Annex 4 Risk Analysis Report

Company Name:	Cellex, Inc.
Company Address:	Headquarter: 76 TW Alexander Drive, Research Triangle Park, NC 27709-0002, USA Manufacture Location: 1F, North Block, 16 Building, 8 Jinfeng Road, Suzhou, New District, Jiangsu, 215163 P.R.China
Product:	Cellex qSARS-CoV-2 IgG/IgM Rapid Test（Lateral Flow Chromatographic Immunoassay）
Model:	20T/Kit
Accessories:	/
Standard:	EN ISO 14971:2012
Result:	All risks associated with the identified hazards have been evaluated. After appropriate measures to reduce these risks have been taken, the overall level of risk of the product is acceptable with regard to the intended application and use of the application.

Compiled by: (Name/Title/Dept.) Yichen Tan R&D Date: 15/01/2020

Reviewed by (Name/Title/Dept.) Hui zhu QA Date: 20/01/2020

Approved by: (Name/Title/Dept.) [signature] QA Date: 20/01/2020

Identification of qualitative and quantitative characteristics (acc. to EN ISO 14971:2012, Annex C.2)

1	Intended use and how to use	Used as a screening test and aid in the diagnosis of SARS-CoV-2 viral infections. Any reactive specimen with the Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test must be confirmed with alternative testing method(s).For in vitro diagnostic use only. For professional use only.
2	Is implanted?	N/A
3	Intended to contact patient or other person	It is the IVD, no contact with patient. But clinical users may contact with the test device and patient samples, when they open the package and use the samples, it may cause some stimulation to skin.
4	Materials/components used	Chemical reagents, biological antibody, shell
5	Energy to/from patient	N/A
6	Substances to /from patient	Need to extract blood samples from patients
7	Biological materials processed	biological antibody
8	Sterile/Intended to be sterilized	N/A
9	Routinely cleaned and disinfected by the user	Single-use
10	Modify patient environment	N/A
11	Measurements	For in vitro quantitative detection of some substance in human serum.
12	Interpretative	The kit is interpreted by visible colored band produced on strip.
13	Use in conjunction with medicines or other medical technologies	N/A
14	Unwanted outputs of energy or substances	The kits consist of chemical and biochemical composition, including aluminum foil package, and paper box. Incorrect discard will cause some pollution. Improper waste disposal will cause pollution.
15	Susceptible to environmental influences	By professional use , and Store at 4～30℃. Avoid freezing at -20℃. Balance to room temperature before use.
16	influence the environment	Used-Cassette has the infectious risk. Directly discarding in the environment will have a certain harm.
17	Consumables/accessories associated	N/A
18	Routine maintenance/calibration	Quality control was performed before the measurement.
19	Software	N/A
20	Restricted "shelf-life":	Store at 4～30℃; 18 months;
21	Delayed and/or long-term use effect	Single-use, delayed use may cause lose its effectiveness

22	Mechanical forces	N/A
23	Lifetime of the device determined	Product formulation, production process and storage, transport conditions can decide or affect the life of the kits.
24	Single use/re-use	Single-use
25	safe decommissioning or disposal	Used reagent include specimen samples and should be processed in accordance with bio-derived waste.
26	Special training required to install or use	By professional person.
27	Information for safe use	Detail information for safe use will be provided in instruction for use in package.
28	New manufacturing processes need to be established or introduced	N/A
29	Successful application of the medical device critically dependent on human factors, such as user interface	N/A
29.1	User interface design features contribute to use error	Wrong labeling may cause misuse
29.2	Used in distraction environment	N/A
29.3	Connecting parts or accessories	N/A
29.4	Control interface	N/A
29.5	Display information	N/A
29.6	Controlled by a menu	N/A
29.7	Used by persons with special needs	Operated by a trained person.
29.8	Initiate user actions	N/A
30	Alarm system	N/A
31	Deliberately misused	N/A
32	Data critical to patient care?	N/A
33	To be mobile or portable	N/A
34	Depend on essential performance?	Essential performance may affect test accuracy. Bad performance may cause low accuracy, and cause information hazard.
Letters in the first column refer to EN ISO 14971:2012, Annex C.2		

Risk Hazard identification according to Annex H in ISO 14971.

The hazard and adverse effect are identified According to Annex H in ISO 14971.

