

Certificat / Certificate: N° 39291 rev. 7

Délivré le / Issued on: May 13th, 2025

Certificat délivré à / Certificate issued to: **bioMérieux, Inc.**

100 Rodolphe Street

Durham, North Carolina 27712 UNITED STATES

SRN: US-MF-000011802

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) T001376, 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 T001376, the quality management system complies with the relevant provisions of the regulation (EU) 2017/746 for the following products:

Dispositifs de diagnostic in vitro: Réactifs et logiciel destinés à être utilisé pour la culture, l'isolement et l'identification d'agents infectieux

In vitro diagnostic device: Reagents and software intended to be used to grow, isolate and identify infectious agents

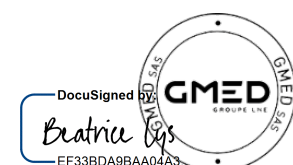
Voir détails sur addendum / See addendum for additional information

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: May 13th, 2025 (included)

Valable jusqu'au / Expiry date: March 28th, 2027 (included)



On behalf of the President

Béatrice LYS

Technical Director

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

bioMérieux SA - 376 Chemin de l'orme, 69280 Marcy l'Etoile, France
 SRN: FR-AR-000004435

2. Identification des sites / Identification of sites:

bioMérieux, Inc.: 100 Rodolphe Street, Durham, NC 27712 USA
 bioMérieux, Inc.: 1101 Hamlin Road, Durham, NC 27704 USA
 bioMérieux, Inc.: 595 Anglum Road, Hazelwood, MO 63042 USA
 bioMérieux, Inc.: 1201 S 4800 W Salt Lake City, UT 84104 USA

3. Identification des dispositifs / Identification of devices:

Dénomination générique associé au dispositif <i>Generic name related to the device</i>	Nom commercial du dispositif <i>Device trade name</i>	Classe du dispositif <i>Device classification</i>	Destination* du dispositif <i>Intended purpose* of the device</i>	Référence au certificat requis pour la mise sur le marché du dispositif <i>Reference to the certificate required for placing on the market the device</i>
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN09	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN13	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN16	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN48	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN66	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN67	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN68	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN69	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN70	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN72	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN73	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN74	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN75	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN77	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN79	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN80	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN81	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN83	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN84	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN86	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN93	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN95	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN99	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N101	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N102	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N169	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N193	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N194	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N195	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N196	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N202	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N203	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N204	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N211	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N212	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N214	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N215	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N222	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N223	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N224	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N225	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N227	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N228	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N229	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N231	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N232	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N233	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N234	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N235	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N238	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N239	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N240	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N242	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N243	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N245	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N246	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N248	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N249	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N250	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N255	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N256	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N257	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N263	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N268	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N269	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N270	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N271	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N272	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N274	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N275	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N276	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N278	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N279	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N280	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N281	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N283	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N288	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N289	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N290	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N291	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N292	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N300	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N303	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N308	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N309	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N311	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N314	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N315	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N317	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N318	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N320	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N321	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N322	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N327	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N340	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N341	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N344	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N347	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N349	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N351	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N352	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N353	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N356	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N357	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N358	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N359	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N360	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N361	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N362	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N363	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N365	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N366	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N367	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N368	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N369	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N371	Class B	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.	N/A

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On behalf of the President
Béatrice LYS
Technical Director

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N372	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N373	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N374	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N375	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N376	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N378	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N379	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N380	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N381	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N382	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N383	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N384	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N385	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N386	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N387	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N388	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N389	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N390	Class B	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.	N/A

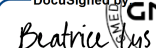
Dénomination générique associé au dispositif <i>Generic name related to the device</i>	Nom commercial du dispositif <i>Device trade name</i>	Classe du dispositif <i>Device classification</i>	Destination* du dispositif <i>Intended purpose* of the device</i>	Référence au certificat requis pour la mise sur le marché du dispositif <i>Reference to the certificate required for placing on the market the device</i>
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N391	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N392	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N395	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N396	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N397	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N398	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N401	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N402	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N403	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N404	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N405	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N408	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N409	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N410	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N411	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N413	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N414	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N415	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N416	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N417	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N419	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N421	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N422	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N424	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N800	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N801	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N802	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN04	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN05	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN06	Class B	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.	N/A

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On behalf of the President
Béatrice LYS
Technical Director

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN08	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN09	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN10	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN11	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN12	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN13	Class B	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.	N/A


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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN14	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN15	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN16	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN17	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN20	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-GN76	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N261	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N293	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N325	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N330	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N331	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N332	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N339	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N343	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N346	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N350	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N437	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N438	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N439	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N440	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N441	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N442	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N443	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N444	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N445	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N446	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N447	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N448	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN26	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN28	Class B	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.	N/A

