software.	B
ID 32 E	32400	ID 32 E is a qualitative standardized system for the identification of Enterobacteriaceae and other non-fastidious Gram-negative rods. It uses miniaturized tests as well as a specially adapted database. After manual inoculation of the strip, reading can be performed either automatically or manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure - Information for Identification Software.	B
ID 32 GN	32100	ID 32 GN is a qualitative standardized system for the automatic identification of Gram negative rods. It uses miniaturized assimilation tests as well as a specially adapted database. After manual inoculation of the strip, reading is performed automatically and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure -Information for Identification Software.	B
ID 32 STAPH	32500	ID 32 STAPH is a qualitative standardized system for the identification of the genera Staphylococcus, Micrococcus and related genera, Rothia and Aerococcus. It uses miniaturized tests as well as a specially adapted database. After manual inoculation of the strip, reading can be performed either automatically or manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure -Information for Identification Software.	B
JAMES	70542	Reagent kit to be used with API® NH (10400), API® 20 E (20100/20160), API® 10 S (10100), RAPID 20 ETM (20701), API® 20 NE (20050), ID 32 E (32400), RAPID ID 32 A (32300), RAPID ID 32 E (32700) => refer to related Intended Use	B
Kit API® 20 E Réactifs	20120	Reagent kit to be used with API® 20 E (20100/20160) => Refer to related Intended Use	B
NIN	70491	Reagent kit to be used with API® 20 STREP (20600), API® CAMPY (20800), RAPID ID 32 STREP (32600) => refer to related Intended Use	B

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NIT 1 + NIT 2	70442	Reagent kit to be used with API® 20 E (20100/20160), API® 10 S (10100), API® 20 NE (20050), API® STAPH (20500), API® CORYNE (20900), API® CAMPY (20800), ID 32 STAPH (32500), RAPID ID 32 A (32300) => refer to related Intended Use	B
PYZ	70492	Reagent kit to be used with API® CORYNE (20900) => refer to related Intended Use	B
RapiD 20 E™	20701	RAPID 20 E™ is a qualitative standardized system for the identification of Enterobacteriaceae in 4 hours, which uses 20 miniaturized biochemical tests chosen for their highly discriminant value and adapted to rapid interpretation. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure - Information for Identification Software.	B
rapid ID 32 A	32300	RAPID ID 32 A is a qualitative standardized system for the identification of anaerobes in four hours. It uses miniaturized tests as well as a specially adapted database. After manual inoculation of the strip, reading can be performed either automatically or manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure -Information for Identification Software.	B
rapid ID 32 E	32700	RAPID ID 32 E is a qualitative standardized system for the identification of Enterobacteriaceae in four hours. It uses miniaturized tests as well as a specially adapted database. After manual inoculation of the strip, reading can be performed either automatically or manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure - Information for Identification Software.	B
rapid ID 32 STREP	32600	RAPID ID 32 STREP is a qualitative standardized system for the identification of streptococci and enterococci, and those most common related organisms, in four hours. It uses miniaturized tests as well as a specially adapted database. After manual inoculation of the strip, reading can be performed either automatically or manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure -Information for Identification Software.	B
TDA	70402	Reagent kit to be used with API® 20 E (20100/20160), API® 10 S (10100) => Refer related Intended Use	B
VP 1 + VP 2	70422	Reagent kit to be used with API® 20 E (20100/20160), RAPID 20 ETM (20701), API® STAPH (20500), API® 20 STREP (20600) => refer to related Intended Use	B
VP A + VP B	70572	Reagent kit to be used with ID 32 STAPH (32500), RAPID ID 32 STREP (32600) => refer to related Intended Use	B

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XYL	70530	Reagent kit to be used with API® 20 A (20300) => refer to related Intended Use	B
Zn	70380	Reagent kit to be used with API® 20 E (20100/20160), API® 20 NE (20050) => Refer to related Intended Use	B
ZYM A	70494	Reagent kit to be used with API® STAPH (20500), API® 20 STREP (20600), API® CORYNE (20900), API® ZYM (25200) => refer to related Intended Use	B
ZYM B	70493	Reagent kit to be used with API® LISTERIA (10300), API® NH (10400), API® STAPH (20500), API® 20 STREP (20600), API® CORYNE (20900), API® ZYM (25200) => refer to related Intended Use	B
ETEST® Benzylpenicillin (PG) (0.016-256 µg/mL)	412263	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® PG can be used to determine the MIC of Benzylpenicillin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B
ETEST® Benzylpenicillin (PG) (0.002-32 µg/mL)	412265	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® PG can be used to determine the MIC of Benzylpenicillin against the following microorganisms: • Streptococci (β-hemolytic and viridans group) • Streptococcus pneumoniae • Neisseria gonorrhoeae	B

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ETEST® Cefotaxime (CT) (0.002-32 µg/mL)	412281	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® CT can be used to determine the MIC of Cefotaxime against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales ◦ Gram-positive aerobes: Staphylococcus • Streptococci (β-hemolytic and viridans group) • Haemophilus influenzae • Streptococcus pneumoniae • Neisseria gonorrhoeae	B
ETEST® Ceftazidime (TZ) (0.016-256 µg/mL)	412293	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® TZ can be used to determine the MIC of Ceftazidime against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Stenotrophomonas maltophilia, Acinetobacter • Haemophilus influenzae	B

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
ETEST® Ceftriaxone (TX) (0.016-256 µg/mL)	412301	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® TX can be used to determine the MIC of Ceftriaxone against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas ◦ Gram-positive aerobes: Staphylococcus • Streptococcus pneumoniae	B
ETEST® Ceftriaxone (TX) (0.002-32 µg/mL)	412303	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® TX can be used to determine the MIC of Ceftriaxone against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales • Streptococcus spp. (excluding Streptococcus pneumoniae) • Haemophilus influenzae • Neisseria gonorrhoeae	B

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
ETEST® Ciprofloxacin (CI) (0.002-32 µg/mL)	412311	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® CI can be used to determine the MIC of Ciprofloxacin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Acinetobacter ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Neisseria gonorrhoeae	B
ETEST® Gentamicin (GM) (0.016-256 µg/mL)	412368	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® GM can be used to determine the MIC of Gentamicin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Acinetobacter ◦ Gram-positive aerobes: Staphylococcus	B

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
ETEST® Imipenem (IP) (0.002-32 µg/mL)	412374	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® IP can be used to determine the MIC of Imipenem against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Acinetobacter ◦ Gram-positive aerobes: Enterococcus • Streptococcus pneumoniae • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B
ETEST® Meropenem (MP) (0.002-32 µg/mL)	412402	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® MP can be used to determine the MIC of Meropenem against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Acinetobacter, Pseudomonas aeruginosa, Stenotrophomonas maltophilia • Haemophilus influenzae • Streptococcus pneumoniae • Streptococcus (others) • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Prevotella, Fusobacterium ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods and Gram-positive cocci	B

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ETEST® Minocycline (MC) (0.016-256 µg/mL)	412409	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® MC can be used to determine the MIC of Minocycline against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Stenotrophomonas maltophilia, Pseudomonas, Acinetobacter ◦ Gram-positive aerobes: Staphylococcus, Enterococcus	B
ETEST® Vancomycin (VA) (0.016-256 µg/mL)	412488	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® VA can be used to determine the MIC of Vancomycin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococcus spp. • Streptococcus pneumoniae	B

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On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • RCS Paris 839 022 522 • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • lne-gmed.com

Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
ETEST® Ceftolozane/ Tazobactam (C/T) (0.016-256/4 µg/mL)	414447	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® C/T can be used to determine the MIC of Ceftolozane/Tazobactam against the following microorganisms: Active both in vitro and in clinical infections: • Gram-negative aerobes: ◦ Enterobacterales: ▪ Enterobacter cloacae ▪ Escherichia coli ▪ Klebsiella oxytoca ▪ Klebsiella pneumoniae ▪ Proteus mirabilis ◦ Pseudomonas aeruginosa	B

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ETEST® Imipenem/Relebactam (IPR) (0.002-32/4 µg/mL)	420925	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE Imipenem/Relebactam has been shown to be active against the Gram-negative aerobic microorganisms listed below according to the EMA or FDA labels for this antimicrobial agent. ETEST® IPR can be used to determine the MIC of Imipenem/Relebactam against the following microorganisms: Active both in vitro and in clinical infections: • Aerobes: o Gram-negative aerobes: - Citrobacter freundii - Enterobacter cloacae/Enterobacter cloacae complex - Escherichia coli - Klebsiella aerogenes - Klebsiella oxytoca - Klebsiella pneumoniae	B
ETEST® Piperacillin/Tazobactam (P/T) (0.016-256/4 µg/mL)	421166	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of both non-fastidious Gram negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE Piperacillin/Tazobactam has been shown to be active against the Gram-negative aerobic microorganisms listed below according to the EMA or FDA label for this antimicrobial agent. ETEST® P/T can be used to determine the MIC of Piperacillin/Tazobactam against the following microorganisms: Active both in vitro and in clinical infections: Enterobacteriaceae ;Pseudomonas aeruginosa ;Acinetobacter spp.	B

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ETEST® Meropenem/Vaborbactam (MEV) (0.004-64/8 µg/mL)	421563	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE Meropenem/Vaborbactam has been shown to be active against the Gram-negative aerobic microorganisms listed below according to the FDA/EMA label for this antimicrobial agent. ETEST® MEV can be used to determine the MIC of Meropenem/Vaborbactam against the following microorganisms: Active both in vitro and in clinical infections: Enterobacter cloacae complex Escherichia coli Klebsiella pneumoniae In vitro data are available for the following microorganisms, but clinical significance is unknown: Citrobacter freundii Citrobacter koseri Klebsiella aerogenes Klebsiella oxytoca Morganella morganii Providencia spp. Serratia marcescens Pseudomonas aeruginosa (EMA only)	B