Items	Characteristic Identification	Potential Hazard	Risk Management Report Item
H.2.1 identification of intended uses	/		
H.2.1.1 General	No		

H.2.1.2 Intended use	qSARS-CoV-2 IgG/IgM Rapid Test kits is intended to be used as a screening test and aid in the diagnosis of SARS-CoV-2 viral infections. Any reactive specimen with the Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test must be confirmed with alternative testing method(s).	Use error	R-001
H.2.1.3 Indications for use	For in vitro diagnostic use only. For professional use only.	Use error	R-001
H.2.2 Identification of possible use errors	No		
H.2.2.1 Use errors	See H.2.2.4		
H.2.2.2 Examples of possible use errors by laboratory personnel	No		
H.2.2.3 Examples of possible use errors by healthcare providers	No		
H.2.2.4 Examples of possible use errors by patients in self-testing	No		
H.2.3 Identification of characteristics related to safety	No		
H.2.3.1 General	No		
H.2.3.2 Performance characteristics of quantitative examination procedures	No		
H.2.3.3 Performance characteristics of qualitative examination procedures	No		
H.2.3.4 Dependability characteristics	No		
H.2.3.5 Ancillary patient information	The sample that the test is intended for is human whole blood/serum/plasma.	Use error	R-020
H.2.4 Identification of known and foreseeable hazards	No		

H.2.4.1 Hazards to the patient	For qualitative examination procedures, results are either correct or incorrect.	False result	R-021
H.2.4.2 Relationship to performance characteristics	Failure to meet specifications	False result	R-022, R-046, R-047
H.2.4.3 Identifying hazards in fault conditions	Performance characteristics was not met	False result	R-023
H.2.4.4 Identifying hazards in normal use	imperfect discrimination between positive and negative samples, uncertainty of measurement, unexpected influence of other constituents, natural heterogeneity of the analyze	False result	R-024, R-053
H.2.4.5 Identifying hazardous situations	No		
H.2.5 Estimation of risks to patients	No		
H.2.5.1 General	No		
H.2.5.2 Estimating severity of harm	See Risk assessment table		
H.2.5.3 Estimating probability of occurrence	See Risk assessment table		
H.2.5.4 Points to consider in estimating risk to the patient	No		
H.2.5.4.1 What is the possibility that an incorrect result would be generated by the IVD medical device?	In reasonably foreseeable misuse	False result	R-025, R-052
H.2.5.4.2 What is the possibility that the incorrect IVD examination result would be detected by a user/laboratory?	If control line is not showed when tested, the test method is incorrect or sample is not enough.	Use error	R-026
H.2.5.4.3 What is the possibility that the incorrect IVD examination result would be detected by the physician?	Improbable	Use error	R-001
H.2.5.4.4 What is the possibility that a physician would	Incredible	Use error	R-001

act or fail to act on the result?			
H.2.5.4.5 What is the possibility that a physician's action/inaction would cause or contribute to harm to the patient?	Improbable	Use error	R-001
H.2.5.4.6 What is the severity of the resulting harm?	Temporary discomfort	Information hazard	R-027
H.2.5.5 Risk information for IVD medical devices	No		
H.2.5.5.1 Adverse event databases	No		
H.2.5.5.2 Consensus survey	No		
H.2.5.5.3 Physician Interviews	No		
H.3 Risk evaluation	See Risk Management Report table		
H.4 Risk control	See Risk Management Report table		
H.4.1 General	No		
H.4.2 Option analysis	No		
H.4.2.1 Inherent safety by design	Precision, trueness, analytical specificity, detection limit or qualitation limit, control of mistake-prone procedural steps, and ease of use of the measuring system, have been verified.	Information hazard	R-028, R-036, R-037, R-038
H.4.2.2 Protective measures	Control line is the protective measures to see if test procedure and sample amount is appropriate.	Information hazard	R-026
H.4.2.3 Information for safety			
H.4.2.3.1 Performance characteristics	Performance characteristics are showed in instruction for use.	Information hazard	R-029
H.4.2.3.2 Information to prevent production of incorrect results	sample collection, storage and preparation requirements, known interfering substances, validated measuring interval and reagent storage requirements and expiration date have been listed in Instruction for use.	Information hazard	R-030
H.4.2.3.3 Information to enable detection of incorrect results	Control line on the test may enable detection of incorrect	Information hazard and use error	R-026
H.4.2.3.4 Training and user qualification	No		
H.4.2.4 Prescribed	Risk control management on Labeling	Information	R-031

