* 1. **INTRODUCTION:**

The Revogene® GBS LB assay performed on the Revogene® instrument is a qualitative *in vitro* diagnostic test designed to detect Group B *Streptococcus* (GBS) DNA from 18-24 hour LIM broth enrichments of vaginal/rectal specimen swabs obtained from pregnant women. The Revogene GBS LB assay utilizes automated sample processing and real-time polymerase chain reaction (PCR) to detect a *cfb* gene sequence specific to the *Streptococcus agalactiae* genome.

The Revogene GBS LB assay is indicated for the identification of antepartum GBS colonization and does not provide susceptibility results. It is not intended to diagnose or monitor treatment of GBS infection. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

* 1. **OBJECTIVE:**

The purpose is to validate the Process control (PrC) to verify that it is sufficient to monitor the analytic process daily. The PrC is incorporated into each PIE to verify sample processing and amplification steps including the verification of potential inhibitor substances as well as microfluidic, instrument or reagent failure. Validation of the PrC will allow external controls to be run per lot or shipment or every 30 days whichever is more frequent.

* 1. **DESCRIPTION:**

To validate the PrC, external controls will be tested each day of patient testing for thirty days. External controls need only be tested on days when patient specimens are tested. If no patient specimens are tested, then document “No patient testing performed” on the data sheet, initial and date the entry. Once the internal control is validated, daily QC will require the PrC to be documented as valid/invalid for each specimen. External controls will need to be run with every lot or shipment or every 30 days, whichever is more frequent.

* 1. **INTERNAL CONTROL VALIDATION:**

External controls or known positive and known negative specimens will be tested each day patients are tested for thirty days. Internal and external control results will be recorded in Table 1. If an invalid result is obtained, the specimens or controls will be repeated and if the repeat is valid, the repeat result will be considered acceptable.

**Table 1 - Internal Control Validation**

Specimen Panel Lot# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Kit Lot#/Exp. Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Date | Specimen ID | Expected Result | PrC Valid (Y/N) | Actual Result | | Performed By |
| **Day 1** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 2** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 3** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 4** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 5** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 6** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 7** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 8** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 9** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 10** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 11** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 12** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 13** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 14** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 15** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 16** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
|  | Date | Specimen ID | Expected Result | PrC Valid (Y/N) | Actual Result | Performed By | |
| **Day 17** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 18** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 19** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 20** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 21** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 22** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 23** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 24** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 25** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 26** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 27** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 28** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 29** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |
| **Day 30** |  | External Negative | Negative |  |  |  | |
| External Positive | Positive |  |  |  | |

This validation study has been reviewed and the performance of the method is considered acceptable for patient testing.

*Reviewed By/Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Approved by/Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

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*(Title)*