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ETEST® Delafloxacin (DFX) (0.002-32 µg/mL)	421771	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE Delafloxacin has been shown to be active against the aerobic microorganisms listed below according to the EMA and FDA labels for this antimicrobial agent. ETEST® DFX can be used to determine the MIC of Delafloxacin against the following microorganisms: Active both in vitro and in clinical infections: · Aerobes: o Gram-positive aerobes: - Staphylococcus aureus (including methicillin-resistant and methicillin-susceptible strains) - Staphylococcus haemolyticus - Staphylococcus lugdunensis - Staphylococcus hominis (EMA only) - Enterococcus faecalis o Gram-negative aerobes: - Pseudomonas aeruginosa	B

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ETEST® Imipenem (IP) (0.002-32 µg/mL)	423635	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® IP can be used to determine the MIC of Imipenem against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Acinetobacter ◦ Gram-positive aerobes: Enterococcus • Streptococcus pneumoniae • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B
ETEST® Benzylpenicillin (PG) (0.016-256 µg/mL)	423764	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® PG can be used to determine the MIC of Benzylpenicillin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B

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ETEST® Ciprofloxacin (CI) (0.002-32 µg/mL)	423766	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® CI can be used to determine the MIC of Ciprofloxacin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Acinetobacter ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Neisseria gonorrhoeae	B
ETEST® Gentamicin (GM) (0.016-256 µg/mL)	423770	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® GM can be used to determine the MIC of Gentamicin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Acinetobacter ◦ Gram-positive aerobes: Staphylococcus	B

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ETEST® Ceftriaxone (TX) (0.016-256 µg/mL)	423772	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® TX can be used to determine the MIC of Ceftriaxone against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas ◦ Gram-positive aerobes: Staphylococcus • Streptococcus pneumoniae	B
ETEST® Cefotaxime (CT) (0.002-32 µg/mL)	423774	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® CT can be used to determine the MIC of Cefotaxime against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales ◦ Gram-positive aerobes: Staphylococcus • Streptococci (β-hemolytic and viridans group) • Haemophilus influenzae • Streptococcus pneumoniae • Neisseria gonorrhoeae	B

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ETEST® Ceftolozane/ Tazobactam (C/T) (0.016-256/4 µg/mL)	423777	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® C/T can be used to determine the MIC of Ceftolozane/Tazobactam against the following microorganisms:Active both in vitro and in clinical infections: • Gram-negative aerobes: ◦ Enterobacterales: ▪ Enterobacter cloacae ▪ Escherichia coli ▪ Klebsiella oxytoca ▪ Klebsiella pneumoniae ▪ Proteus mirabilis ◦ Pseudomonas aeruginosa	B
ETEST® Ceftazidime (TZ) (0.016-256 µg/mL)	423779	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® TZ can be used to determine the MIC of Ceftazidime against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Stenotrophomonas maltophilia, Acinetobacter • Haemophilus influenzae	B

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ETEST® Ceftriaxone (TX) (0.002-32 µg/mL)	423781	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® TX can be used to determine the MIC of Ceftriaxone against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales • Streptococcus spp. (excluding Streptococcus pneumoniae) • Haemophilus influenzae • Neisseria gonorrhoeae	B
ETEST® Piperacillin/Tazobactam (P/T) (0.016-256/4 µg/mL)	423783	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE Piperacillin/Tazobactam has been shown to be active against the Gram-negative aerobic microorganisms listed below according to the EMA and/or FDA labels for this antimicrobial agent. ETEST® P/T can be used to determine the MIC of Piperacillin/Tazobactam against the following microorganisms: Active both in vitro and in clinical infections: • Gram-negative aerobes: Enterobacterales, Pseudomonas aeruginosa, Acinetobacter spp.	B

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ETEST® Meropenem (MP) (0.002-32 µg/mL)	423785	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® MP can be used to determine the MIC of Meropenem against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Acinetobacter, Pseudomonas aeruginosa, Stenotrophomonas, maltophilia • Haemophilus influenzae • Streptococcus pneumoniae • Streptococcus (others) • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Prevotella, Fusobacterium ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods and Gram-positive cocci	B
ETEST® Vancomycin (VA) (0.016-256 µg/mL)	423787	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® VA can be used to determine the MIC of Vancomycin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococcus spp. • Streptococcus pneumoniae	B

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ETEST® Benzylpenicillin (PG) (0.002-32 µg/mL)	423791	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® PG can be used to determine the MIC of Benzylpenicillin against the following microorganisms: • Streptococci (β-hemolytic and viridans group) • Streptococcus pneumoniae • Neisseria gonorrhoeae	B
Mueller Hinton agar with 5 % horse blood + 20 mg/L ß-NAD	43901 43904	Study of the antimicrobial susceptibility of fastidious microorganisms. This medium is a medium for disk diffusion antimicrobial susceptibility testing of fastidious microorganisms (pneumococci and other streptococci, Haemophilus, Moraxella, Campylobacter, Pasteurella, Listeria monocytogenes and Corynebacterium). The medium has been developed according to EUCAST [European Committee on Antimicrobial Susceptibility Testing] recommendations.	B
RPMI agar	421988 AEB122182	Antifungal susceptibility testing of yeasts and moulds with ETEST®. This culture medium is specially formulated for carrying out antifungal susceptibility testing of yeasts and molds when using ETEST® method. It is recommended for the antifungal susceptibility testing with ETEST® (for example: caspofungin, fluconazole, flucytosine, ketoconazole, voriconazole, itraconazole, amphotericin B, posaconzole, anidulafungin, micafungin).	B
MUELLER HINTON CLOXA agar	421989 AEB120291	Confirmation of ESBL-producing bacteria. The Mueller-Hinton medium supplemented with cloxacillin is dedicated to the confirmation of Enterobacteriaceae strains potentially ESBL (Extended-Spectrum β-Lactamase-producing Enterobacteriaceae). The ESBL characteristic can be masked by an overproduction of cephalosporinase in Mueller-Hinton conventional media and become undetectable by the usual confirmation techniques (for example: ETEST® method, “champagne cork” synergy method, combined disks method).	B
VITEK® MS Prime Software (v1.1)	423882	VITEK® MS PRIME is a mass spectrometry system using matrix-assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) for the identification of microorganisms cultured from human specimens. The VITEK® MS PRIME System is a qualitative in vitro diagnostic device used in conjunction with other laboratory tests to aid in the diagnosis of bacterial, yeast and mould infections.	B

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EF33BDA9BAA04A3...
GMED GROUPE LNE

On behalf of the President
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Technical Director

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ETEST® Amikacin (AK) (0.016-256 µg/mL)	412219	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® AK can be used to determine the MIC of Amikacin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas aeruginosa, Stenotrophomonas maltophilia, Acinetobacter ◦ Gram-positive aerobes: Staphylococcus, Enterococcus	B
ETEST® Ampicillin (AM) (0.016-256 µg/mL)	412253	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® AM can be used to determine the MIC of Ampicillin against the following microorganisms: - Aerobes: o Gram-negative aerobes: Enterobacterales o Gram-positive aerobes: Staphylococcus, Enterococcus - Haemophilus influenzae	B

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ETEST® Azithromycin (AZ) (0.016-256 µg/mL)	412257	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® AZ can be used to determine the MIC of Azithromycin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphyloccocus • Streptococcus pneumoniae • Haemophilus influenzae	B
ETEST® Cefepime (PM) (0.016-256 µg/mL)	412273	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® PM can be used to determine the MIC of Cefepime against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas aeruginosa, Stenotrophomonas maltophilia, Acinetobacter • Streptococcus pneumoniae • Haemophilus influenzae	B

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ETEST® Clindamycin (CM) (0.016-256 µg/mL)	412315	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® CM can be used to determine the MIC of Clindamycin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococcus • Streptococcus pneumoniae • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B
ETEST® Linezolid (LZ) (0.016-256 µg/mL)	412396	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® LZ can be used to determine the MIC of Linezolid against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococcus pneumoniae	B

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ETEST® Metronidazole (MZ) (0.016-256 µg/mL)	412404	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® MZ can be used to determine the MIC of Metronidazole against the following microorganisms: • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B
ETEST® Teicoplanin (TP) (0.016-256 µg/mL)	412461	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® TP can be used to determine the MIC of Teicoplanin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus aureus, Enterococcus	B
ETEST® Tobramycin (TM) (0.016-256 µg/mL)	412479	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® TM can be used to determine the MIC of Tobramycin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas aeruginosa, Acinetobacter ◦ Gram-positive aerobes: Staphylococcus aureus	B

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On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • RCS Paris 839 022 522 • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • lne-gmed.com

Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
ETEST® Ceftazidime/Avibactam (CZA) (0.016-256/4 µg/mL)	419556	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE Ceftazidime/Avibactam has been shown to be active against the Gram-negative aerobic microorganisms listed below according to the EMA and/or FDA labels for this antimicrobial agent. ETEST® CZA can be used to determine the MIC of Ceftazidime/Avibactam against the following microorganisms: Active both in vitro and in clinical infections: • Gram-negative aerobes: ◦ Enterobacterales: ▪ Citrobacter freundii ▪ Enterobacter cloacae ▪ Escherichia coli ▪ Klebsiella oxytoca ▪ Klebsiella pneumoniae ▪ Proteus mirabilis ▪ Serratia marcescens ◦ Pseudomonas aeruginosa In vitro data are available for the following microorganisms, but clinical significance is unknown: • Citrobacter koseri • Enterobacter aerogenes • Morganella morganii • Providencia rettgeri • Providencia stuartii (FDA only) • Proteus vulgaris (EMA only)	B