information for safety	has been indicated in the Instruction for use and Labeling.	hazard	
H.4.2.5 Warnings, precautions and limitations	Warnings, precautions and limitations are showed in the Instruction for use	Information hazard	R-032, R-048 – R051
H.4.2.6 IVD medical device standards	The test conform to related IVD medical devices standards.	Information hazard	R-033
H.4.3 Verifying risk control effectiveness	The risk control has been verified in the Risk Management Report table, see risk assessment after Mitigation.	/	/
H.5 Production and post-production monitoring	No		
H.5.1 External performance monitoring	adverse event reports, complaints, and performance evaluations performed by independent laboratories are being monitored	Information hazard	R-034
H.5.2 Internal performance monitoring	process monitoring, stability monitoring, calibrator value assignments, acceptance testing, and validation activities are being monitored	Information hazard	R-035, R-039 – R-045

Risk Management Report Table										
Hazard	Risk Assessment before Mitigation					Risk Control Measure	Risk Addessment after Mitigation			Item
	Adverse Effect	Cause	Risk Definition		Risk Evaluation		Risk Definition		Risk Evaluation	
			Severity	Probability of Occurrence			Severity	Probability of Occurrence		
Use error	Users requires medical attention	use the test for other purpose	Critical	Occasional	Unacceptable	Indicate the intended use on the Instruction of use and Labeling	Critical	Remote	ALRP	R-001
Use error	Users requires medical attention	when they open the package and use the samples, it may cause some stimulation to skin	Critical	Occasional	Unacceptable	Indicate protective measures to avoid contacting the test or samples	Critical	Remote	ALRP	R-002
False Results	Users requires medical attention	Critical raw material (antigen with latex particles)	Critical	Occasional	Unacceptable	Design control review reports require product testing, verification & validation; incoming QC inspection must be done	Critical	Remote	ALRP	R-003
		Inadequate stability of the raw material (antigen with latex particles)	Critical	Occasional	Unacceptable	Qualification of alternate suppliers if possible, appropriate QC inspection criteria. Stability testing should be done.	Critical	Improbable	ALRP	R-004
Information hazard	Users requires medical attention	Not intended for measuring the substance in human Whole blood and plasma	Critical	Occasional	Unacceptable	Indicate the intended use on Instruction of use and Labeling	Critical	Remote	ALRP	R-005
Use error	Users requires medical attention	Storage conditions are not correct (4°C to 30°C)	Critical	Occasional	Unacceptable	Package insert and Labeling provides the proper storage conditions.	Critical	Improbable	ALRP	R-006
Environme-ntal hazard	Health Risk	Incorrect discard will cause some pollution. Improper waste disposal will cause pollution.	Marginal	Remote	Acceptable	Indicate the correct waste disposal on the Instruction of use and Labeling	Marginal	Improbable	Acceptable	R-007

Risk Management Report Table										
Hazard	**Risk Assessment before Mitigation**					**Risk Control Measure**	**Risk Addessment after Mitigation**			**Item**
	Adverse Effect	**Cause**	**Risk Definition**		**Risk Evaluation**		**Risk Definition**		**Risk Evaluation**	
			Severity	**Probability of Occurrence**			**Severity**	**Probability of Occurrence**		
Environmental Hazard	Health Risk	Removal of the test that contains (BSA, antibodies)	Marginal	Remote	Acceptable	The package insert warns the user about the removal conditions, The raw material is controlled to insure the absence of infectious Ab. The antibody and BSA are in very low concentrations and under a dry form on the membrane, label pad.	Marginal	Improbable	Acceptable	R-008
Environmental Hazard	Health Risk	Non recycling plastic (Adhesive backing)	Marginal	Occasional	Unacceptable	Adhesive backing should be recyclable	Marginal	Improbable	Acceptable	R-009
		Non recycled packaging	Marginal	Occasional	Unacceptable	Packaging recyclable	Marginal	Improbable	Acceptable	R-010
Information hazard	Users requires medical attention	Improper storage will affect bad quality, and cause information hazard.	Critical	Occasional	Unacceptable	Indicate the storage condition on the Instruction for use and Labeling	Critical	Improbable	ALRP	R-011
False result	Users requires medical attention	Nature stability, storage condition (including delivery), package character and sealing extent. Quality reduction, causing information hazard	Critical	Occasional	Unacceptable	Validate the packaging method, indicate the correct storage condition.	Critical	Improbable	ALRP	R-012
Use error	Users requires medical attention	Reuse will cause incorrect results.	Critical	Occasional	Unacceptable	'Do not reuse ' Information is on the package insert and Labeling	Critical	Improbable	ALRP	R-013

