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. 2

Délivré le/*Issued on:* September 19th, 2022

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 sur le(s) rapport(s) d'audit du système de gestion de la qualité référencé(s) P602831 - P604661 - P604659, 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 contained in the quality management system audit report(s) referenced P602831 - P604661 - P604659, 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 C (près du patient, autodiagnostic ou diagnostic compagnon) et/ou de classe D, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/746 est requis.

For the purpose of placing on the market class C in vitro diagnostic devices (devices for self-testing, near patient testing or companion diagnostics) and / or class D, another certificate issued in accordance with the provisions of Regulation (EU) 2017/746 is required.

Début de validité /*Effective date:* September 19th, 2022 (included)

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

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.

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.

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MARJORIE PERRIMON
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On behalf of the President
Marjorie PERRIMON
Certification Director

GMED - 38817 rev. 2
Modifie le certificat 38817-1

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Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • lne-gmed.com

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. - 5 rue des Berges - 38024 GRENOBLE CEDEX 01 - FRANCE
   BIOMERIEUX S.A. - Avenue des Bergeries - 01150 SAINT VULBAS - FRANCE
   BIOMERIEUX S.A. - 138 rue Louis Pasteur - Parc Technologique Delta SUD - 09340 VERNIOLLE - 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. - Route de Dol – 35270 COMBOURG - FRANCE

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

Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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

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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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
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

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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
ATB™ G- CLSI (12)	412064	The ATB™ G- CLSI (12) strip is a qualitative standardized technique for the determination of the susceptibility of Enterobacterales to antibiotics in a semi-solid medium under conditions similar to the reference methods for agar dilution or microdilution (according to CLSI recommendations). The ATB™ G- CLSI (12) strip was designed following CLSI 20131 committee recommendations.	B
ATB™ G- EU (08)	14318	The ATB™ G- EU (08) strip is a qualitative standardized technique for the determination of the susceptibility of Enterobacterales to antibiotics in a semi-solid medium under conditions similar to the reference methods for agar dilution or micro-dilution.	B

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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
ATB™ STREP CLSI (12)	412068	The ATB™ STREP CLSI (12) strip is a qualitative standardized technique for the determination of the susceptibility of streptococci and pneumococci to antibiotics in a semi-solid medium under conditions similar to the reference methods for agar dilution or microdilution (according to CLSI recommendations). The ATB™ STREP CLSI (12) strip was designed following CLSI 20131 committee recommendations, except for TET which follows CLSI 20122 committee recommendations.	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
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

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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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
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

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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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
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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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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 *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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 *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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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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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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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 - Pseudomonas aeruginosa	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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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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
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

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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
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

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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
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

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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
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

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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
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 43919	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

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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
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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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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
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
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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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
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

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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
ATB™ STAPH EU (08)	14328	The ATB™ STAPH EU (08) strip is a qualitative standardized technique for the determination of the susceptibility of staphylococci to antibiotics in a semi-solid medium under conditions similar to the reference methods for agar dilution or microdilution. The ATB™ STAPH EU (08) strip was designed following the EUCAST 2008 committee recommendations1 and the CASFM 2008 committee2 (Kanamycin, Lincomycin and Pristinamycin).	B
ATB™ UR EU (08)	14338	The ATB™ UR EU (08) strip is a qualitative standardized technique for the determination of the susceptibility of Enterobacterales of urinary origin to antibiotics in a semi-solid medium under conditions similar to the reference methods for agar dilution or microdilution. The ATB™ UR EU (08) strip was designed following the EUCAST 2008 committee recommendations1 and the CASFM 2008 2 or CLSI 20083 committees (Cefuroxime oral, Nalidixic acid, Cephalothin, Cefoxitin and Cefixime). Genera formerly included in the family Enterobacteriaceae were reorganized to an order (Enterobacterales) containing seven families: Budviciaceae, Enterobacteriaceae, Erwiniaceae, Hafniaceae, Morganellaceae, Pectobacteriaceae,Yersiniaceae.	B
ATB™ PSE EU (08)	14348	The ATB™ PSE EU (08) strip is a qualitative standardized technique for the determination of the susceptibility of Pseudomonas and other nonfermenting Gram-negative rods to antibiotics in a semi-solid medium under conditions similar to the reference methods for agar dilution or microdilution. The ATB™ PSE EU (08) strip was designed following the EUCAST 2008 committee and the CASFM 2008 committee recommendations (Ciprofloxacin and Rifampicin).	B

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ATB™ STAPH CLSI (12)	412065	The ATB™ STAPH CLSI (12) strip is a qualitative standardized technique for the determination of the susceptibility of staphylococci to antibiotics in a semi-solid medium under conditions similar to the reference methods for agar dilution or micro-dilution (according to CLSI® recommendations). The ATB™ STAPH CLSI (12) strip was designed following CLSI 2013 committee recommendations.	B
ATB™ PSE CLSI (12)	412067	The ATB™ PSE CLSI (12) strip is a qualitative standardized technique for the determination of the susceptibility of Pseudomonas and other nonfermenting Gram (-) rods to antibiotics in a semi-solid medium under conditions similar to the reference methods for agar dilution or micro-dilution (according to CLSI® recommendations). The ATB™ PSE CLSI (12) strip was designed following CLSI 2013 committee recommendations.	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
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

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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
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

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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 *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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
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-negative aerobes: Enterobacterales, Pseudomonas, Acinetobacter ◦ Gram-positive aerobes: Staphylococcus, Enterococcus* * suitable for the detection of high-level aminoglycoside resistance (HLAR)	B

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Nom commercial *Commercial name*	Références commerciales *Commercial references*	Destination *Intended use*	Classe du DM DIV *IVD MD Class*
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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4. Historique du certificat / *Certificate history:*

Référence au certificat précédent *Reference to the previous certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
N° 38817 rev. 0	06/04/2022 *04/06/2022*	Ajout de références *Addition of references* - ETEST® Cefixime (IX) (0.016-256 µg/mL) - ETEST® Cefixime (IX) (0.016-256 µg/mL) - ETEST® Daptomycin (DPC) (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® Doxycycline (DC) (0.016-256 µg/mL) - ETEST® Ertapenem (ETP) (0.002-32 µg/mL) - ETEST® Ertapenem (ETP) (0.002-32 µg/mL) - CHROMID® CPS® Elite Agar (CPSE) - CHROMID® CPS® Elite Agar (CPSO)
N° 38817 rev. 1	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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5. **Le cas échéant, les informations spécifiques relatives aux limitations de la validité du certificat /** *If applicable, specific information relating to the limitations to the validity of the certificate:* Non Applicable / *Not applicable*

6. **Le cas échéant, les informations spécifiques relatives à la surveillance effectuée dans le cadre du maintien du certificat /** *If applicable, specific information relating to the surveillance carried out in the context of maintaining the certificate :* Non Applicable / *Not applicable*

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