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ETEST® Azithromycin (AZ) (0.016-256 µg/mL)	423789	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® AZ can be used to determine the MIC of Azithromycin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphyloccocus • Streptococcus pneumoniae • Haemophilus influenzae	B
ETEST® Tobramycin (TM) (0.016-256 µg/mL)	423793	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® TM can be used to determine the MIC of Tobramycin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas aeruginosa, Acinetobacter ◦ Gram-positive aerobes: Staphylococcus aureus	B
ETEST® Teicoplanin (TP) (0.016-256 µg/mL)	423795	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® TP can be used to determine the MIC of Teicoplanin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus aureus, Enterococcus	B

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ETEST® Cefepime (PM) (0.016-256 µg/mL)	423796	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® PM can be used to determine the MIC of Cefepime against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas aeruginosa, Stenotrophomonas maltophilia, Acinetobacter • Streptococcus pneumoniae • Haemophilus influenzae	B
ETEST® Metronidazole (MZ) (0.016-256 µg/mL)	423798	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® MZ can be used to determine the MIC of Metronidazole against the following microorganisms: • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B

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ETEST® Amikacin (AK) (0.016-256 µg/mL)	423800	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® AK can be used to determine the MIC of Amikacin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas aeruginosa, Stenotrophomonas maltophilia, Acinetobacter ◦ Gram-positive aerobes: Staphylococcus, Enterococcus	B

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ETEST® Ceftazidime/Avibactam (CZA) (0.016-256/4 µg/mL)	423802	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE Ceftazidime/Avibactam has been shown to be active against the Gram-negative aerobic microorganisms listed below according to the EMA and/or FDA labels for this antimicrobial agent. ETEST® CZA can be used to determine the MIC of Ceftazidime/Avibactam against the following microorganisms: Active both in vitro and in clinical infections: • Gram-negative aerobes: ◦ Enterobacterales: ▪ Citrobacter freundii ▪ Enterobacter cloacae ▪ Escherichia coli ▪ Klebsiella oxytoca ▪ Klebsiella pneumoniae ▪ Proteus mirabilis ▪ Serratia marcescens ◦ Pseudomonas aeruginosa In vitro data are available for the following microorganisms, but clinical significance is unknown: • Citrobacter koseri • Enterobacter aerogenes • Morganella morganii • Providencia rettgeri • Providencia stuartii (FDA only) • Proteus vulgaris (EMA only)	B

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ETEST® Linezolid (LZ) (0.016-256 µg/mL)	423804	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® LZ can be used to determine the MIC of Linezolid against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococcus pneumoniae	B
ETEST® Ampicillin (AM) (0.016-256 µg/mL)	423806	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® LZ can be used to determine the MIC of Linezolid against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococcus pneumoniae	B

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ETEST® Clindamycin (CM) (0.016-256 µg/mL)	423808	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® CM can be used to determine the MIC of Clindamycin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococcus • Streptococcus pneumoniae • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B
ETEST® Cefixime (IX) (0.016-256 µg/mL)	412275	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® IX can be used to determine the MIC of Cefixime against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales	B

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ETEST® Cefixime (IX) (0.016-256 µg/mL)	423981	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® IX can be used to determine the MIC of Cefixime against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales	B
ETEST® Daptomycin (DPC) (0.016-256 µg/mL)	412324	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/ml) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® DPC can be used to determine the MIC of Daptomycin against the following microorganisms: • Aerobes ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococci: S. pyogenes A, S. agalactiae B, S. dysgalactiae	B

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ETEST® Daptomycin (DPC) (0.016-256 µg/mL)	423812	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/ml) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® DPC can be used to determine the MIC of Daptomycin against the following microorganisms: • Aerobes ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococci: S. pyogenes A, S. agalactiae B, S. dysgalactiae	B

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
ETEST® Doripenem (DOR) (0.002-32 µg/mL)	412326	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/ml) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® DOR 32 can be used to determine the MIC of Doripenem against the following microorganisms: Aerobes: - Gram-negative aerobes: Enterobacterales, Pseudomonas aeruginosa, Acinetobacter baumannii Anaerobes: - Gram-positive anaerobes Peptostreptococcus spp. - Gram-negative anaerobes: Bacteroides.	B

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ETEST® Doxycycline (DC) (0.016-256 µg/mL)	412328	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® DC can be used to determine the MIC of Doxycycline against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Acinetobacter, Pseudomonas aeruginosa, Stenotrophomonas maltophilia ◦ Gram-positive aerobes: Staphylococcus, Enterococcus	B
ETEST® Doxycycline (DC) (0.016-256 µg/mL)	424152	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® DC can be used to determine the MIC of Doxycycline against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Acinetobacter, Pseudomonas aeruginosa, Stenotrophomonas maltophilia ◦ Gram-positive aerobes: Staphylococcus, Enterococcus	B

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
ETEST® Ertapenem (ETP) (0.002-32 µg/mL)	412332	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® ETP can be used to determine the MIC of Ertapenem against the following microorganisms: • Aerobes: o Gram-negative aerobes: Escherichia coli, Klebsiella pneumoniae • Haemophilus influenzae • Anaerobes: o Gram-negative anaerobes: Bacteroides, Prevotella o Gram-positive anaerobes: non-sporeforming Gram-positive rods, Gram-positive cocci	B

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ETEST® Ertapenem (ETP) (0.002-32 µg/mL)	423768	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE ETEST® ETP can be used to determine the MIC of Ertapenem against the following microorganisms: • Aerobes: oGram-negative aerobes: Escherichia coli, Klebsiella pneumoniae • Haemophilus influenzae • Anaerobes: o Gram-negative anaerobes: Bacteroides, Prevotella o Gram-positive anaerobes: non-sporeforming Gram-positive rods, Gram-positive cocci	B
API® 50 CH	50300	API® 50 CH is a qualitative standardized system, associating 50 biochemical tests for the study of the carbohydrate metabolism of microorganisms. API® 50 CH is used in conjunction with API® 50 CHL Medium for the identification of Lactobacillus and related genera and with API® 50 CHB/E Medium for the identification of Bacillus and related genera, Enterobacteriaceae, and Vibrionaceae. Inoculation and reading of the strip are performed manually and the identification is obtained using an identification software. The complete list of those organisms that it is possible to identify with this system is given in the Technical Brochure - Information for Identification Software.	B

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API® 50 CHL Medium	50410	API® 50 CHL Medium, intended for the identification of the genus Lactobacillus and related genera, is a ready-to-use medium which allows the study of the fermentation of the 49 carbohydrates on the API® 50 CH strip.	B
API® 50 CHB/E Medium	50430	API® 50 CHB/E Medium is intended for the identification of Bacillus and related genera, as well as Gram-negative rods belonging to the Enterobacteriaceae and Vibrionaceae families. It is a ready-to-use medium which allows the study of the fermentation of the 49 carbohydrates on the API® 50 CH strip. Note: Genera formerly included in the family Enterobacteriaceae were reorganized to an order (Enterobacterales) containing seven families: Budviciaceae, Enterobacteriaceae, Erwiniaceae, Hafniaceae, Morganellaceae, Pectobacteriaceae, Yersiniaceae. Therefore, the bacterial species identified belong to the family Enterobacteriaceae and to one or more species in the other families mentioned.	B
RAPIDEC® CARBA NP	415418 417498	The RAPIDEC® CARBA NP test is a ready-to-use qualitative standardized system for the rapid detection of Carbapenemase producing Gram-negative bacilli such as Enterobacterales, Pseudomonas aeruginosa and Acinetobacter baumannii, using bacteria cultured on an agar medium.	B
CHROMID® CPS® Elite Agar (CPSE)	418284 416172	CHROMID® CPS® Elite agar is an isolation, enumeration and identification medium for urine specimens. This medium enables: • the microbial enumeration of the specimen by means of standardized inoculation methods. • the direct identification of Escherichia coli • the presumptive identification of the following bacterial species or genera: - Enterococcus, - Klebsiella, Enterobacter, Serratia, Citrobacter (KESC), - Proteus, Providencia, Morganella (Proteeae).	B

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CHROMID® CPS® Elite Agar (CPSO)	418206 416173	CHROMID® CPS® Elite agar is an isolation, enumeration and identification medium for urine specimens. This medium enables: • the microbial enumeration of the specimen by means of standardized inoculation methods. • the direct identification of Escherichia coli • the presumptive identification of the following bacterial species or genera: - Enterococcus, - Klebsiella, Enterobacter, Serratia, Citrobacter (KESC), - Proteus, Providencia, Morganella (Proteeae).	B
CHROMID® MRSA agar	43451 43459	Chromogenic medium for the screening of methicillin-resistant Staphylococcus aureus (MRSA). This chromogenic medium is intended for the screening of methicillin-resistant S. aureus (MRSA) in chronic carriers or patients who are at risk for MRSA. This medium does not replace conventional antimicrobial susceptibility tests. MRSA are multi-resistant bacteria which may cause nosocomial infections. The detection of MRSA carriers is particularly important for the epidemiological prevention and monitoring of these infections. In this context, the use of this medium contributes towards the active surveillance of MRSA.	C
CHROMID® Strepto B agar	43461	Selective chromogenic medium for the screening of group B streptococci (S. agalactiae). This selective chromogenic medium is intended for the screening of S. agalactiae carriage in pregnant women specimens. S. agalactiae can cause serious and potentially fatal infections in newborns. Detection of S. agalactiae carriage in pregnant women allows antimicrobial prophylaxis to be administered at the time of delivery to prevent perinatal infections.	C

