



Group B *Streptococcus* Test Data Sheet

Catalog Number	300781
Suggested CPT code	87653
Sample Type	Vaginal/rectal swab enriched in LIM broth 18-29 hrs
Sample Stability	4 days at 2°- 8°C; 12 hrs at RT
Kit Storage	2°- 8°C
Intended Use	Antepartum screening at 35-37 weeks of pregnancy
Hands-on Time	1 min
TTR	~105 min
Sensitivity	97.9%
Specificity	96.0%
Target	Conserved genetic region of <i>Streptococcus agalactiae</i>
Limit of Detection (LoD)	2.4 – 3.9 CFU/reaction (refer to Package Insert for details)
Reported Result	Positive or Negative for Group B <i>Streptococcus</i>
CLIA Categorization	Moderate complexity
Technology	PCR amplification (NAAT)
Suggested External Positive Controls	<ul style="list-style-type: none"> • <i>S. agalactiae</i> strain (ATCC 12403 or ATCC BAA-1177) grown according to manufacturer's instructions and enriched in LIM broth, or • ZeptoMetrix NATtrol™ GBS Positive Control (Catalog Number NATSAG-6MC), or • LIM enriched known positive patient specimen
Suggested External Negative Controls	<ul style="list-style-type: none"> • Pure LIM broth
Pipette	50µL fixed volume (provided)
Recommended Pipette Tips	200µL sterile barrier tips <ul style="list-style-type: none"> • Fisher Catalog Number: 07-200-504 (extended length) • Corning Catalog Number: 4139
Proficiency Surveys	<ul style="list-style-type: none"> • API: #315 and #929 • CAP: D8

Please refer to Package Insert for more detailed information.