

Smart GBS

Better Group B *Streptococcus* answers.



defining *on-demand* molecular diagnostics.

Smart GBS: Better Group B *Streptococcus* answers

The Cepheid Smart GBS test, performed on the SmartCycler® System, is a qualitative *in vitro* diagnostic test designed to detect Group B *Streptococcus* (GBS) DNA in vaginal/rectal specimens using proven real-time PCR technology. When run directly from LIM broth cultures, Smart GBS delivers the most accurate GBS test results available today. Smart GBS – better Group B *Streptococcus* answers.

problem:

According to the CDC, Group B *Streptococcus* (GBS) bacterium is the most common cause of life-threatening infections in newborns and is the leading cause of neonatal morbidity and mortality. Untreated, GBS can lead to the development of sepsis, pneumonia and meningitis. GBS sepsis and meningitis in newborns result in an approximate 4% fatality rate of those infected and roughly \$300 million in healthcare costs' annually.

Currently, the standard of care for preventing neonatal GBS disease is screening pregnant women at 35–37 weeks of gestation to determine their GBS colonization status'.

Transmission of GBS occurs from GBS-colonized women to their babies during childbirth. Most GBS testing is performed by culture and typically takes up to 4 days to final results. This process can be both laborious and error prone, due to the numerous steps involved and possible limitations in identifying lightly colonized GBS specimens.

solution:

Smart GBS is the first FDA cleared product that can be run from LIM broth cultures or directly from vaginal/rectal specimens, providing your laboratory with the greatest flexibility to meet your physician needs. Through real-time PCR technology, lightly colonized specimens are easily identified. In addition, antepartum testing utilizing Smart GBS with

Smart: in action

LIM broth provides the highest level of sensitivity available for a GBS test.

impact:

With Smart GBS, time to result and labor costs are significantly decreased when compared to culture. More importantly, Smart GBS can better help guide physicians in the appropriate treatment of GBS colonization, therefore significantly decreasing the risk of perinatal GBS disease.

integrated:

The SmartCycler System® is one of today's most flexible, easy to use and sensitive real-time PCR testing platforms.

With the SmartCycler System, inefficient batch processing is no longer your only option. Specimens can now be processed as they arrive in your laboratory. Runs can be started at different times, allowing multiple operators to use the SmartCycler simultaneously.

flexible:

The SmartCycler System's unique random-access capability enables users to conduct up to 96 different molecular tests concurrently. With only two SmartCycler instruments (32 sites) an equal or greater number of samples can be processed than with a 96-well instrument through the course of a day.

Smart: by design

easy to use:

At the heart of the SmartCycler System is a reliable, solid-state optical system with no moving parts. Each of the 16 modules requires no warm-up time, no routine maintenance, and no normalization dye. Choose an instrument system or protocol that fits your testing requirements. As testing volumes expand, you can add more capacity to the system as required.



Flexible:

Protocols for both antepartum and intrapartum testing.

Comparison of Smart GBS with LIM broth pre-enrichment and the CDC culture technique for antepartum testing.

		Culture		
		+	-	Totals
Smart GBS	+	74	22	96
	-	1	209	210
		75	231	306

Sensitivity: 98.7%
 Specificity: 90.4%
 PPV: 77.1%
 NPV: 99.5%

Comparison of Smart GBS from direct vaginal/rectal specimens and the CDC culture technique for antepartum and intrapartum testing.

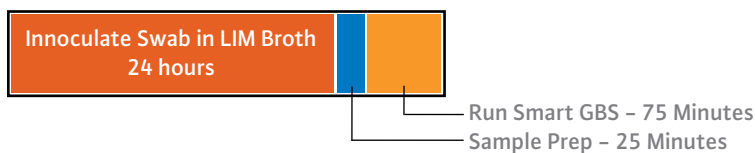
		Culture		
		+	-	Totals
Smart GBS	+	151	21	172
	-	34	568	602
		185	589	774

Sensitivity: 81.6%
 Specificity: 96.3%
 PPV: 87.8%
 NPV: 94.4%

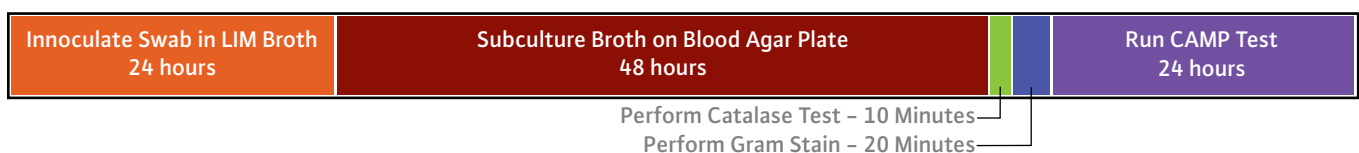
Enhanced Workflow:

Save time and increase sensitivity.

Smart GBS Process



Standard Culture Procedure



The Cepheid advantage: Comprehensive GBS testing solution

Xpert™ GBS and Smart GBS offer your laboratory the only comprehensive solution for both antepartum and intrapartum GBS testing. Choose the solution that is right for your laboratory and physicians:

Smart™ GBS: Ultimate Flexibility

- FDA cleared *in vitro* molecular diagnostic protocols for direct specimen from vaginal/rectal swabs and/or from LIM broth
- Standardizes antepartum testing, producing highly accurate results
- Fits perfectly into the workflow of busy molecular laboratories
- Random access provides testing flexibility



Xpert™ GBS: Ultimate Simplicity

- First CLIA “Moderately Complex” molecular *in vitro* diagnostic GBS test
- Fully automated process reduces handling time
- On-demand testing available 24/7
- Ease of use for both clinical laboratories and near-patient applications
- Rapid results in just 75 minutes



Ordering Information

Smart GBS Catalog No. SCGBS-100N-50
(50 tests)

Cepheid GBS Collection Device..... Catalog No. 900-0370
(100 swabs)

References:

1 Centers for Disease Control and Prevention. Prevention of Perinatal Group B Streptococcal Disease. MMWR 2002; 51 (No. RR-11): 1-26.

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Practice of the patented polymerase chain reaction (PCR) process requires a license. The SmartCycler® System is an authorized thermal cycler and may be used with PCR licenses available from Applied Biosystems. Its use with authorized reagents also provides a limited PCR license in accordance with the label rights accompanying such reagents. Purchase of this instrument does not convey any right to practice the 5' nuclease assay or any of the other real-time methods covered by patents owned or controlled by Roche or Applied Biosystems. Cepheid's SmartCycler® System is a licensed real-time thermal cycler under Applera's European Patent No. EP 0 872 562, Japanese Patent No. JP 3136129 and patents pending, for all fields including human *in vitro* diagnostics except for diagnosis and monitoring of HIV and HCV infections. This product is made using components and licensed by Eppendorf AG. The purchase price of this product includes limited, nontransferable rights to use only this amount of the product to practice the method for reversible inhibition of thermostable polymerase as claimed in U.S. Patent No. 6,667,165.

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