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CHROMID® VRE agar	43004	Selective chromogenic medium for the detection and differentiation of Enterococcus faecium and Enterococcus faecalis showing acquired vancomycin resistance (VRE). CHROMID® VRE Agar is a selective chromogenic medium for the detection of E. faecium and E. faecalis showing acquired vancomycin resistance (VRE) in at risk patients. It enables the differentiation of E. faecium and E. faecalis. The E. faecium and E. faecalis with acquired vancomycin resistance (mainly genotypes vanA and vanB are multi-resistant bacteria which can be responsible for health care-associated infections. The detection of this resistance is particularly important for the prevention and epidemiological surveillance of these infections and also to prevent the emergence of vancomycin-resistant Staphylococcus aureus (VRSA), by transmission of the vanA gene. This medium is not a substitute for the conventional antimicrobial susceptibility test methods.	C
GRANADA™ AGAR	43712	Selective medium for the screening and identification of group B streptococci (S. agalactiae). This selective medium is intended for the screening and direct identification of Streptococcus agalactiae carriage in pregnant women and newborns using clinical specimens. The medium was first described by Dr De La Rosa et al. It was developed from the previous work of A.K.M.S Islam and Dr De La Rosa. S. agalactiae are responsible for serious infections in newborns (meningitis). Their detection is particularly important for the prevention, treatment, and monitoring of infections.	C
ETEST® Anidulafungin (AND) (0.002-32 µg/mL)	423998	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts and moulds. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® AND can be used to determine the MIC of Anidulafungin against the following microorganisms: • Yeasts: Candida spp. • Moulds: Aspergillus spp., Fusarium spp., Rhizopus spp.	B

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On behalf of the President
Béatrice LYS
Technical Director

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ETEST® Ceftaroline (CPT) (0.002-32 µg/mL)	424000	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® CPT can be used to determine the MIC of Ceftaroline against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphyloccocus aureus • Streptococcus pneumoniae • Streptococcus agalactiae • Haemophilus influenzae	B
ETEST® Gentamicin (GM) (0.064-1024 µg/mL)	424004	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® GM can be used to determine the MIC of Gentamicin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Enterococcus* * suitable for the detection of high-level aminoglycoside resistance (HLAR)	B

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
ETEST® Imipenem/Relecbactamn (IPR) (0.002-32/4 µg/mL)	423988	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. Imipenem/Relebactam has been shown to be active against the Gram-negative aerobic microorganisms listed below according to the EMA or FDA labels for this antimicrobial agent. ETEST® IPR can be used to determine the MIC of Imipenem/Relebactam against the following microorganisms: Active both in vitro and in clinical infections: • Citrobacter freundii • Enterobacter cloacae/Enterobacter cloacae complex • Escherichia coli • Klebsiella aerogenes • Klebsiella oxytoca • Klebsiella pneumoniae	B
ETEST® Micafungin (MYC) (0.002-32 µg/mL)	424008	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® MYC can be used to determine the MIC of Micafungin against the following microorganisms: • Yeasts: Candida spp.	B
ETEST® Mupirocin (MU) (0.064-1024 µg/mL)	424011	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® MU can be used to determine the MIC of Mupirocin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus	B

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CHROMID® S.aureus Elite agar	419042	This chromogenic medium is intended for the selective isolation and the direct identification of S. aureus in human specimens: • in 18 to 24 hours for the following specimens: blood cultures, nasal swabs, suppurations, ear/nose/throat samples, genital samples, stool samples, skin samples from serious burn victims, respiratory samples (including respiratory samples from patients with cystic fibrosis), • and up to 48 to 72 hours for respiratory samples from patients with cystic fibrosis. This medium is intended for the prevention and diagnosis of S. aureus infections using samples of human origin.	C
CHROMID® P. aeruginosa Agar	43462	This medium is intended for the direct identification of Pseudomonas aeruginosa in pulmonary specimens. Pseudomonas aeruginosa is the primary cause of nosocomial pneumopathies. It is also responsible for chronic infections in cystic fibrosis patients.	C
ETEST® Cefoxitin (FX) (0.016-256 µg/mL)	423826 412285	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® FX can be used to determine the MIC of Cefoxitin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales ◦ Gram-positive aerobes: Staphylococcus • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B

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ETEST® Ampicillin/Sulbactam (2/1) (AB) (0.016-256 µg/mL)	412251	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® AB can be used to determine the MIC of Ampicillin/Sulbactam (2/1) against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales • Haemophilus influenzae • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium, Prevotella ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B
ETEST® Amoxicillin/Clavulanic Acid (2/1) (XL) (0.016-256 µg/mL)	412241	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® XL can be used to determine the MIC of Amoxicillin/Clavulanic Acid (2/1) against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales • Streptococcus pneumoniae • Haemophilus influenzae • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium, Prevotella ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B

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ETEST® Rifampicin (RI) (0.002-32 µg/mL)	412450 423825	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® RI can be used to determine the MIC of Rifampicin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococcus pneumoniae	B
ETEST® Piperacillin (PP) (0.016-256 µg/mL)	412436	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® PP can be used to determine the MIC of Piperacillin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Acinetobacter	B
VITEK® MS KB 3.3	424203	VITEK® MS is a mass spectrometry system using matrix-assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) for the identification of microorganisms cultured from human specimens. The VITEK® MS System is a qualitative in vitro diagnostic device used in conjunction with other laboratory tests to aid in the diagnosis of bacterial, yeast and mould infections.	B

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ETEST® ESBL Ceftazidime/Ceftazidime + Clavulanic Acid (TZ/TZL) (0.5-32/0.064-4 µg/mL)	423992	ETEST® ESBL Cefotaxime/Cefotaxime + Clavulanic Acid (CT/CTL) and ETEST® ESBL Ceftazidime/Ceftazidime + Clavulanic Acid (TZ/TZL) strips are designed to confirm the presence of Clavulanic Acid inhibitable ESBL (Extended Spectrum β-Lactamase) enzymes in Enterobacterales using a manual, qualitative technique. The suspected presence of ESBL in strains with phenotypic susceptibility patterns, where Minimum Inhibitory Concentration (MIC) values of Aztreonam, Cefotaxime, Ceftazidime, Ceftriaxone or Cefpodoxime are ≥ 1 µg/mL, should be confirmed using both ETEST® ESBL CT/CTL and ETEST® ESBL TZ/TZL strips. ETEST® ESBL CT/CTL and ETEST® ESBL TZ/TZL can be used to confirm the presence of Clavulanic Acid inhibitable ESBL (Extended Spectrum β-lactamase) enzymes in the following microorganisms: Enterobacterales: Escherichia coli, Klebsiella spp.	B
ETEST® ESBL Cefotaxime/Cefotaxime + Clavulanic Acid (CT/CTL) (0.25-16/0.016-1 µg/mL)	423994	ETEST® ESBL Cefotaxime/Cefotaxime + Clavulanic Acid (CT/CTL) and ETEST® ESBL Ceftazidime/Ceftazidime + Clavulanic Acid (TZ/TZL) strips are designed to confirm the presence of Clavulanic Acid inhibitable ESBL (Extended Spectrum β-Lactamase) enzymes in Enterobacterales using a manual, qualitative technique. The suspected presence of ESBL in strains with phenotypic susceptibility patterns, where Minimum Inhibitory Concentration (MIC) values of Aztreonam, Cefotaxime, Ceftazidime, Ceftriaxone or Cefpodoxime are ≥ 1 µg/mL, should be confirmed using both ETEST® ESBL CT/CTL and ETEST® ESBL TZ/TZL strips. ETEST® ESBL CT/CTL and ETEST® ESBL TZ/TZL can be used to confirm the presence of Clavulanic Acid inhibitable ESBL (Extended Spectrum β-lactamase) enzymes in the following microorganisms: Enterobacterales: Escherichia coli, Klebsiella spp.	B

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ETEST® ESBL Cefepime/Cefepime + Clavulanic Acid (PM/PML) (0.25-16/0.064-4 µg/mL)	423996	ETEST® ESBL Cefepime/Cefepime + Clavulanic Acid (PM/PML) strips are designed to confirm the presence of Clavulanic Acid inhibitable ESBL (Extended Spectrum β-Lactamase) enzymes in Enterobacterales using a manual, qualitative technique. The suspected presence of ESBL in strains with phenotypic susceptibility patterns, where Minimum Inhibitory Concentration (MIC) values of Aztreonam, Cefotaxime, Ceftazidime, Ceftriaxone or Cefpodoxime are ≥ 1 µg/mL, should be confirmed using both ETEST® ESBL Cefotaxime/Cefotaxime + Clavulanic Acid (CT/CTL) and ETEST® ESBL Ceftazidime/Ceftazidime + Clavulanic Acid (TZ/TZL) strips. ETEST® ESBL PM/PML should be used to test Enterobacterales showing ESBL results that are not determinable with ETEST® ESBL CT/CTL and ETEST® ESBL TZ/TZL. ETEST® ESBL PM/PML should be used in conjunction with ETEST® ESBL CT/CTL and ETEST® ESBL TZ/TZL for confirmation of ESBL, when testing organisms where inducible chromosomal AmpC β-lactamases can interfere with the Clavulanic Acid synergy (for example, Enterobacter). ETEST® ESBL PM/PML can be used to confirm the presence of Clavulanic Acid inhibitable ESBL (Extended Spectrum β-lactamase) enzymes in the following microorganisms: Enterobacterales: Escherichia coli, Klebsiella spp.	B
ETEST® MBL Imipenem/Imipenem + EDTA (IP/IPI) (4-256/1-64 µg/mL)	424006	ETEST® MBL Imipenem/Imipenem + EDTA (IP/IPI) strips are designed to detect Metallo β-Lactamases (MBL) in Gram-negative aerobes using a manual, qualitative technique. ETEST® MBL IP/IPI can be used to detect Metallo β-lactamases in the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Pseudomonas, Stenotrophomonas maltophilia	B
ETEST® MBL Meropenem/Meropenem + EDTA (MP/MPI) (0.125-8/0.032-2 µg/mL)	424020	ETEST® MBL Meropenem/Meropenem + EDTA (MP/MPI) strips are designed to detect Metallo β-Lactamases (MBL) in Enterobacterales using a manual, qualitative technique. ETEST® MBL MP/MPI can be used to detect Metallo β-lactamases in the following microorganisms: • Enterobacterales: Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Serratia marcescens	B

