The following information is intended as an aid in the development of your facility's IQCP Risk Assessment and Quality Control Plan for the Sure-Vue Signature Cryptosporidium/Giardia Test for stool specimens.

This document is not intended to replace the Package Insert. Any modifications to this document are the sole responsibility of the facility.

Information from the Sure-Vue Signature Cryptosporidium/Giardia Kit Package Insert (PN: 23-200-277).

Risk Assessment Component	Possible Sources of Error / Failure	Possible Cause(s)	Potential Effect(s) of Failure	*Sure-Vue Signature Cryptosporidium/Giardia* Risk Mitigation Features	Can Identified source of error be reduced? Yes/No or N/A	Laboratory Risk Mitigation	Laboratory Documentation
Improper sample handling	Inappropriate sample	Incorrect sample type collected or the use of non-validated sample type	Test performance may be impacted	**Sure-Vue Signature C/G PI** – *Limitations of the Procedure:* The test is designed for use with stool samples collected in an acceptable transport media. The use of colonic washes, aspirates or other diluted sample types has not been established and could affect the performance of the assay			
	Improper sample storage	Sample tested beyond assay claims	Results may be compromised	**Sure-Vue Signature C/G PI** - *Specimen Collection and Handling:* Fresh samples and specimens in Stuart's media should be tested as soon as possible after collection, as extended storage conditions have not been validated. (reference Specimen Collection and Handling for specific specimen stability with transport media)			
	Improper sample handling	Unacceptable Transport Media Used	Results may be compromised	**Sure-Vue Signature C/G PI** – *Specimen Collection and Handling:* Samples collected in SAF, 10% formalin, MIF, Cary-Blair, C&S or Stuart's transport media are the preferred media for specimen collection, transport and test. Samples in PVA are not suitable.			
		Fresh Samples not diluted 1:4	Test performance may be impacted	**Sure-Vue Signature C/G PI** - *Specimen Collection and Handling:* Solid, semi-solid or liquid samples are acceptable but must be diluted 1:4 in an acceptable transport media before running the test.			

Environment	Improper kit storage	Test kits stored at facility outside of assay temperature/humidity requirements	Test performance may be impacted	**Sure-Vue Signature C/G PI** – *Storage:* Store kit refrigerated (2-8°C) and return kit to refrigerator promptly after each use. DO NOT FREEZE.			
	Improper kit shipping and handling	Kits not received at proper temperature (2-8°C) with cold packs)	Test performance may be impacted	Contact distributor to report delivery under improper storage conditions			
Reagent	Improper kit or kit component storage	Use of reagent that has been frozen or stored at room temperature	Test performance may be impacted	**Sure-Vue Signature C/G PI** – *Storage:* Return kit to the refrigerator promptly after each use. DO NOT FREEZE			
	Improper reagent handling	Reagents used after expiration date	Test performance may be impacted	**Sure-Vue Signature C/G PI** – *Warnings and Precautions:* Do not use kit beyond the printed expiration date.			
	Improper reagent handling	Reagents not brought to room temperature prior to testing	Test performance may be impacted	**Sure-Vue Signature C/G PI -** *Procedures Notes:* Allow kit components to equilibrate to room temperature before use…Return kit to refrigerator promptly after each use.			
	Improper reagent handling	Foil pouch not intact or left opened for prolonged period of time	Test performance may be impacted	**Sure-Vue Signature C/G PI -** *Procedures Notes:* Do not unpouch the test device until ready for use			

Test System	Misuse of test	Test not used within limitations and intended use	Results may be compromised	**Sure-Vue Signature C/G PI** - *Intended use and Limitations (see insert)*			
	QC Results: Internal Control Failure	Patient results reported after an Internal control failure	Results may be compromised	**Sure-Vue Signature C/G PI** - *Quality Control (see insert);* Call Sekisui Diagnostics Technical Assistance for continued failures			
	QC Results: External Control Failure	Patient results reported after an External control failure	Results may be compromised	**Sure-Vue Signature C/G PI** - *Quality Control (see insert);* Call Sekisui Diagnostics Technical Assistance for continued failures			
	Incorrect use of External controls	Recommendation for External control testing not followed	Results may be compromised	**Sure-Vue Signature C/G PI** – *Quality Control:* Minimally positive and negative external controls be run with each new lot and with each new untrained operator.			
Testing Personnel	Incorrect Procedure (Operator Error)	Operator did not follow the test procedure per the manufacturer's instructions: Kit and samples not brought to room temperature Failure to place device on flat surface Failure to adequately mix reagents and sample Use of concentrated sample Addition of reagents and sample in the incorrect order Incorrect sample and/or reagent volume Incorrect read time	Results may be compromised	**Sure-Vue Signature C/G PI** – *Procedures notes and Test Procedure (see insert)*			
	Misinterpretation of results (Operator Error)	Operator did not interpret the test per the manufacturer's instructions	Results may be compromised	**Sure-Vue Signature C/G PI** - *Interpretation of Results (see insert)*			

	Improper Specimen handling	Patient ID error/mislabeling or mixing specimens during batch testing	Results may be compromised	N/A			
	Improper results reporting	Transcription errors when reporting results	Results may be compromised	N/A			

*Not all sources of error have been identified. Risk Assessment information provided is only to be used as a supplement to your IQCP. Please enter information that is specific to your facility protocols/regulations.

*Any modification to this IQCP Template is the sole responsibility of the end user site.