Risk Management Report Table										
Hazard	Risk Assessment before Mitigation					Risk Control Measure	Risk Addessment after Mitigation			Item
	Adverse Effect	Cause	Risk Definition		Risk Evaluation		Risk Definition		Risk Evaluation	
			Severity	Probability of Occurrence			Severity	Probability of Occurrence		
Environmental hazard	Health risk	Used test device may contain potential human infection source. After usage, dispose carefully as medical waste. Improper disposal of waste will cause pollution.	Marginal	Occasional	Unacceptable	Adhesive backing should be recyclable	Marginal	Improbable	Acceptable	R-014
Use error	Users requires medical attention	Detail information for safe use will be not provided in instruction for use in package.	Critical	Occasional	Unacceptable	Indicate detail information for safe use on the instruction for use and Labeling	Critical	Improbable	ALRP	R-015
Use error	Users requires medical attention	Result display information on device. Fuzziness on device may cause incorrect results	Critical	Occasional	Unacceptable	Manufacturing & QC inspection documents; training procedures	Critical	Improbable	ALRP	R-016
Use error	Users requires medical attention	it can be use at home. Incorrect instruction for use may cause improper use.	Critical	Occasional	Unacceptable	Indicate the intended use on the instruction for use and Labeling	Critical	Improbable	ALRP	R-017
False result	Users requires medical attention	essential performance may affect test accuracy. Bad performance may cause low accuracy, and cause information hazard.	Critical	Occasional	Unacceptable	Make sure the raw material, process, and storage is appropriate, raw material test, process monitoring, final product control procedure.	Critical	Improbable	ALRP	R-018

Risk Management Report Table											
Hazard	Risk Assessment before Mitigation					Risk Control Measure	Risk Addessment after Mitigation				Item
	Adverse Effect	Cause	Risk Definition		Risk Evaluation		Risk Definition		Risk Evaluation		
			Severity	Probability of Occurrence			Severity	Probability of Occurrence			
Use error	Users requires medical attention	using insufficient volume of sample; dividing reagent strips, disabling or failing to enable safety features, storing reagent in inappropriate conditions	Critical	Occasional	Unacceptable	Indicate volume of sample to be used, not dividing reagent strips, and appropriate storing reagent conditions on the instruction for use and Labeling	Critical	Improbable	ALRP	R-019
Use error	Users requires medical attention	The sample that the test is intended for is human serum	Critical	Occasional	Unacceptable	Indicate the urine sample to be used on the instruction for use and Labeling	Critical	Improbable	ALRP	R-020
False result	Users requires medical attention	For qualitative examination procedures, results of either correct or incorrect are not clear	Critical	Occasional	Unacceptable	Final product control procedure check this characteristic	Critical	Improbable	ALRP	R-021
False result	Users requires medical attention	Failure to meet specifications	Critical	Occasional	Unacceptable	Final product control procedure check specification of the device	Critical	Improbable	ALRP	R-022
False result	Users requires medical attention	Performance characteristics was not met	Critical	Occasional	Unacceptable	Final product control procedure checks the performance characteristics of the device	Critical	Improbable	ALRP	R-023

Risk Management Report Table										
Hazard	Risk Assessment before Mitigation					Risk Control Measure	Risk Addessment after Mitigation			Item
	Adverse Effect	Cause	Risk Definition		Risk Evaluation		Risk Definition		Risk Evaluation	
			Severity	Probability of Occurrence			Severity	Probability of Occurrence		
False result	Users requires medical attention	imperfect discrimination between positive and negative samples, uncertainty of measurement, unexpected influence of other constituents , natural heterogeneity of the analyte	Critical	Occasional	Unacceptable	Final product control procedure checks the performance characteristics of the device. Product development considers the discrimination between positive and negative.	Critical	Improbable	ALRP	R-024
False result	Users requires medical attention	In reasonably foreseeable misuse	Critical	Occasional	Unacceptable	Indicate the misuse situation on instruction for use and Labeling	Critical	Improbable	ALRP	R-025
Use error	Users requires medical attention	The test method is incorrect or sample volume is not enough.	Critical	Occasional	Unacceptable	Indicate correct use method and sample volume on the instruction for use and Labeling	Critical	Improbable	ALRP	R-026
Information hazard	Users requires medical attention	Temporary discomfort	Critical	Occasional	Unacceptable	Indicate the test need to integrate other diagnosis decision on the instruction for use and Labeling	Critical	Improbable	ALRP	R-027