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ETEST® Amoxicillin (AC) (0.016-256 µg/mL)	412243	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® AC can be used to determine the MIC of Amoxicillin against the following microorganisms: • Streptococcus pneumoniae	B
ETEST® Amoxicillin (AC) (0.016-256 µg/mL)	423816	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® AC can be used to determine the MIC of Amoxicillin against the following microorganisms: • Streptococcus pneumoniae	B
ETEST® Ticarcillin/Clavulanic Acid (TLc) (0.016-256/2 µg/mL)	412473	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® TLc can be used to determine the MIC of Ticarcillin/Clavulanic Acid against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas spp., Stenotrophomonas maltophilia, Acinetobacter spp. • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium, Prevotella, Gram-negative cocci ◦ Gram-positive anaerobes: Clostridium, Gram-positive cocci	B

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ETEST® Aztreonam (AT) (0.016-256 µg/mL)	423971	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® AT can be used to determine the MIC of Aztreonam against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Acinetobacter	B
ETEST® Aztreonam (AT) (0.016-256 µg/mL)	412259	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® AT can be used to determine the MIC of Aztreonam against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Acinetobacter	B
ETEST® Chloramphenicol (CL) (0.016-256 µgmL)	412309	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® CL can be used to determine the MIC of Chloramphenicol against the following microorganisms: • Streptococcus • Streptococcus pneumoniae • Haemophilus influenzae • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides ◦ Gram-positive anaerobes: Clostridium	B

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ETEST® Erythromycin (EM) (0.016-256 µg/mL)	412334	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® EM can be used to determine the MIC of Erythromycin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus, ß-hemolytic streptococci • Streptococcus pneumoniae	B
ETEST® Erythromycin (EM) (0.016-256 µg/mL)	423823	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® EM can be used to determine the MIC of Erythromycin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus, ß-hemolytic streptococci • Streptococcus pneumoniae	B
ETEST® Levofloxacin (LE) (0.002-32 µg/mL)	423965	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® LE can be used to determine the MIC of Levofloxacin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Acinetobacter, Stenotrophomonas maltophilia ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococcus pneumoniae • Haemophilus influenzae	B

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ETEST® Levofloxacin (LE) (0.002-32 µg/mL)	412393	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® LE can be used to determine the MIC of Levofloxacin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Acinetobacter, Stenotrophomonas maltophilia ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococcus pneumoniae • Haemophilus influenzae	B
ETEST® Oxacillin (OX) (0.016-256 µg/mL)	412432	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® OX can be used to determine the MIC of Oxacillin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus	B

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ETEST® Tetracycline (TC) (0.016-256 µg/mL)	412471	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® TC can be used to determine the MIC of Tetracycline against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales ◦ Gram-positive aerobes: Staphylococcus, Enterococcus, Streptococcus • Haemophilus influenzae • Streptococcus pneumoniae • Neisseria gonorrhoeae • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium, Prevotella ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B
ETEST® Tetracycline (TC) (0.016-256 µg/mL)	423818	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® TC can be used to determine the MIC of Tetracycline against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales ◦ Gram-positive aerobes: Staphylococcus, Enterococcus, Streptococcus • Haemophilus influenzae • Streptococcus pneumoniae • Neisseria gonorrhoeae • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium, Prevotella ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B

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On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • RCS Paris 839 022 522 • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • lne-gmed.com

Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
ETEST® Tigecycline (TGC) (0.016-256 µg/mL)	423821	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® TGC can be used to determine the MIC of Tigecycline against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Haemophilus influenzae • Streptococcus pneumoniae • Streptococcus (others) • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides	B
ETEST® Tigecycline (TGC) (0.016-256 µg/mL)	424314	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® TGC can be used to determine the MIC of Tigecycline against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Haemophilus influenzae • Streptococcus pneumoniae • Streptococcus (others) • Anaerobes: ◦ Gram-negative anaerobes: Bacteroides	B

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ETEST® Trimethoprim/Sulfamethoxazole (1/19) (TS) (0.002-32 µg/mL)	412481	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® TS can be used to determine the MIC of Trimethoprim/Sulfamethoxazole (1/19) against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Stenotrophomonas maltophilia, Acinetobacter ◦ Gram-positive aerobes: Staphyloccocus, Enterococcus • Haemophilus influenzae • Streptococcus pneumoniae	B
ETEST® Trimethoprim/Sulfamethoxazole (1/19) (TS) (0.002-32 µg/mL)	423967	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® TS can be used to determine the MIC of Trimethoprim/Sulfamethoxazole (1/19) against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Stenotrophomonas maltophilia, Acinetobacter ◦ Gram-positive aerobes: Staphyloccocus, Enterococcus • Haemophilus influenzae • Streptococcus pneumoniae	B

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ETEST® Fluconazole (FL) (0.016-256 µg/mL)	423969	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® FL can be used to determine the MIC of Fluconazole against the following microorganisms: • Yeasts: Candida spp. (excluding C. krusei), Cryptococcus neoformans	B
ETEST® Fluconazole (FL) (0.016-256 µg/mL)	412350	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® FL can be used to determine the MIC of Fluconazole against the following microorganisms: • Yeasts: Candida spp. (excluding C. krusei), Cryptococcus neoformans	B
ETEST® Amphotericin B (AP) (0.002-32 µg/mL)	424316	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts and moulds. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® AP can be used to determine the MIC of Amphotericin B against the following microorganisms: • Yeasts: Candida spp., Cryptococcus neoformans • Moulds: Aspergillus, Fusarium	B

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ETEST® Amphotericin B (AP) (0.002-32 µg/mL)	423817	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts and moulds. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® AP can be used to determine the MIC of Amphotericin B against the following microorganisms: • Yeasts: Candida spp., Cryptococcus neoformans • Moulds: Aspergillus, Fusarium	B
ETEST® Voriconazole (VO) (0.002-32 µgmL)	412490	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts and moulds. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® VO can be used to determine the MIC of Voriconazole against the following microorganisms: • Yeasts: Candida spp., Cryptococcus neoformans • Moulds: Aspergillus spp.	B
ETEST® Voriconazole (VO) (0.002-32 µgmL)	423811	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts and moulds. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® VO can be used to determine the MIC of Voriconazole against the following microorganisms: • Yeasts: Candida spp., Cryptococcus neoformans • Moulds: Aspergillus spp.	B

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CHROMID® MRSA SMART Agar	413050	Chromogenic medium for the screening of methicillin-resistant Staphylococcus aureus (MRSA). This medium is a chromogenic medium for the screening of methicillin-resistant S. aureus (MRSA) in chronic carriers or patients at risk of carriage. This medium does not replace conventional antimicrobial susceptibility tests for the diagnosis of methicillin resistance. MRSA are multi-resistant bacteria which may cause nosocomial infections. The detection of MRSA carriers is particularly important for the epidemiological prevention and monitoring of these infections. In this context, the use of CHROMID® MRSA SMART Agar contributes towards the active surveillance of MRSAc	C
ETEST® Meropenem/Vaborbactam (MEV) (0.004-64/8 µg/mL)	423986	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. INDICATIONS FOR USE Meropenem/Vaborbactam has been shown to be active against the Gram-negative aerobic microorganisms listed below according to the FDA/EMA label for this antimicrobial agent. ETEST® MEV can be used to determine the MIC of Meropenem/Vaborbactam against the following microorganisms: Active both in vitro and in clinical infections: Enterobacter cloacae complex Escherichia coli Klebsiella pneumoniae In vitro data are available for the following microorganisms, but clinical significance is unknown: Citrobacter freundii Citrobacter koseri Klebsiella aerogenes Klebsiella oxytoca Morganella morganii Providencia spp. Serratia marcescens Pseudomonas aeruginosa (EMA only)	B

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ETEST® Clarithromycin (CH) (0.016-256 µg/mL)	412313	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® CH can be used to determine the MIC of Clarithromycin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus • Streptococcus pneumoniae • Haemophilus influenzae	B
ETEST® Kanamycin (KM) (0.016-256 µg/mL)	412382	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® KM can be used to determine the MIC of Kanamycin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales	B
ETEST® Ofloxacin (OF) (0.002-32 µg/mL)	412430	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® OF can be used to determine the MIC of Ofloxacin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Acinetobacter, Stenotrophomonas maltophilia ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococcus spp. • Haemophilus influenzae • Streptococcus pneumoniae	B

