



BD MAX™ System Product Overview

BD MAX™ CE-IVD Assays

Assay kits contain Unitised Reagent Strips, Extraction Tubes, complete Master Mix Tubes and Sample Buffer Tubes (when applicable) for 24 tests.

BD REF	Product	Intended Use	Targets
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Healthcare-Associated Infection

442555	BD MAX™ Cdiff	Direct detection (stool)	Toxin B gene
443419	BD MAX™ StaphSR	Pre-surgical screening (nasal swab)	MRSA (11 MREJ-types) MSSA <i>mecA</i> & <i>mecC</i>
443461	BD MAX™ MRSA XT	Active surveillance (nasal swab)	MRSA (11 MREJ-types) <i>mecA</i> & <i>mecC</i>
445262	BD MAX™ CPO	Direct detection (rectal swab)	KPC NDM OXA-48 VIM & IMP

Gastrointestinal Infection

442963	BD MAX™ Enteric Bacterial Panel	Direct detection (stool)	<i>Salmonella</i> spp. <i>Shigella</i> spp. and EIEC <i>Campylobacter</i> spp. Shiga toxins 1&2 (STEC)
443812	BD MAX™ Extended Enteric Bacterial Panel	Direct detection (stool sample) – master mix only kit to run with BD MAX™ Enteric Bacterial Panel	<i>Yersinia enterocolitica</i> <i>Plesiomonas shigelloides</i> <i>Vibrio cholera</i> , <i>vulnificus</i> & <i>parahaemolyticus</i> ETEC (LT/ST)
442960	BD MAX™ Enteric Parasite Panel	Direct detection (stool)	<i>Giardia lamblia</i> <i>Entamoeba histolytica</i> <i>Cryptosporidium parvum</i> & <i>hominis</i>
443985	BD MAX™ Enteric Viral Panel	Direct detection (stool)	Norovirus GI/GII Rotavirus A Adenovirus (40/41) Sapovirus Astrovirus
443987	BD MAX™ Enteric Viral Panel-NR	Direct detection (stool)	Norovirus GI/GII Rotavirus A

BD REF	Product	Intended Use	Targets
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Respiratory Tract Infection

443878	BD MAX™ MDR-TB	Direct detection (sputum)	<i>Mycobacterium tuberculosis</i> complex, RIF resistance INH resistance
443806	BD MAX™ STR	with BD MAX™ MDR-TB	Pack of 48 tubes, 8 ml per tube
445003-01	BD SARS-CoV-2 Reagents for BD MAX™ System	Direct detection (nasal swab, naso/oropharyngeal swab, saliva)	SARS-CoV-2 N1 SARS-CoV-2 N2 (IC= RNase P)
445011	BD SARS-CoV-2/Flu for BD MAX™ System	Direct detection (nasopharyngeal swab, nasal swab)	SARS-CoV-2 Flu A Flu B
445215	BD Respiratory Viral Panel for BD MAX™ System	Direct detection (nasopharyngeal swab, nasal swab)	SARS-CoV-2 Flu A Flu B RSV

Sexually Transmitted Infection and Women's Health

441772	BD MAX™ GBS	Detection after broth enrichment (vaginal-rectal swab)	Group B <i>Streptococcus</i>
443712	BD MAX™ Vaginal Panel	Direct detection (vaginal swab)	Bacterial vaginosis <i>Candida</i> spp. <i>Candida glabrata</i> <i>Candida krusei</i> <i>Trichomonas vaginalis</i>
443905	BD CTGC2 for BD MAX™ System	Direct detection (urine, vaginal swab, endocervical swab, LBC)	<i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i>
443906	BD CTGCTV2 for BD MAX™ System	Direct detection (urine, vaginal swab, endocervical swab, LBC)	<i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i> <i>Trichomonas vaginalis</i>
443486	BD MAX™ GC real-time PCR	Confirmation of Viper GC positive	<i>Neisseria gonorrhoeae</i>

