TEST SY			
Steps	**Failure Mode**	**Cause**	***Internal Controls***
List the stage or aspect of the test system's process under investigation.	*List all manners in which failure could occur in this step.*	*List all causes of the failure mode that have the potential to produce incorrect test results.*	*Are there internal biological or procedural controls to detect failure?*
Samples Received Stool Samples	Sample Collection Integrity	Urine, or toilet paper	No
		Storage	No
	Improper Sample	Aspirate or Wash	No
		Formed Stool	No

TEST SY			
Steps	**Failure Mode**	**Cause**	***Internal Controls***
Samples Received Stool Samples	Sample Collection	Specimen contains excess known inhibitors (See PI) or is overinoculated introducing excess inhibitors. No risk to patient results as excess inhibitors will inhibit the PrC and be unresolved	Yes
		Outpatient improper collection	No
Specimens and Reagents	Sample Processing	Inadequate volume of specimen used	No

TEST SY			
Steps	**Failure Mode**	**Cause**	***Internal Controls***
Specimens and Reagents	Sample Processing	DNA Contamination from PIE incorrectly closed	No
		Amplicon Contamination	No
		Specimen Crossover Contamination	No

TEST SY			
Steps	**Failure Mode**	**Cause**	***Internal Controls***
Test Kit and Reagents	Test Kit Degradation	Shipping	Yes, PrC to detect reagent integrity
		Storage	Yes
		Used past expiration	No

TEST SY			
Steps	**Failure Mode**	**Cause**	***Internal Controls***
Reagents	Improper use	Preparation and Use	Yes, internal control to detect operator errors in use of reagents
		Pie not closed correctly	No
		PIE not inserted into instrument correclty	Yes
Operator	Operator Capacity	Training inadequate, Untrained Operator or Short Staffing	Yes, Internal process control
	Operator Staffing	Correct Staffing (MLT or MLSs)	Yes, Internal process control
Laboratory Environment	Atmospheric Environment	Dust	No
		Temperature	Yes, if the temperature is not accurate, the PrC will not amplify and and will report as Unresolved
	Atmospheric Environment	Humidity	Yes, Internal control to monitor reagent reactivity.

TEST SY			
Steps	**Failure Mode**	**Cause**	***Internal Controls***
Laboratory Environment	Utility Environment	Electrical	No
Laboratory Equipment	Run not initiated	Run button not selected	No
	Incubation temperature incorrect	Software failure	No
	Specimen Amplification and endpoint result	PIE not inserted correctly	yes, results would be unresolved
		optics blocked or not not connected	
		Lid not completely closed	
Post Analytic	Transcription Errors	Incorrect results input for patient	No
	Timely reporting of results	Failure to report results in a timely manner	No

STEM: Revogene C. difficile

		Means of Failure Detection
External Controls	***Engineering Controls***	***Operator Training***
Can external controls increase the probability to detect failure?	*Are there manufacturer checks to reduce the probability of failure?*	*Can operators reduce or detect failures through training?*
No	No	Yes- Techs are trained to reject specimens based on lab policy
No	No	Yes
No	No	Yes
No	No	Yes

STEM: Revogene C. difficile

Means of Failure Detection		
External Controls	***Engineering Controls***	***Operator Training***
No	No	Yes
No	No	No
No	No	Yes

STEM: Revogene C. difficile

		Means of Failure Detection
External Controls	***Engineering Controls***	***Operator Training***
Yes	No	Yes, Staff is trained to proper closure of the PIE
Yes	Yes, latch closes the device and cannot be opened without excessive force	Staff is trained to good molecular practice.
No	No	Yes, Staff is trained to only have one PIE open at a time.

STEM: Revogene C. difficile

Means of Failure Detection		
External Controls	***Engineering Controls***	***Operator Training***
Yes, Test external quality control (QC) prior to use to detect deterioration during shipping.	No	Yes, Techs are trained to perform external QC testing prior to putting a test kit into use.
No	No	Yes, Staff is trained to inspect temperature ranges labelled on the test kit.
No	PIEs are all Barcode scanned and cannot be used past expiration.	Yes

STEM: Revogene C. difficile

Means of Failure Detection		
External Controls	***Engineering Controls***	***Operator Training***
No	No	Yes. Training provided on running the assay by manufacturer or a trained operator.
No	yes, the retention ring will close the PIE when it is latched onto the rotor if the PIE is not already closed	Yes
No	Yes	Yes
No	Must sign in to start a run.	Yes - Moderate complexity tests. Must be a trained operator. Only Operators have a user name and password.
No	Must sign in to start a run.	Yes - Moderate complexity tests. Must be a trained operator. Only Operators have a user name and password.
No	No	Yes, Staff instructed to keep lids closed unless loading devices.
No	Yes, software monitors temperature.	No
No	No	Yes, users are instructed to use reagents within 1 hour of opening.