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On behalf of the President
Béatrice LYS
Technical Director

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N436	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N449	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N450	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N451	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N454	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N453	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N455	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N456	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N457	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N458	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N459	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N460	Class B	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.	N/A


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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N461	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N462	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N463	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N464	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N465	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N466	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N467	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N468	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N469	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N470	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N471	Class B	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	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N475	Class B	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	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N476	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N477	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N478	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N804	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N806	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N807	Class B	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.	N/A

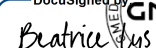
Dénomination générique associé au dispositif <i>Generic name related to the device</i>	Nom commercial du dispositif <i>Device trade name</i>	Classe du dispositif <i>Device classification</i>	Destination* du dispositif <i>Intended purpose* of the device</i>	Référence au certificat requis pour la mise sur le marché du dispositif <i>Reference to the certificate required for placing on the market the device</i>
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N808	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N809	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N810	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N811	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N812	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N813	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N814	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN30	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN31	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN32	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN33	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN35	Class B	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.	N/A

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On behalf of the President
Béatrice LYS
Technical Director

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN36	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N479	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN38	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N480	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N481	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN39	Class B	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.	N/A


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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N483	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN40	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N425	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N426	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N428	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N429	Class B	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.	N/A

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In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N430	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N431	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N432	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N484	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N485	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N486	Class B	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.	N/A

Dénomination générique associé au dispositif <i>Generic name related to the device</i>	Nom commercial du dispositif <i>Device trade name</i>	Classe du dispositif <i>Device classification</i>	Destination* du dispositif <i>Intended purpose* of the device</i>	Référence au certificat requis pour la mise sur le marché du dispositif <i>Reference to the certificate required for placing on the market the device</i>
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N487	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N488	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N489	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N490	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N491	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-N494	Class B	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.	N/A

DocuSigned by:

 EF33BDA9BA04A3

On behalf of the President
Béatrice LYS
Technical Director

Dénomination générique associé au dispositif <i>Generic name related to the device</i>	Nom commercial du dispositif <i>Device trade name</i>	Classe du dispositif <i>Device classification</i>	Destination* du dispositif <i>Intended purpose* of the device</i>	Référence au certificat requis pour la mise sur le marché du dispositif <i>Reference to the certificate required for placing on the market the device</i>
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN22	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN24	Class B	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.	N/A
In vitro diagnostic device: Reagents and software intended to be used to grow/isolate/identify infectious agents	VITEK® 2 AST-XN41	Class B	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.	N/A

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

4. Historique du certificat / *Certificate history:*

Version du certificat <i>Version of the certificate</i>	Date de délivrance <i>Date of issue</i>	Modifications apportées <i>Identification of the changes</i>
39291-0	23/05/2023 05/23/2023	Extension de la liste des dispositifs couverts par le certificat N° 38919 rev. 2, et création de trois nouveaux certificats couvrant les dispositifs ajoutés: N° 39290 rev. 0, N° 39291 rev. 0 et N° 39293 rev. 0 / <i>Extension of the list of devices covered by the certificate N° 38919 rev. 2, and creation of three new certificates covering the added devices: N#39290 rev. 0, N° 39291 rev. 0 and N#39293 rev. 0</i>

Version du certificat <i>Version of the certificate</i>	Date de délivrance <i>Date of issue</i>	Modifications apportées <i>Identification of the changes</i>
39291-1	23/06/2023 06/23/2023	Mise à jour de la liste des références <i>Update of list of references</i> Nouvelle(s) référence(s) de rapport dans le cadre du maintien de la certification <i>New file reference(s) in the framework of the maintenance of the certification</i> Correction d'un terme dans le scope en français <i>Correction of a word in the French translation of the scope</i>
39291-2	16/10/2023 10/16/2023	Mise à jour du champ d'application <i>Update of scope</i>
39291-3	19/03/2024 03/19/2024	Mise à jour de la liste des références <i>Update of list of references</i>
39291-4	14/05/2024 05/14/2024	Mise à jour de la liste des références <i>Update of list of references</i>
39291-5	21/11/2024 11/21/2024	Mise à jour de la liste des références <i>Update of list of references</i>
39291-6	04/03/2025 03/04/2025	Mise à jour de la liste des références <i>Update of list of references</i>
39291-7	13/05/2025 05/13/2025	Ajout de dispositifs suite à l'extension de gamme T002226-P4-REA <i>Addition of devices further to the Range Extension T002226-P4-REA</i>

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*