Risk Management Report

CoV g-03-06

SARS-CoV-2 Antigen Rapid Test

Revision	Description	By	Date
A	Initial release	Diana Zheng	2020.09.01

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1. Introduction

The SARS-CoV-2 Antigen Rapid Test is a qualitative detection based on lateral immunoassay for SARS-CoV-2 antigen.

2. Overview

This document provides a safety risk management for SARS-CoV-2 Antigen Rapid Test.

3. Intended Use/Purpose

1） Medical purpose:

Qualitative detection of SARS-CoV-2 antigen.

For professional in vitro diagnostic use only.

2）Part of the body, type of tissue applied to or interacted with, or sample type：

This product is intended to test nasal swab specimens.

3）Operator profile：

Read the package insert carefully before the test. No special training is required.

4）Application：

Add 4~5 drops (approximately 100~125 ul) samples onto the Specimen well of the test cassette, and then start the timer. Wait for the colored line(s) to appear. Read results at 15~20minutes. Allow the test, the specimen should reach room temperature (15-30℃) prior to testing.

4. Scope

This risk management report addresses the safety risks that may affect the patient or the operator as associated with the operation of the SARS-CoV-2 Antigen Rapid Test.

5. Software Safety Classification

There is no software related with this product.

6. Definitions:

i. Severity Safety Classification:

Severity Ranking	Severity Ranking (Descriptive)	S/W Safety Classification	Description
1	Negligible	Class A	Inconvenience or temporary discomfort; no injury to user / operator.

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2	Minor	Class B	Results in temporary injury or impairment to user / operator. Not requiring professional medical intervention.
3	Serious	Class C	Results in injury or impairment requiring professional medical intervention.
4	Critical		Results in permanent impairment or life-threatening injury.
5	Catastrophic		Results in patient death.

ii. Probability of Occurrence

Severity Ranking	Likelihood	Description	Probability Range
1	Improbable	Almost impossible to occur	$< 10^{-6}$
2	Remote	Unlikely to occur	$< 10^{-5}$ and $\geq 10^{-6}$
3	Occasional	Unlikely but possible to occur sometime	$< 10^{-4}$ and $\geq 10^{-5}$
4	Probable	Likely to occur	$< 10^{-3}$ and $\geq 10^{-4}$
5	Frequent	Likely to occur several times	$> 10^{-3}$

iii. Risk Assessment Table:

Risk Assessment

Probability	Negligible	Minor	Serious	Critical	Catastrophic
Frequent					
Probable					
Occasional					
Remote					
Improbable					

Severity

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iv. Risk Assessment Levels:

Level	Risk Acceptability	Description
Grey	Unacceptable Risk	Risk in this region is not tolerated Resolution Required – Redesign, Do not release
Clear	Acceptable risk	Risk is considered to be negligible compared to the risk of other hazards.

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7. Failure Mode and Effects Analysis Table:

For Risk analysis it is recommended to consider each of these potential sources of error, as applicable to the device, and also consider any other potential system failures that may be specific to the device.

Potential source of Error				Adverse effect	Risk Assessment before mitigation			Risk Control Measure/ Mitigation	Risk Assessment after mitigation			Supporting Documents (Risk control Measure/Risk Mitigation
					Risk Definition				Risk Definition			
Risk Factor	Possible Error	Cause	Hazard		Severity	Probability of Occurrence	Risk Evaluation		Severity	Probability of Occurrence	Risk Evaluation	
	Use of incorrect specimen type	Use of specimen other than nasal swab	Wrong test result	Misdiagnosis	Serious	Occasional	Unacceptable	Product labeling instruct user to use appropriate specimen type	Serious	Improbable	Acceptable	Package Insert
	Incorrect application of the specimen or buffer to the device	Insufficient specimen /buffer or too much specimen/buffer	Wrong test result	Misdiagnosis	Serious	Occasional	Unacceptable	1.Product labeling instruct user to get enough specimen; 2.A control line is set to ensure enough specimen 3. Sample volume flex study was performed in validation study report	Serious	Improbable	Acceptable	Package Insert Validation Study Report, sample and buffer volume flex study
		Incorrect placement specimen	Wrong test result	Misdiagnosis	Serious	Occasional	Unacceptable	Product labeling instruct user how to apply specimen	Serious	Improbable	Acceptable	Package Insert

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Operator error/ Human factors	Incorrect handling of reagents	Device pouch was opened for long time before test	Wrong test result	Misdiagnosis	Serious	Occasional	Unacceptable	Product labeling instruct user to use the test as soon as possible after the sealed pouch is opened	Serious	Improbable	Acceptable	Package Insert Validation Study Report, Open pouch study
		Control swab pouch was opened for long time before test	Wrong test result	Misdiagnosis	Serious	Occasional	Unacceptable	Product labeling instruct user to use the test as soon as possible after the sealed pouch is opened	Serious	Improbable	Acceptable	Package Insert Validation Study Report, Open pouch study
	Incorrect placement of device	The device doesn't lay on a flat surface after specimen applying	Wrong test result	Misdiagnosis t	Serious	Probable	Unacceptable	Product labeling instruct user to lay the device on a flat surface before specimen applying	Serious	Improbable	Acceptable	Package Insert
	Incorrect timing of procedures	Read result before the time required	Wrong test result	Misdiagnosis	Serious	Occasional	Unacceptable	1. Time flex study was performed 2. Product labeling instruct user to read the result at appropriate time interval	Serious	Improbable	Acceptable	Package Insert Validation Study Report, time flex study
		Read result after the time required	Wrong test result	Misdiagnosis	Serious	Occasional	Unacceptable	1. Time flex study was performed 2. Product labeling instruct user to read the result at appropriate time interval	Serious	Improbable	Acceptable	Package Insert Validation Study Report, time flex study
	Incorrect reading of test results	Confuse the control line and the test line	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Product labeling instruct user to read the appropriate result.	Serious	Improbable	Acceptable	Package Insert