Risk Management Report Table										
Hazard	**Risk Assessment before Mitigation**					**Risk Control Measure**	**Risk Addessment after Mitigation**			**Item**
	Adverse Effect	**Cause**	**Risk Definition**		**Risk Evaluation**		**Risk Definition**		**Risk Evaluation**	
			Severity	**Probability of Occurrence**			**Severity**	**Probability of Occurrence**		
False result	Users requires medical attention	Precision, trueness, analytical specificity, detection limit or quantitation limit, automation of mistake-prone procedural steps, and ease of use of the measuring system, were not good.	Critical	Occasional	Unacceptable	Precision, trueness, analytical specificity, detection limit or quantitation limit, automation of mistake-prone procedural steps, and ease of use of the measuring system, has been verified when product development and Inherent safety by design has been considered.	Critical	Improbable	ALRP	R-028
Information hazard	Users requires medical attention	Performance characteristics are not clear for users	Critical	Occasional	Unacceptable	Performance characteristics are showed in instruction for use.	Critical	Improbable	ALRP	R-029
Information hazard	Users requires medical attention	sample collection, storage and preparation requirements, known interfering substances, validated measuring interval and reagent storage requirements and expiration date are not able to be known.	Critical	Occasional	Unacceptable	sample collection, storage and preparation requirements, known interfering substances, validated measuring interval and reagent storage requirements and expiration date have been listed in Instruction for use.	Critical	Improbable	ALRP	R-030

Risk Management Report Table											
Hazard	Risk Assessment before Mitigation					Risk Control Measure	Risk Addessment after Mitigation				Item
	Adverse Effect	Cause	Risk Definition		Risk Evaluation		Risk Definition		Risk Evaluation		
			Severity	Probability of Occurrence			Severity	Probability of Occurrence			
Information hazard	Users requires medical attention	Risk control management on Labeling is not clear.	Critical	Occasional	Unacceptable	Risk control management on Labeling has been indicated in the Instruction for use and Labeling.	Critical	Improbable	ALRP		R-031
Information hazard	Users requires medical attention	Warnings, precautions and limitations are not showed in the Instruction for use	Critical	Occasional	Unacceptable	Warnings, precautions and limitations are showed in the Instruction for use	Critical	Improbable	ALRP		R-032
Information hazard	Users requires medical attention	The test does not conform to related IVD medical devices standards.	Critical	Occasional	Unacceptable	Check the IVD medical devices standards; List of Applicable Standards	Critical	Improbable	ALRP		R-033
Information hazard	Users requires medical attention	adverse event reports, complaints, and performance evaluations performed by independent laboratories are not being monitored	Critical	Occasional	Unacceptable	Establish the adverse event reports procedure, complaints management procedure.	Critical	Improbable	ALRP		R-034
Information hazard	Users requires medical attention	process monitoring, stability monitoring, calibrator value assignments, acceptance testing, and validation activities are being monitored	Critical	Occasional	Unacceptable	Establish the procedure and SOPs of process monitoring, stability monitoring, calibrator value assignments, acceptance testing, and validation activities	Critical	Improbable	ALRP		R-035

Risk Management Report Table											
Hazard	Risk Assessment before Mitigation					Risk Control Measure	Risk Addessment after Mitigation				Item
	Adverse Effect	Cause	Risk Definition		Risk Evaluation		Risk Definition		Risk Evaluation		
			Severity	Probability of Occurrence			Severity	Probability of Occurrence			
False Results	Users requires medical attention	The quality of the antibody does not produce the expected performance	Critical	Occasional	Unacceptable	Design control phase 3 & 4 reports require verification and validation. Incoming QC inspection documents	Critical	Improbable	ALRP	R-036
		The sample pad does not conform to specifications	Critical	Occasional	Unacceptable	Manufacture Process Control Procedure, Incoming QC inspection documents, and Manufacture SOPs	Critical	Improbable	ALRP	R-037
		The label pad does not conform to specifications	Critical	Occasional	Unacceptable	Manufacture Process Control Procedure, Incoming QC inspection documents, and Manufacture SOPs	Critical	Improbable	ALRP	R-038
False Results	Users requires medical attention	The raw material Storage conditions not correct	Critical	Occasional	Unacceptable	The shelf life of the raw material should be defined in COA from vender and validated by R&D during the product development; Manufacturing SOPs	Critical	Improbable	ALRP	R-039
		Operator not following manufacturing procedures.	Critical	Occasional	Unacceptable	C line solution, T line solution, Label pad manufacturing SOPs & QC inspection documents; training procedures	Critical	Improbable	ALRP	R-040

