



BD MAX™ System Product Overview

BD MAX™ CE-IVD Assays

Assay kits contain strips, extraction reagents and complete master mix

BD REF	Product	Intended Use	Targets
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Healthcare-Associated Infection

442555	BD MAX™ Cdiff	Direct detection (stool sample)	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>
278102	BD MAX™ Check-Points CPO	Direct detection (rectal swab)	KPC NDM OXA-48 VIM & IMP

Gastrointestinal Infection

442963	BD MAX™ Enteric Bacterial Panel	Direct detection (stool sample)	<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) – Run with BD MAX™ Enteric Bacterial Panel (442963)	<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 sample)	<i>Giardia lamblia</i> <i>Entamoeba histolytica</i> <i>Cryptosporidium parvum</i> & <i>hominis</i>
443985	BD MAX™ Enteric Viral Panel	Direct detection (stool sample)	Norovirus GI/GII Rotavirus A Adenovirus (40/41) Sapovirus Astrovirus
443987	BD MAX™ Enteric Viral Panel-NR	Direct detection (stool sample)	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 sample)	<i>Mycobacterium tuberculosis</i> complex, RIF resistance INH resistance
443806	BD MAX™ STR	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 (IC= RNase P)

Sexually Transmitted Infection and Women's Health

441772	BD MAX™ GBS	Detection after broth enrichment	Group B Streptococcus
443486	BD MAX™ GC real-time PCR	Confirmation of Viper GC positive	<i>Neisseria gonorrhoeae</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>
443924	BD Molecular Urine Transport Kit	BD CTGC2, BD CTGCTV2	Pack of 100 kits: BD Molecular Swab Sample Buffer Tube & collection swab
443925	BD Molecular Swab Collection Kit	BD CTGC2, BD CTGCTV2, Vaginal Panel	96 tubes (4 x 24 tubes) 100 pipettes (4 x 25 pipettes)
443923	BD Molecular LBC Sample Buffer Tubes	BD CTGC2, BD CTGCTV2	Pack of 48 tubes
440296	BD Molecular Swab Sample Buffer Tubes	BD CTGC2, BD CTGCTV2, Vaginal Panel	Pack of 48 tubes
443712	BD MAX™ Vaginal Panel	Direct detection (vaginal swab)	Bacterial Vaginosis: <i>Lactobacillus</i> spp., <i>G. vaginalis</i> , <i>A. vaginae</i> , <i>BVAB-2</i> and <i>Megasphaera-1</i> Vaginitis: <i>Candida</i> spp. <i>Candida glabrata</i> <i>Candida krusei</i> <i>Trichomonas vaginalis</i>

BD MAX™ Open System Reagents (OSRs)

BD REF	Product	Intended Use
Extraction Reagents		
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 Reagents		
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 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 Conical Tubes in Holder 443412
444159	BD MAX™ 3 codes Seal Sheets	Codes 00, 01, 02. Pack with 16 sheets per code (48 sheets total, 2592 tests)
444160	BD MAX™ 5 codes Seal Sheets	Codes 03, 04, 05, 06, 07. Pack with 10 sheets per code (50 sheets 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 OSRs

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)	Mutations P681R & 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
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>
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>

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 & Extended Enteric Bacterial Panels, BD MAX™ Enteric Viral Panel, BD MAX™ Enteric Viral Panel-NR, BD MAX™ Enteric Parasite Panel, BD MAX™ Vaginal Panel, BD MAX™ Check-Points CPO, Check-Direct CPE for BD MAX™, 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, 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 *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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