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ETEST® Cefpodoxime (PX) (0.016-256 µg/mL)	412289	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® PX can be used to determine the MIC of Cefpodoxime against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales	B
ETEST® Quinupristin/Dalfopristin (QDA) (0.002-32 µg/mL)	412444	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® QDA can be used to determine the MIC of Quinupristin/Dalfopristin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococcus pneumoniae	B
ETEST® Spectinomycin (SC) (0.064-1024 µg/mL)	412452	ETEST® is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® SC can be used to determine the MIC of Spectinomycin against the following microorganisms: • Neisseria gonorrhoeae	B

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ETEST® Trimethoprim (TR) (0.002-32 µg/mL)	412483	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® TR can be used to determine the MIC of Trimethoprim against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales ◦ Gram-positive aerobes: Staphylococcus • Haemophilus influenzae	B
ETEST® Cefuroxime (XM) (0.016-256 µg/mL)	412305	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® XM can be used to determine the MIC of Cefuroxime against the following microorganisms: • Aerobes ◦ Gram-negative aerobes: Enterobacterales ◦ Gram-positive aerobes: ß-hemolytic streptococci • Streptococcus pneumoniae	B
ETEST® Posaconazole (POS) (0.002-32 µg/mL)	424479	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts and/or moulds. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® POS can be used to determine the MIC of Posaconazole against the following microorganisms: • Yeasts: Candida spp. • Moulds: Aspergillus spp., Fusarium spp., Rhizopus spp.	B

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ETEST® Tobramycin (TM) (0.064-1024 µg/mL)	424013	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® TM can be used to determine the MIC of Tobramycin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas aeruginosa, Acinetobacter ◦ Gram-positive aerobes: Staphylococcus aureus	B
ETEST® Streptomycin (SM) (0.064-1024 µg/mL)	424015	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® SM can be used to determine the MIC of Streptomycin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Enterococcus* * suitable for the detection of high-level Streptomycin resistance	B
ETEST® Nitrofurantoin (NI) (0.032-512 µg/mL)	424018	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® NI can be used to determine the MIC of Nitrofurantoin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas, Acinetobacter ◦ Gram-positive aerobes: Staphylococcus, Enterococcus	B

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ETEST® Nalidixic Acid (NA) (0.016-256 µg/mL)	424022	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® NA can be used to determine the MIC of Nalidixic Acid against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales	B
ETEST® Norfloxacin (NX) (0.016-256 µg/mL)	424024	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® NX can be used to determine the MIC of Norfloxacin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales, Pseudomonas aeruginosa ◦ Gram-positive aerobes: Staphylococcus, Enterococcus	B
ETEST® Mecillinam (MM) (0.016-256 µg/mL)	424030	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® MM can be used to determine the MIC of Mecillinam against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales	B

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ETEST® Amoxicillin/Clavulanic Acid (ACC) (0.016-256/2 µg/mL)	423446	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. Amoxicillin/Clavulanic Acid has been shown to be active against the Gram-negative aerobic and anaerobic microorganisms listed below according to the EMA label for this antimicrobial agent. ETEST® ACC can be used to determine the MIC of Amoxicillin/Clavulanic Acid against the following microorganisms: Active both in vitro and in clinical infections: • Escherichia coli • Klebsiella pneumoniae • Klebsiella oxytoca • Proteus mirabilis • Proteus vulgaris • Haemophilus influenzae • Bacteroides fragilis • Fusobacterium nucleatum • Prevotella spp.	B

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ETEST® Amoxicillin/Clavulanic Acid (ACC) (0.016-256/2 µg/mL)	423810	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. Amoxicillin/Clavulanic Acid has been shown to be active against the Gram-negative aerobic and anaerobic microorganisms listed below according to the EMA label for this antimicrobial agent. ETEST® ACC can be used to determine the MIC of Amoxicillin/Clavulanic Acid against the following microorganisms: Active both in vitro and in clinical infections: • Escherichia coli • Klebsiella pneumoniae • Klebsiella oxytoca • Proteus mirabilis • Proteus vulgaris • Haemophilus influenzae • Bacteroides fragilis • Fusobacterium nucleatum • Prevotella spp.	B
ETEST® Caspofungin (CS) (0.002-32 µg/mL)	412269	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts and/or moulds. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® CS can be used to determine the MIC of Caspofungin against the following microorganisms: • Yeasts: Candida spp.	B

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ETEST® Flucytosine (FC) (0.002-32 µg/mL)	412352	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® FC can be used to determine the MIC of Flucytosine against the following microorganisms: • Yeasts: Candida spp.	B
ETEST® Itraconazole (IT) (0.002-32 µg/mL)	412380	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts and moulds. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® IT can be used to determine the MIC of Itraconazole against the following microorganisms: • Yeasts: Candida spp. • Moulds: Aspergillus spp.	B
ETEST® Ketoconazole (KE) (0.002-32 µg/mL)	412391	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® KE can be used to determine the MIC of Ketoconazole against the following microorganisms: • Yeasts: Candida spp., Cryptococcus neoformans	B

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
ETEST® Moxifloxacin (MX) (0.002-32 µg/mL)	412411 423983	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® MX can be used to determine the MIC of Moxifloxacin against the following microorganisms: • Aerobes: ◦ Gram-negative aerobes: Enterobacterales ◦ Gram-positive aerobes: Staphylococcus • Haemophilus influenzae • Streptococcus pneumoniae • Anaerobes ◦ Gram-negative anaerobes: Bacteroides, Fusobacterium, Prevotella ◦ Gram-positive anaerobes: Clostridium, non-sporeforming Gram-positive rods, Gram-positive cocci	B
Mueller Hinton E Agar (MHE)	413822 413824 413825	Study of antimicrobial susceptibility. Mueller Hinton E Agar is a medium for disk diffusion antimicrobial susceptibility testing and the determination of Minimal Inhibitory Concentrations (MIC) using the ETEST® method. The medium has been developed according to EUCAST (European Committee on Antimicrobial Susceptibility Testing) and CLSI (Clinical Laboratory and Standards Institute, Inc.) recommendations.	B

Signé par :
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On behalf of the President
Béatrice LYS
Technical Director

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
CHROMID® SMART MRSA / S. AUREUS (MRSM/SAIDE)	419398	Chromogenic medium for the screening of methicillin-resistant Staphylococcus aureus (MRSA) and Chromogenic medium for the selective isolation and the direct identification of S. aureus. This product consists of two culture media, dispensed into one Petri dish containing separate compartments. CHROMID® MRSA SMART (MRSM) Agar. This medium is a chromogenic medium for the screening of methicillin-resistant S. aureus (MRSA) in chronic carriers or patients at risk of carriage. This medium does not replace conventional antimicrobial susceptibility tests for the diagnosis of methicillin resistance. MRSA are multi-resistant bacteria which may cause nosocomial infections. The detection of MRSA carriers is particularly important for the epidemiological prevention and monitoring of these infections. In this context, the use of CHROMID®MRSA SMART Agar contributes towards the active surveillance of MRSA. CHROMID® S. aureus Elite (SAIDE) Agar. This chromogenic medium is intended for the selective isolation and the direct identification of S. aureus in 18 to 24 hours for the following human specimens: nasal swabs, suppurations, ear/nose/throat samples, skin samples from serious burn victims. This medium is intended for the prevention and diagnosis of S. aureus infections using samples of human origin.	C
ETEST® Sulbactam/Durlobactam (SUD) (0.004/4-64/4 µg/mL)	423575	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. Sulbactam/Durlobactam has been shown to be active against the Gram-negative aerobic microorganisms listed below according to the FDA label for this antimicrobial agent. ETEST® SUD can be used to determine the MIC of Sulbactam/Durlobactam against the following microorganisms: • Acinetobacter baumannii-calcoaceticus complex	B
VITEK® 2 AST-N399	423701	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	B
VITEK® 2 AST-XN18	423874	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	B

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
VITEK® 2 AST-N452	424751	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	B
VITEK® 2 AST-XN34	424752	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	B
ETEST® Aztreonam/Avibactam (AZA) (0.016/4-256/4 µg/mL)	424460	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. Aztreonam/Avibactam has been shown to be active against the Gram-negative aerobic microorganisms listed according to the EMA label for this antimicrobial agent. ETEST® AZA can be used to determine the MIC of Aztreonam/Avibactam against the following microorganisms: • Escherichia coli • Klebsiella pneumoniae • Klebsiella oxytoca • Enterobacter cloacae complex • Citrobacter freundii complex • Klebsiella aerogenes • Proteus mirabilis • Proteus vulgaris • Citrobacter koseri • Morganella morganii • Serratia marcescens • Providencia stuartii	B

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
VITEK® MS Software V1.2	424774 424938	VITEK® MS is a mass spectrometry system using matrix-assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) for the identification of microorganisms cultured from human specimens. The VITEK® MS System is a qualitative in vitro diagnostic device used in conjunction with other laboratory tests to aid in the diagnosis of bacterial, yeast and mould infections	B
ETEST® Fosfomycin (FO) (0.032-512 µg/mL)	423442 423815	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. Fosfomycin has been shown to be active against the aerobic microorganisms listed below according to the EMA and FDA labels for this antimicrobial agent.ETEST® FO can be used to determine the MIC of Fosfomycin against the following microorganisms: Active both in vitro and in clinical infections: EMA Label: • Citrobacter freundii • Citrobacter koseri • Escherichia coli • Klebsiella aerogenes • Klebsiella pneumoniae • Klebsiella oxytoca • Salmonella enterica • Serratia marcescens • Staphyloccocus aureus • Staphyloccocus epidermidis FDA Label: • Enterococcus faecalis • Escherichia coli	B
VITEK® 2 AST-P674	425099	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae t antimicrobial agents when used as instructed.	B

