Revogene® C. *difficile* Internal Control Validation

A. INTRODUCTION:

The Revogene® C. *difficile* assay performed on the Revogene® instrument is a qualitative in vitro diagnostic test that utilizes automated sample processing and real-time polymerase chain reaction (PCR) to detect the toxin B (tcdB) gene of toxigenic Clostridium difficile (C. *difficile*) in unformed (liquid or soft) stool specimens obtained from patients suspected of having C. *difficile* infection (CDI). The Revogene C. *difficile* assay is intended to aid in the diagnosis of CDI.

B. 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 Process Control will allow the PrC to be used as the daily control for the Revogene C. *difficile* assay. External controls will then be tested per lot or shipment or every 30 days whichever is more frequent.

C. 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.

D. 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.

Revogene® C. *difficile* Internal Control Validation

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			

Revogene® C. *difficile* Internal Control Validation

	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)