STEM: Revogene C. difficile

Means of Failure Detection		
External Controls	***Engineering Controls***	***Operator Training***
No	Instrument will not function or will abort run if there is an electrical disturbance	No
No	Stand by mode after 15 minutes and user is logged off	Yes
No	Yes, Error Code Displayed	No
No	Yes Optics cannot correctly read fluorecence so unresolved or indeterminant is reported.	No
No	No	Yes
No	No	Yes

Laboratory's Mitigating Actions
What other processes can the laboratory implement to reduce failure?
Laboratory policy states specimens obviously contaminated with urine, toilet paper are rejected.
All specimens are labelled with collection date and time. Specimens from outreach facilities are shipped with cold packs. Out patients are logged in by Lab assistants and specimens are put in the refrigerator until processed. Techs check to ensure Specimens meet storage criteria. C. diffs are batched at least once per day. If requested, specimen may be run STAT.
Lab policy states to reject specimens that are not stool specimens.
Lab rejects any specimens that do not form to the container. Physician's office is notified if a specimen is rejected.

Laboratory's Mitigating Actions
Collecting persons are trained to the appropriate specimen type. Operators are trained to repeat specimen once if it is unresolved and if specimen is unresolved a second time it is reported as invalid and a recollect requested.
Patient instructions are provided to out-patients to ensure specimen integrity. Laboratory personnel verify the collection date and time is on the container. Techs in the lab ensure storage has been appropriate for the assay.
1. Training and competency assessment must be completed and signed off prior to performing any testing where patient results are reported. 2. Each Year competency is completed for each technologist who performs testing. 3. Each technologist participates in proficiency testing.

Laboratory's Mitigating Actions
1. Daily Cleaning Logs for Benches and Equipment. 2. Amplified devices are discarded in a biohazard container that is removed from the lab daily. 3. Infection Control Monitors positivity rate 4. System is a closed so amplicon contamination is rare.
1. Accession numbers are unique to each patient. Each tube is labelled with an id to ensure the correct patient is processed thru the entire test process. 2. Daily Cleaning Logs for Benches and Equipment. 3. Competency is performed yearly to ensure proper labeling of specimens and devices.

Laboratory's Mitigating Actions
Product is shipped in labelled boxes that detail storage conditions. Warehouse checks all product in and delivers product to the lab same day. Staff is instructed to verify integrity of shipping material such as leakage etc…
All coolers ard rooms have temperature monitored and recorded daily.
Expiration date checked and documented with each run via PIE Barcode.

Laboratory's Mitigating Actions
1. Training and competency assessment must be completed and signed off prior to performing any testing where patient results are reported. 2. Yearly competency testing 3. Each Operator participates in proficiency testing
The PIE closes when retention ring is added. The closure is secure and cannot be opened without signifcant force once closed.
Operators are trained to proper insertion of the PIE. If not inserted correctly, the specimen will be reported as unresolved so no risk to patient results.
In the event of short staffing, Untrained operator would never be allowed to run the test. Specimens that are STAT may be batched and TAT may be impacted. However, prior to leaving, all specimens are either reported or are sent out for testing.
Human Resources is required to get diploma and registration for every laboratory tech and they check its validity and keep it on file.
Reaction occurs in a closed device so dust would not impact the reaction.
Reaction occurs in the Revogene. The instrument temperature cycling is monitored by the software.
Test kit does not have humidity requirements. Internal control is present to monitor reagent reactivity.
Working humidity is 0-80-% RH

Laboratory's Mitigating Actions
No risk to patient results as a run could not progress if there was an electrical disturbance.
No risk to patient results
Immediately contact device manufacturer technical support for replacement and notify immediate supervisor.
No risk to patient results as an unresolved or indeterminant result would be reported.
Log is kept of all results that are corrected. Audit all results reported. Results are spot checked for accuracy prior to reporting
Pending list printed twice per shift. Techs trained to report results upon completion of the test. All results reported before leaving. No results are left to be reported on the next shift.