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
ETEST® Imipenem/relebactam P. aeruginosa (IRPA) (0.008/4-128/4 µg/mL)	424547	Imipenem/Relebactam has been shown to be active against the Gram-negative aerobic microorganism listed below according to the EMA and FDA labels for this antimicrobial agent. ETEST® IRPA can be used to determine the MIC of Imipenem/Relebactam against the following microorganism: Active both in vitro and in clinical infections: Pseudomonas aeruginosa	B
VITEK® 2 AST-ST03	421344	The VITEK® 2 Streptococcus Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of S. pneumoniae, beta-hemolytic Steptococcus, and Viridans Streptococcus to antimicrobial agents when used as instructed.	B
ETEST® Isavuconazole (ISA) (0.002-32 µg/mL)	424229 424238	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts and/or moulds. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. ETEST® ISA can be used to determine the MIC of Isavuconazole against the following microorganisms: Active both in vitro and in clinical infections: • Aspergillus fumigatus • Aspergillus flavus	B

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
CHROMID® ESBL agar / CHROMID® VRE agar (ESBL/VRE)	43470	Selective chromogenic medium for the screening of Extended Spectrum β-Lactamase-producing Enterobacterales (ESBL). Selective chromogenic medium for the detection and differentiation of Enterococcus faecium and E. faecalis showing acquired vancomycin resistance (VRE). This product consists of two culture media, dispensed into one Petri dish containing separate compartments. It is intended for use with clinical specimens. ESBL part. This medium is a selective chromogenic medium for the screening of Extended Spectrum β-Lactamase-producing Enterobacterales in chronic carrier patients or patients at risk. ESBL-producing Enterobacterales are multi-resistant bacteria which can be responsible for nosocomial infections. The detection of ESBL-producing Enterobacterales carriers is particularly important for the prevention and epidemiological monitoring of these infections. In this context, the use of CHROMID® ESBL agar contributes to the active surveillance of ESBL-producing Enterobacterales. VRE part. This medium is a selective chromogenic medium for the detection of E. faecium and E. faecalis showing acquired vancomycin resistance (VRE), in at risk patients. It enables the differentiation of E. faecium and E. faecalis. The E. faecium and E. faecalis with acquired vancomycin resistance (mainly genotypes vanA and vanB) are multiresistant bacteria which can be responsible for health care-associated infections. The detection of this resistance is particularly important for the prevention and epidemiological surveillance of these infections and also to prevent the emergence of vancomycin-resistant Staphylococcus aureus (VRSA), by transmission of the vanA gene. This medium is not a substitute for the conventional antimicrobial susceptibility test methods.	C
VITEK® 2 AST-N503	425490	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	B
VITEK® 2 AST-N504	425491	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	B
VITEK® 2 AST-YS08	421409	The VITEK® 2 Fungal Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant yeasts to antifungal agents when used as instructed.	B
VITEK® 2 AST-YS11	425466	The VITEK® 2 Fungal Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant yeasts to antifungal agents when used as instructed.	B

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
CHROMID® Candida Agar (CAN2)	43631 43639	Chromogenic medium for the selective isolation of yeasts and the direct identification of *Candida albicans*. This medium is a medium for: • the selective isolation of yeasts, • the identification of the species *C. albicans*, • the presumptive differentiation of a group of species comprising C. tropicalis, C. lusitaniae and C. kefyr.	B
CHROMID® Candida / Sabouraud Gentamicin Chloramphenicol 2 Agars (CAN2/SGC2)	43464	Chromogenic medium for the selective isolation of yeasts and the direct identification of Candida albicans. Selective isolation of yeasts and molds. This product consists of two culture media dispensed into a single Petri dish divided into two compartments. It is intended for use with clinical specimens. CHROMID® Candida Agar: This medium is intended for: • the selective isolation of yeasts, • the identification of the species C. albicans, • the presumptive differentiation of a group of species comprising C. tropicalis, C. lusitaniae and C. kefyr. Sabouraud Gentamicin Chloramphenicol 2 Agar: This selective medium is recommended for the isolation of yeasts and molds from polymicrobial specimens.	B
MYCOPLASMA IST 3	422083	MYCOPLASMA IST 3 is a manual qualitative and semi-quantitative in vitro diagnostic test for the culture, identification, semi-quantitative enumeration and antibiotic susceptibility testing of Mycoplasma hominis and Ureaplasma spp. including Ureaplasma parvum and Ureaplasma urealyticum. It is intended as an aid to diagnosis and prediction of treatment response in adults suspected of having urogenital mycoplasma infection, using urethral swabs, vaginal and cervical swabs, semen and male urine samples. This assay is intended for use in clinical laboratories by laboratory health professionals.	C
ETEST® Gepotidacin (GEP) (0.016-256 µg/mL)	424037	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of yeasts and moulds. The system comprises a predefined antifungal gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation.	B

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Nom commercial du dispositif *Device trade name*	Références commerciales *Commercial references*	Destination* du dispositif *Intended purpose* of the device*	Classe du dispositif *Device classification*
VITEK® 2 AST-P639	418662	The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of Staphylococcus spp., Enterococcus spp., and S. agalactiae t antimicrobial agents when used as instructed.	B
Brucella Blood Agar	411968	Isolation of anaerobic microorganisms and MIC determination using the ETEST® method. Brucella Blood Agar (BBA) is a nutritive medium for the isolation and culture of obligate anaerobes in clinical specimens. It is recommended for the determination of the MIC (Minimum Inhibitory Concentration) for anaerobic microorganisms, using the ETEST® method.	B
VITEK® 2 AST-N-334	418984	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	B
VITEK® 2 AST-N-335	418985	The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	B
VITEK® MS Knowledge Base v3.4	425140	VITEK® MS is a mass spectrometry system using matrix-assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) for the identification of microorganisms cultured from human specimens. The VITEK® MS System is a qualitative in vitro diagnostic device used in conjunction with other laboratory tests to aid in the diagnosis of bacterial, yeast and mould infections The VITEK® MS Knowledge Base is intended to support microorganism identification by incorporating newly recognized and emerging species or pathogens and by reflecting current taxonomic updates.	B

*mentionnée par le fabricant dans la notice d'utilisation / *as included by the manufacturer in the instructions for use*

Signé par :
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GMED SAS GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

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4. Historique du certificat / *Certificate history:*

Version du certificat Version of the certificate	Date de délivrance Date of issue	Modifications apportées Identification of the changes
38817 rev. 0	06/04/2022 *04/06/2022*	NA : création / *NA: creation*
38817 rev. 1	13/06/2022 *06/13/2022*	Ajout de références / *Addition of references* - ETEST® Cefixime (IX) (0.016-256 µg/mL) - ETEST® Daptomycin (DPC) (0.016-256 µg/mL) - ETEST® Doripenem (DOR) (0.002-32 µg/mL) - ETEST® Doxycycline (DC) (0.016-256 µg/mL) - ETEST® Ertapenem (ETP) (0.002-32 µg/mL) - CHROMID® CPS® Elite Agar (CPSE) - CHROMID® CPS® Elite Agar (CPSO)
38817 rev. 2	19/09/2022 *09/19/2022*	Ajout de références / *Addition of references* - ETEST® Anidulafungin (AND) (0.002-32 µg/mL) - ETEST® Ceftaroline (CPT) (0.002-32 µg/mL) - ETEST® Gentamicin (GM) (0.064-1024 µg/mL) - ETEST® Imipenem/Relecbactamn (IPR) (0.002-32/4 µg/mL) - ETEST® Micafungin (MYC) (0.002-32 µg/mL) - ETEST® Mupirocin (MU) (0.064-1024 µg/mL)

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Version du certificat Version of the certificate	Date de délivrance Date of issue	Modifications apportées Identification of the changes
38817 rev. 3	26/09/2022 *09/26/2022*	Retrait de la mention de la bactérie Pseudomonas Aeruginosa de la destination du dispositif ETEST® Imipenem/Relebactam (IPR) (0.002-32/4 µg/mL) *Removal of the mention of Pseudomonas Aeruginosa from the intended use of the device ETEST® Imipenem/Relebactam (IPR) device (0.002-32/4 µg/mL)*
38817 rev. 4	15/12/2022 *12/15/2022*	Ajout de références / *Addition of references* - CHROMID® S.aureus Elite agar - - CHROMID® P. aeruginosa agar - ETEST® Cefoxitin (FX) (0.016-256 µg/mL) - ETEST® Ampicillin/Sulbactam (2/1) (AB) (0.016-256 µg/mL) - ETEST® Amoxicillin/Clavulanic Acid (2/1) (XL) (0.016-256 µg/mL) - ETEST® Rifampicin (RI) (0.002-32 µg/mL) - ETEST® Piperacillin (PP) (0.016-256 µg/mL) - Vitek® MS KB 3.3
38817 rev. 5	27/02/2023 *02/27/2023*	Ajout de références / *Addition of references* - ETEST® MBL Imipenem/Imipenem + EDTA (IP/IPI) (4-256/1-64 µg/mL) - ETEST® MBL Meropenem/Meropenem + EDTA (MP/MPI) (0.125-8/0.032-2 µg/mL) - ETEST® ESBL Ceftazidime/Ceftazidime + Clavulanic Acid (TZ/TZL) (0.5-32/0.064-4 µg/mL) - ETEST® ESBL Cefotaxime/Cefotaxime + Clavulanic Acid (CT/CTL) (0.25-16/0.016-1 µg/mL) - ETEST® ESBL Cefepime/Cefepime + Clavulanic Acid (PM/PML) (0.25-16/0.064-4 µg/mL) Retrait de références /*Withdrawal of references* - ATB™ G- CLSI (12) - ATB™ G- EU (08) - ATB™ STREP CLSI (12) - ATB™ STAPH EU (08) - ATB™ UR EU (08) - ATB™ PSE EU (08) - ATB™ STAPH CLSI (12) - ATB™ PSE CLSI (12)