BD MAX™ CE-IVD Collection Kits and separate Sample Buffer Tubes

BD REF	Product	Intended Use	Quantity
443924	BD Molecular Urine Transport Kit	with BD CTGC2 and BD CTGCTV2	96 BD Molecular Urine Sample Buffer Tubes (4 x 24 tubes) 100 pipettes (4 x 25 pipettes)
443925	BD Molecular Swab Collection Kit	with BD CTGC2, BD CTGCTV2, and Vaginal Panel	Pack of 100 kits: BD Molecular Swab Sample Buffer Tube & collection swab
443923	BD Molecular LBC Sample Buffer Tubes	with BD CTGC2 and BD CTGCTV2	Pack of 48 tubes
440296	BD Molecular Swab Sample Buffer Tubes	with BD CTGC2, BD CTGCTV2, and Vaginal Panel	Pack of 48 tubes

BD MAX™ Open System Reagents (OSRs)

Extraction kits contain Unitised Reagent Strips, Extraction Tubes, and Sample Buffer Tubes for 24 tests.

Master mix kits contain 24 tubes of master mix and appropriate Primers and Probes Diluent.

BD REF	Product	Intended Use
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Extraction Kits

442818	BD MAX™ ExK™ DNA-1	Serum, Plasma, Urine
442820	BD MAX™ ExK™ DNA-2	Dry Swab, CSF
442826	BD MAX™ ExK™ TNA-2	CSF
442828	BD MAX™ ExK™ TNA-3	UTM

Master Mix Kits

442829	BD MAX™ DNA MMK(SPC)	DNA master mix with Sample Processing Control
442848	BD MAX™ DNA MMK	DNA master mix
442830	BD MAX™ TNA MMK(SPC)	TNA master mix with Sample Processing Control

Sealing Solution

437016	BD MAX™ Conical Tubes	Pack of 100 empty conical tubes
443412	BD MAX™ Conical Tube Holder	Block to hold BD MAX™ Conical Tubes for sealing in Axygen PlateMax HS-1230
443413	BD MAX™ 5-Color Seal Sheets	Pack of 50 sheets (10 per color) for sealing BD MAX™ Conical Tubes in Holder 443412 (total 2700 tests)
444159	BD MAX™ 3 codes Seal Sheets	Pack of 48 sheets for sealing BD MAX™ Conical Tubes. Barcodes 00, 01, 02 (16 sheets per code, total 2592 tests)
444160	BD MAX™ 5 codes Seal Sheets	Pack of 50 sheets for sealing BD MAX™ Conical Tubes. Barcodes 03, 04, 05, 06, 07 (10 sheets per code, total 2700 tests)

BD MAX™ PCR Cartridge

Required for all CE-IVD and OSR assays

BD REF	Product	Intended Use	Quantity
437519	PCR Cartridge	All assays	24 cartridges per pack

BD MAX™ CE-IVD Partner Assays

All CerTest Biotec assays require 1 PCR kit and the necessary extraction kit

BD REF	Product	Intended Use	Targets
Respiratory Tract Infection			
444200 442828	VIASURE Flu A, Flu B & RSV Kit BD MAX™ ExK™ TNA-3	Direct detection (oropharyngeal swab)	Influenza A Influenza B RSV
444215 442828	VIASURE SARS-CoV-2 (N1+N2) Kit BD MAX™ ExK™ TNA-3	Direct detection (naso/oropharyngeal swab, saliva)	SARS-CoV-2 N1 SARS-CoV-2 N2 (IC= RNase P)
444216 442828	VIASURE SARS-CoV-2 Variant Kit BD MAX™ ExK™ TNA-3	Direct detection (naso/oropharyngeal swab, saliva)	HV 69/70 deletion (Alpha) K417N mutation (Beta) K417T mutation (Gamma)
444218 442828	VIASURE SARS-CoV-2 Variant II Kit BD MAX™ ExK™ TNA-3	Direct detection (naso/oropharyngeal swab, saliva)	Mutation P681R and L452R (Delta)
444217 442828	VIASURE SARS-CoV-2, Flu (A+B) & RSV Kit BD MAX™ ExK™ TNA-3	Direct detection (naso/oropharyngeal swab)	SARS-CoV-2 N1 SARS-CoV-2 N2 Influenza A Influenza B RSV
444219 442828	VIASURE Respiratory Viral Mix I Kit BD MAX™ ExK™ TNA-3	Direct detection (nasopharyngeal swab)	SARS-CoV-2 Influenza A Influenza B RSV
444207 442828	VIASURE <i>Pneumocystis jirovecii</i> Kit BD MAX™ ExK™ TNA-3	Direct detection (bronchoalveolar lavage)	<i>P. jirovecii</i>
444204* 442828	VIASURE <i>Bordetella</i> Kit* BD MAX™ ExK™ TNA-3	Direct detection (nasopharyngeal swab/aspirate)	<i>B. pertussis</i> <i>B. parapertussis</i> <i>B. holmesii</i>
*Product not available for sale in Germany, France or United Kingdom			