Risk Management Report Table										
Hazard	**Risk Assessment before Mitigation**					**Risk Control Measure**	**Risk Addessment after Mitigation**			**Item**
	Adverse Effect	**Cause**	**Risk Definition**		**Risk Evaluation**		**Risk Definition**		**Risk Evaluation**	
			Severity	**Probability of Occurrence**			**Severity**	**Probability of Occurrence**		
False Results	Users requires medical attention	Bad adhesive ability of the component (deviation from specifications)	Critical	Occasional	Unacceptable	(White Polystyrene Backing Splits Inspection Specification)	Critical	Improbable	ALRP	R-041
		The desiccant is missing	Critical	Occasional	Unacceptable	(Desiccant Inspection Specification)	Critical	Improbable	ALRP	R-042
		Incorrect QC Samples used, inappropriate QC procedure	Critical	Occasional	Unacceptable	Manufacturing & QC inspection documents; training procedures	Critical	Improbable	ALRP	R-043
		The Labeling is altered or lost	Critical	Remote	ALRP	Manufacturing SOPs & QC inspection documents	Critical	Improbable	ALRP	R-043
		Incorrect test strip is assembled	Critical	Remote	ALRP	Manufacturing SOPs & QC inspection documents	Critical	Improbable	ALRP	R-044
		The nature/characteristic of the sample gives interference	Critical	Occasional	Unacceptable	Validation studies	Critical	Improbable	ALRP	R-045
False Results	Users requires medical attention	Cross reaction with other interference substances	Critical	Occasional	Unacceptable	Interferences substances were tested during development and field trials	Critical	Improbable	ALRP	R-046
False Results	Users requires medical attention	Cross reaction with other interference substances	Critical	Occasional	Unacceptable	Interferences substances were tested during development and field trials	Critical	Improbable	ALRP	R-046
		Interferences due to the different types of samples	Critical	Probable	Unacceptable	The different samples to use are tested during development and field trials. The package insert indicates which samples to use.	Critical	Improbable	ALRP	R-047

Risk Management Report Table										
Hazard	**Risk Assessment before Mitigation**					**Risk Control Measure**	**Risk Addessment after Mitigation**			**Item**
	Adverse Effect	**Cause**	**Risk Definition**		**Risk Evaluation**		**Risk Definition**		**Risk Evaluation**	
			Severity	**Probability of Occurrence**			**Severity**	**Probability of Occurrence**		
False Results	Users requires medical attention	Finger contact leads to contamination of the test	Critical	Probable	Unacceptable	The package insert warns the user not to touch the membrane	Critical	Improbable	ALRP	R-048
Incorrect Reading	Users requires medical attention	Device was removed before measurement complete	Critical	Probable	Unacceptable	The package insert warns the user not to remove the test before measurement complete	Critical	Improbable	ALRP	R-049
Incorrect Reading	Users requires medical attention	Insufficient or superabundant sample applied	Critical	Occasional	Unacceptable	Provide the sample amount to use information in the package insert	Critical	Improbable	ALRP	R-050
		Ambient temperature too high or too low	Critical	Remote	ALRP	The storage conditions of the sample are established during development and validation. The package insert mentions the condition of sample storage	Critical	Improbable	ALRP	R-051
Incorrect Reading	Users requires medical attention	Instructions for use regarding Read Result Time not followed.	Critical	Occasional	Unacceptable	The read result times are established during development and validated during the validation studies. The package insert describes the correct reading time.	Critical	Improbable	ALRP	R-052
		Confusion results of the Analyzer	Critical	Occasional	Unacceptable	The information presented in the package insert	Critical	Improbable	ALRP	R-053

Conclusion: The Risk Control Measure Effectiveness and Verification Methods Effectiveness has been reviewed and all hazards / risks are either acceptable or ALRP.