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Version du certificat *Version of the certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
38817 rev. 6	17/03/2023 03/17/2023	Modification de l'adresse du site de Combourg *Change of address of the Combourg site*
38817 rev. 7	22/06/2023 *06/22/2023*	Ajout de références / *Addition of references* - ETEST® Amoxicillin (AC) (0.016-256 µg/mL) - 412243 - ETEST® Amoxicillin (AC) (0.016-256 µg/mL) - 423816 - ETEST® Ticarcillin/Clavulanic Acid (TLc) (0.016-256/2 µg/mL) – 412473 - ETEST® Aztreonam (AT) (0.016-256 µg/mL) - 423971 - ETEST® Aztreonam (AT) (0.016-256 µg/mL) - 412259 - ETEST® Chloramphenicol (CL) (0.016-256 µgmL) - 412309 - ETEST® Erythromycin (EM) (0.016-256 µg/mL) - 412334 - ETEST® Erythromycin (EM) (0.016-256 µg/mL) - 423823 - ETEST® Levofloxacin (LE) (0.002-32 µg/mL) - 423965 - ETEST® Levofloxacin (LE) (0.002-32 µg/mL) - 412393 - ETEST® Oxacillin (OX) (0.016-256 µg/mL) - 412432 - ETEST® Tetracycline (TC) (0.016-256 µg/mL) - 412471 - ETEST® Tetracycline (TC) (0.016-256 µg/mL) - 423818 - ETEST® Tigecycline (TGC) (0.016-256 µg/mL) - 423821 - ETEST® Tigecycline (TGC) (0.016-256 µg/mL) - 424314 - ETEST® Trimethoprim/Sulfamethoxazole (1/19) (TS) (0.002-32 µg/mL) - 412481 - ETEST® Trimethoprim/Sulfamethoxazole (1/19) (TS) (0.002-32 µg/mL) - 423967 - ETEST® Fluconazole (FL) (0.016-256 µg/mL) - 423969 - ETEST® Fluconazole (FL) (0.016-256 µg/mL) - 412350 - ETEST® Amphotericin B (AP) (0.002-32 µg/mL) - 424316 - ETEST® Amphotericin B (AP) (0.002-32 µg/mL) - 423817 - ETEST® Voriconazole (VO) (0.002-32 µgmL) - 412490 - ETEST® Voriconazole (VO) (0.002-32 µgmL) - 423811 - CHROMID® MRSA SMART Agar – 413050/413051 - ETEST® Meropenem/Vaborbactam (MEV) (0.004-64/8 µg/mL) - 423986

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Version du certificat *Version of the certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
38817 rev. 8	13/09/2023 *09/13/2023*	Ajout de références / *Addition of references* - ETEST® Clarithromycin (CH) (0.016-256 µg/mL) - 412313 - ETEST® Kanamycin (KM) (0.016-256 µg/mL) - 412382 - ETEST® Ofloxacin (OF) (0.002-32 µg/mL) - 412430 - ETEST® Cefpodoxime (PX) (0.016-256 µg/mL) - 412289 - ETEST® Quinupristin/Dalfopristin (QDA) (0.002-32 µg/mL) - 412444 - ETEST® Spectinomycin (SC) (0.064-1024 µg/mL) - 412452 - ETEST® Trimethoprim (TR) (0.002-32 µg/mL) - 412483 - ETEST® Cefuroxime (XM) (0.016-256 µg/mL) - 412305
38817 rev. 9	02/11/2023 *11/02/2023*	Ajout de références / *Addition of references* - ETEST® Posaconazole (POS) (0.002-32 µg/mL) réf. 424479 - ETEST® Tobramycin (TM) (0.064-1024 µg/mL) réf. 424013 - ETEST® Streptomycin (SM) (0.064-1024 µg/mL) réf. 424015 - ETEST® Nitrofurantoin (NI) (0.032-512 µg/mL) réf. 424018 - ETEST® Nalidixic Acid (NA) (0.016-256 µg/mL) réf. 424022 - ETEST® Norfloxacin (NX) (0.016-256 µg/mL) réf. 424024 - ETEST® Mecillinam (MM) (0.016-256 µg/mL) réf. 424030 - ETEST® Amoxicillin/Clavulanic Acid (ACC) (0.016-256/2 µg/mL) réf. 423446 (Single pack blister 30 WW) - ETEST® Amoxicillin/Clavulanic Acid (ACC) (0.016-256/2 µg/mL) réf. 423810 (Multi pack blister 100 WW)
38817 rev. 10	18/01/2024 *01/18/2024*	Ajout de références / *Addition of references* - ETEST® Caspofungin (CS) (0.002-32 µg/mL) - réf. 412269 - ETEST® Flucytosine (FC) (0.002-32 µg/mL) - réf. 412352 - ETEST® Itraconazole (IT) (0.002-32 µg/mL) - réf. 412380 - ETEST® Ketoconazole (KE) (0.002-32 µg/mL) - réf. 412391 - ETEST® Moxifloxacin (MX) (0.002-32 µg/mL) - réf. 412411 / 423983 - Mueller Hinton E Agar (MHE) - réf. 413822 / 413824 / 413825

Signé par :
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On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • RCS Paris 839 022 522 • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • lne-gmed.com

Version du certificat *Version of the certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
38817 rev. 11	22/02/2024 *02/22/2024*	Ajout de références / Addition of references - CHROMID® SMART MRSA / S. AUREUS (MRSM/SAIDE) – Réf. 419398 - ETEST® Sulbactam/Durlobactam (SUD) (0.004/4-64/4 µg/mL) – Réf. 423575
38817 rev. 12	19/06/2024 *06/19/2024*	Ajout de références / *Addition of references* - VITEK® 2 AST-XN18 - 423874 - VITEK® 2 AST-N399 - 423701 - VITEK® 2 AST-N452 - 424751 - VITEK® 2 AST-XN34 - 424752
38817 rev. 13	02/10/2024 10/02/2024	Ajout de références / *Addition of references* - ETEST® Aztreonam/Avibactam (AZA) (0.016/4-256/4 µg/mL) – Ref. 424460
38817 rev. 14	31/01/2025 *01/31/2025*	Ajout de références / *Addition of references* - VITEK® MS Software V1.2– Ref. 424774, 424938– Class B - ETEST® Fosfomycin (FO) (0.032-512 µg/mL) - Ref. 423442 / 423815 - Class B - VITEK® 2 AST-P674 - Ref. 425099 - Class B
38817 rev. 15	06/05/2025 *05/06/2025*	Modification de la destination du dispositif ETEST® Gentamicin (GM) Réf. 424004 *Change of the Intended purpose of the device ETEST® Gentamicin (GM) Ref. 424004* Ajout de référence / *Addition of reference* ETEST® Imipenem/relebactam P. aeruginosa (IRPA) (0.008/4-128/4 µg/mL)– Ref. 424547
38817 rev. 16	06/11/2025 *11/06/2025*	Ajout de références / *Addition of references* - VITEK® 2 AST-ST03 - Ref. 421344 - ETEST® Isavuconazole (ISA) (0.002-32 µg/mL) – Ref. 424229 / 424238 - CHROMID® ESBL agar / CHROMID® VRE agar (ESBL/VRE) – Ref. 43470

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Version du certificat *Version of the certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
38817 rev. 17	10/03/2026 *03/10/2026*	Ajout de références / *Addition of references* - VITEK® 2 AST-N503 – Ref. 425490 - VITEK® 2 AST-N504 – Ref. 425491 - VITEK® 2 AST-YS08 – Ref. 421409
38817 rev. 18	16/07/2026 *07/16/2026*	Retrait de références /*Withdrawal of references* - CHROMID® MRSA SMART Agar (ref. 413051) - Mueller Hinton agar with 5% horse blood + 20 mg/L β-NAD (ref. 43919)
38817 rev. 19	22/07/2026 *07/22/2026*	Ajout de références / *Addition of references* - VITEK® 2 AST-YS11 - Ref. 425466 - CHROMID® Candida Agar (CAN2) – Ref. 43631 -and 43639 - CHROMID® Candida / Sabouraud Gentamicin Chloramphenicol 2 Agars (CAN2/SGC2) – Ref. 43464 - MYCOPLASMA IST 3 – Ref. 422083 - ETEST® Gepotidacin (GEP) (0.016-256 µg/mL) – Ref. 424037
38817 rev. 20	01/09/2026 *09/01/2026*	Ajout de références /*Addition of references* - VITEK® 2 AST-P639- Ref. 418662 - Brucella Blood Agar - Ref. 411968
38817 rev. 21	30/09/2026 *09/30/2026*	Produit : Ajout de dispositifs /*Product : Addition of devices* - VITEK® 2 AST-N-334 – ref. 418984 - VITEK® 2 AST-N-335 – ref. 418985 - VITEK® MS Knowledge Base v3.4 – ref. 425140

5. **Le cas échéant, les informations spécifiques relatives aux conditions ou limitations de la validité du certificat /** *If applicable, specific information relating to the conditions for or limitations to the validity of the certificate:* Non Applicable / *Not applicable*

6. **Le cas échéant, les informations spécifiques relatives à la surveillance effectuée par l'organisme notifié /** *If applicable, specific information about the surveillance carried out by the notified body:* Non Applicable / *Not applicable*

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