BD MAX™ GBS
Real-time PCR assay

The need for Group B *Streptococcus* testing

Group B *Streptococcus* (GBS) is a gram-positive bacterium that causes invasive diseases primarily in infants, pregnant or postpartum women and older adults, with the highest incidence among young infants. The Centers for Disease Control (CDC) estimates that in recent years, GBS has caused approximately **1,200 cases of early-onset invasive disease per year;** approximately **70% of cases are among babies born at term** (=37 weeks gestation).[1]

The current standard of care for preventing neonatal GBS disease is **screening pregnant women at 35–37 weeks of gestation** to determine their GBS colonisation status. Most GBS testing is performed by culture and can take up to 48 hours for definitive identification of GBS following the initial ≥ 18 hours incubation of vaginal-rectal swabs in a selective broth medium.

Discover the assay

The **BD MAX™ GBS** is an automated assay including nucleic acid extraction and real-time polymerase chain reaction (PCR) for direct and qualitative detection **of GBS DNA in Lim Broth cultures,** after incubation for ≥ 18 hours.

This test also includes a sample processing control.

The **BD MAX™ GBS** assay does not provide susceptibility results.

Sample types

- Vaginal-rectal swab

Workflow and time to results

Results obtained in approximately 2 hours for 24 samples after the initial ≥18 hours incubation/enrichment step, limiting the need for operator intervention from the time the sample is placed onto the BD MAX™ System until results are available

Less than **1.5 minutes of hands-on time** in sample preparation

As an exception to other BD MAX™ assays, the **BD MAX™ GBS assay is NOT run or rack compatible**, still you have the possibility to run from 1 to 24 specimens in the same batch

Scientific evaluation

Read more about the **BD MAX™ GBS assay** from molecular studies and publications.

Bogiel et al., Application of the appropriate molecular biology-based method significantly increases the sensitivity of GBS detection results., J Hosp Infect. 2021 Jun;112:21-26.

Ready-to-use reagents storable at room temperature

REF	Contents	Quantity
441772	**BD MAX™ GBS Master Mix (GB)** Freeze-dried PCR Master Mix containing GBS-specific Scorpions probes and primers along with Sample Processing Control and PCR enzyme	24 tests (2 x 12 tubes)
	BD MAX™ DNA Unitised Reagent Strip Unitised reagent strip containing reagent buffer, elution buffer, and buffer 3D reagents, as well as disposable pipette tips necessary for sample processing DNA extraction	24 strips
	BD MAX™ GBS Extraction Reagent (E3) Freeze-dried DNA magnetic affinity beads, Mutanolysin, Protease reagents and Sample Processing Control	24 tests (2 x 12 tubes)
	BD MAX™ Sample Preparation Reagent	24 tubes
	Septum Cap	25

Rapid, targeted testing on the BD MAX™ System

The innovation of the BD MAX™ System offers you a **fully integrated, automated real-time PCR platform** with the possibility of running multiple assays simultaneously.* Its automated workflow **reduces manual tasks** to achieve rapid, reliable results and facilitates off-hour testing, helping to **offset molecular testing costs**.** [2,3]

Snap

Assemble unitised reagent strips with ready-to-use reagents.

Load

Load Sample Buffer Tubes, Racks and PCR cartridges.

Go

Come back in an average of 2.5 hours for results.***

Discover our full assay portfolio and the BD MAX™ System

advancing-diagnostics.eu advancingdiagnostics@bd.com

BD MAX™ GBS [IFU 441772], Franklin Lakes, NJ: Becton, Dickinson and Company; 2021.

1.Centers for Disease Control and Prevention. Prevention of Perinatal Group B Streptococcal Disease: Revised Guideline from CDC, 2010 **2.** Mortensen JE, et al. Comparison of time-motion analysis of conventional stool culture and the BD MAX™ Enteric Bacterial Panel (EBP). BMC Clin Pathol. 2015;15:9.. **3.** Hirvonen JJ, et al. Comparison of BD Max Cdiff and GenomEra C. difficile molecular assays for detection of toxigenic Clostridium difficile from stools in conventional sample containers and in FecalSwabs. Eur J Clin Microbiol Infect Dis. 2015;34(5):1005-1009.

* BD assays are run & rack compatible – Only MDR-TB and GBS are not run and rack compatible / Vaginal Panel and open systems' assays are only run compatible.
** When compared to culture or immunochromatographic antigen (IA).
*** Time is assay dependent. 4 hours for full results on MDR-TB assay.

The BD MAX™ System and BD MAX™ GBS assay are in-vitro diagnostic medical devices bearing a CE-mark.

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