

# BD MAX™ Assays

## Healthcare Associated Infection [HAI]

Product	Description	Claim	Specimen	Cat N°	Size
<b>MRSA XT</b>	<b>To identify Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) carriers and prevent transmission and infection:</b> detection of MRSA strains (mecA, mecC, 10 MREJ types)	CE-IVD and US-IVD (FDA)	Nasal swabs	443461	24 tests
<b>StaphSR</b>	<b>To identify <i>Staphylococcus aureus</i> and MRSA carriers, and prevent surgical infections:</b> detection & differentiation of <i>Staphylococcus aureus</i> and MRSA strains (mecA, mecC, 10 MREJ types)	CE-IVD and US-IVD (FDA)	Nasal swabs	443419	24 tests
<b>Cdiff</b>	<b>To detect <i>Clostridium difficile</i> in liquid or soft stool specimens and prevent transmission:</b> detection of Toxin B gene	CE-IVD and US-IVD (FDA)	Stool	442555	24 tests
<b>Check-Points CPO</b>	<b>To identify Carbapenemase Producing Organisms (CPO) carriers and prevent transmission and infection:</b> detection and differentiation of KPC, NDM, VIM/IMP and OXA-48 related	CE-IVD	Rectal ESwab	278102	24 tests
<b>Check-Direct CPE</b>	<b>To confirm Carbapenemase Producing <i>Enterobacteriaceae</i> (CPE):</b> detection and differentiation of KPC, NDM, VIM and OXA-48 related <i>To be ordered together with Cat No 442818 (ExK DNA-1) and Cat No 442848 (DNA MMK)</i>	CE-IVD	Bacterial Colonies	278101	24 tests
<b>VanR (CerTest)</b>	<b>To detect and differentiate vanA and vanB genes in perianal swabs, rectal swabs and bacterial colonies suspensions</b> <i>To be ordered together with Cat No 442826 (ExK TNA-2)</i>	CE-IVD	Perianal ESwab, Rectal ESwab, Bacterial Colonies	444201	24 tests

## Enteric Disease

Product	Description	Claim	Specimen	Cat N°	Size
<b>Enteric Bacterial Panel</b>	<b>To detect bacteria causing diarrhea in liquid or soft stool specimens:</b> detection & differentiation of <i>Salmonella</i> spp, <i>Campylobacter</i> spp, <i>Shigella</i> spp., and Shiga Toxin Producing <i>E.coli</i> (STEC)	CE-IVD and US-IVD (FDA)	Stool	442963	24 tests
<b>Extended Enteric Bacterial Panel</b>	<b>To detect bacteria causing diarrhea in liquid or soft stool specimens:</b> detection & differentiation of <i>Yersinia</i> spp, ETEC, <i>Vibrio</i> spp and <i>Plesiomonas</i> <i>To be ordered together with Cat No 442963 (EBP)</i>	CE-IVD and US-IVD (FDA)	Stool	443812	24 tests
<b>Enteric Parasite Panel</b>	<b>To detect parasites causing diarrhea in liquid or soft stool specimens:</b> detection & differentiation of <i>Giardia lamblia</i> , <i>Entamoeba histolytica</i> and <i>Cryptosporidium parvum</i>	CE-IVD and US-IVD (FDA)	Stool	442960	24 tests
<b>Enteric Viral Panel</b>	<b>To detect virus causing diarrhea in liquid or soft stool specimens:</b> detection & differentiation of Norovirus, Rotavirus, Sapovirus, Astrovirus and Adenovirus	CE-IVD and US-IVD (FDA)	Stool	443985	24 tests



## Sexually transmitted infection / reproductive infectious disease

Product	Description	Claim	Specimen	Cat N°	Size
<b>GBS</b>	<b>For screening of pregnant women to prevent Group B streptococcal disease in newborns:</b> detection of Group B Streptococcus (GBS) from enriched media after 18h incubation	CE-IVD & US-IVD (FDA)	Vaginal-rectal swabs inoculated in Enriched media	441772	24 tests
<b>Vaginal Panel</b>	<b>To detect organisms associated with Bacterial Vaginosis, Candidiasis and Trichomoniasis:</b> detection & differentiation of <i>Lactobacillus</i> spp., <i>G. vaginalis</i> , <i>Atopobium vaginae</i> , <i>BVAB-2</i> & <i>Megasphaera-1</i> (Bacterial Vaginosis) and <i>Candida</i> spp., <i>C. glabrata</i> , <i>C. krusei</i> , & <i>Trichomonas vaginalis</i> (Vaginitis) <i>To be ordered together with Cat No 443376 (UVE Specimen Collection Kit, 100 tests)</i>	CE-IVD and US-IVD (FDA)	Vaginal swab	443712	24 tests
<b>CT/GC/TV CT/GC</b>	<b>To detect pathogens causing Sexually Transmitted Infections:</b> <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> and <i>Trichomonas vaginalis</i> <i>To be ordered together with Cat No 443376 (UVE Specimen Collection Kit, 100 tests) or Cat No 443420 (UVE Sample Buffer Tubes, 48 tests)</i>	CE-IVD and US-IVD (FDA)	Vaginal and Endocervical swabs, Urine	442970 442969	24 tests

## Respiratory disease

Product	Description	Claim	Specimen	Cat N°	Size
<b>MDR TB</b>	<b>To detect Tuberculosis and resistance to Rifampicin and Isoniazid in respiratory samples from patients with signs and symptoms</b> detection of <i>Mycobacterium tuberculosis</i> complex and mutations in <i>rpoB</i> gene (Rifampin resistance), <i>inhA</i> gene and <i>katG</i> promoter region (Isoniazid resistance) <i>To be ordered together with Cat No 443806, STR</i>	CE-IVD	Sputum	443878	24 tests
<b>Influenza A/B, RSV (CerTest)</b>	<b>To detect Influenza and Human Respiratory Syncytial Virus (RSV) in respiratory samples from patients with signs and symptoms</b> detection & differentiation of Influenza A, Influenza B and RSV <i>To be ordered together with Cat No 442828, ExK TNA-3</i>	CE-IVD	Throat swab	444200	24 tests
<b>SARS CoV-2</b>	<b>To detect SARS-CoV-2 in nasal, nasopharyngeal, and oropharyngeal swab samples from individuals suspected of COVID-19 by their healthcare provider:</b> Detection of the nucleocapsid phosphoprotein gene (N1 and N2) and the human RNase P gene (control)	CE-IVD and EUA-FDA	Nasal, nasopharyngeal, or oropharyngeal	445003-01	24 tests
<b>SARS-CoV-2 / Flu</b>	<b>To detect SARS-CoV-2, influenza A and influenza B in nasopharyngeal swabs samples from individuals suspected of COVID-19 or flu by their healthcare provider</b> Detection of SARS-CoV-2 nucleocapsid phosphoprotein genes (N1, N2), influenza A M1 gene and influenza B M1 and HA genes, and the human RNase P gene (control)	CE-IVD and EUA-FDA	Nasopharyngeal	445011	24 tests