Healthcare-Associated Infection

444202 442826	VIASURE Vancomycin resistance Kit BD MAX™ ExK™ TNA-2	Direct detection (rectal/perianal swab)	<i>vanA</i> <i>vanB</i>
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BD MAX™ Research Use Only Tests

All CerTest Biotec RUO tests require 1 PCR kit and the necessary extraction kit

444211 442828	VIASURE Monkeypox virus RUO Kit BD MAX™ ExK™ TNA-3	Research Use Only	G2R & F3L genes
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Other commercially available assays that could be used on the BD MAX™ System

For CE-IVD assays with Check-Points, please speak to your local BD representative

Biolegio READYMAX™ (www.biolegio.com): LUO

All assays require the necessary extraction kit: 442818 BD MAX™ ExK™ DNA-1 or 442820 BD MAX™ ExK™ DNA-2

BioGX (<https://biogx.com/products/biogx-eu/bd-max-system>): CE-IVD and LUO

All assays require the necessary extraction kit:

442818 BD MAX™ ExK™ DNA-1, 442820 BD MAX™ ExK™ DNA-2, 442822 BD MAX™ ExK™ DNA-3, 442826 BD MAX™ ExK™ TNA-2, or 442828 BD MAX™ ExK™ TNA-3

The BD MAX™ System, BD MAX™ Enteric Bacterial Panel, BD MAX™ Extended Enteric Bacterial Panel, BD MAX™ Enteric Viral Panel, BD MAX™ Enteric Viral Panel-NR, BD MAX™ Enteric Parasite Panel, BD MAX™ Vaginal Panel, BD MAX™ CPO, BD MAX™ MRSA XT, BD MAX™ StaphSR, BD MAX™ Cdiff, BD MAX™ MDR-TB, BD MAX™ STR, BD SARS-CoV-2 Reagents for BD MAX™ System, BD SARS-CoV-2/Flu for BD MAX™ System, BD Respiratory Viral Panel for BD MAX™ System, VIASURE SARS-CoV-2 (N1+N2) Real Time PCR Detection Kit for BD MAX™ System, VIASURE SARS-CoV-2 Variant Real Time PCR Detection Kit for BD MAX™, VIASURE SARS-CoV-2 Variant II Real Time PCR Detection Kit for BD MAX™, VIASURE SARS-CoV-2, Flu (A+B), RSV Real Time PCR Detection Kit for BD MAX™ System, VIASURE Flu A, Flu B & RSV Real Time PCR Detection Kit for BD MAX™ System, VIASURE Vancomycin Resistance Real Time PCR Detection Kit for BD MAX™ System, VIASURE Respiratory Viral Mix I Real Time PCR Detection Kit for BD MAX™ System, VIASURE Pneumocystis jirovecii Real Time PCR Detection Kit for BD MAX™ System and VIASURE Bordetella Real Time PCR Detection Kit for BD MAX™ System are in vitro diagnostic medical devices bearing a CE mark.

The BD CTGCTV2 and BD CTGC2 for BD MAX™ System are in vitro diagnostic medical devices bearing a CE mark and are CE certified by BSI Group The Netherlands B.V. (Notified Body Number = 2797).

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