								Product labeling add the graphic result display.				
	Incorrect reading due to color blindness	Lose sight of the low positive line	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Product labeling instruct user to read the appropriate result. Product labeling add the graphic result display.	Serious	Improbable	Acceptable	Package Insert
	Use of polluted device or control swab	Reuse of device	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Product labeling instruct user not to reuse	Serious	Improbable	Acceptable	Package Insert
		Reuse of control swab	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Product labeling instruct user not to reuse	Serious	Improbable	Acceptable	Package Insert
Specimen Integrity and Handling	Error in specimen handling	The swab is not swirled in the fluid	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Product labeling instruct user to swirl the swab in the fluid	Serious	Improbable	Acceptable	Package Insert
		The sample temperature doesn't reach to room temperature prior to testing	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Product labeling instruct user to bring specimens to room temperature prior to testing	Serious	Improbable	Acceptable	Package Insert
	Use of inappropriate swab	swab interference	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Product labeling instruct user to use the appointed swab	Serious	Improbable	Acceptable	package Insert

	Incorrect specimen transport and/or storage.	The specimen is not stored in appropriate temperature and time	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Product labeling instruct user to store the specimen in appropriate temperature and time	Serious	Improbable	Acceptable	Package Insert Sample stability study
	Presence of interfering substances	The test is interfered by other antigens in specimen	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Product design to eliminate the interference from other disease.	Serious	Improbable	Acceptable	Validation Study Report, cross reaction study
Reagent integrity	Use of Improperly Stored Test reagent	The test is damaged by high temperature	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Product labeling instruct user to store the test in the appropriate temperature	Serious	Improbable	Acceptable	Package Insert Stability study
		The test is damaged by high humidity	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Product designed to packaged with a desiccant	Serious	Improbable	Acceptable	Package Insert
	Use of Outdated/ Expired reagents	The product is Outdated	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Product labeling instruct user to run the test before the expiration date.	Serious	Improbable	Acceptable	Package Insert

Environmental Factors	Impact of key environmental factors (heat, humidity, barometric pressure changes, altitude (if applicable), sunlight, surface angle, device movement, etc.) on reagents, specimens, and test results.	The environmental temperature is too low or too high	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Product labeling instruct user to run the test in appropriate environmental temperature	Serious	Improbable	Acceptable	Validation Study Report, temperature flex study
Product package factors	Impact of pouch on testing results such as material and integrity, or impact of product appearance shape on pouch integrity	The product was damaged when transporting	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Shipping study was performed to validate the packaging	Serious	Improbable	Acceptable	Shipping study report
		The desiccant is missing or disabled in the pouch	Wrong test result	Misdiagnosis	Serious	Probable	Unacceptable	Double check the desiccant in the manufacture. Raw material inspection.	Serious	Improbable	Acceptable	C-0828 Packaging SOP

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8. Signature Page

The Risk Management Plan has been effectively implemented for this device. The Risk Control Measures' effectiveness and verification methods have been reviewed and all hazards and risks have been reduced to acceptable levels.

Product Identification: SARS-CoV-2 Antigen Rapid Test

Team Leader: Jianxi Kong

Risk Analysis Team Membership **Date:** 2020.09.09

Attendees:

Printed Name	Signature	Department	Affiliation
Jordan Chen	Jordan Chen	MF	Acon bio
Sihong Zhang	Sihong Zhang	RC	Acon bio
Eden Jiang	Eden Jiang	Quality	Acon bio
Lily Tan	Lily Tan	Int'l RA	Acon bio
Daniel Tao	Daniel Tao	IP	Acon bio
Nancy	Nancy	MFT	Acon bio

Design Review Committee Disposition

Department	Recommend Approval	Printed Name	Signature	Date
R & D	[Y] Yes [ ] No [ ] Cond	Tao Shang	Tao Shang	2020.09.09
Manufacturing	[X] Yes [ ] No [ ] Cond	Winston Chen	Winston Chen	2020.9.9
QC	[X] Yes [ ] No [ ] Cond	Andy Xu	Andy Xu	2020.9.9
Regulatory	[X] Yes [ ] No [ ] Cond	Alyssa Lu	Alyssa Lu	2020.9.11
Marketing	[X] Yes [ ] No [ ] Cond	William Chang	William Chang	2020.9.9

Risk Analysis Report Final Disposition (The final disposition is ruled by majority vote of the Design Review Committee. This portion is filled out by the Regulatory representative.)

☐ Approved

☐ Approved, but requires follow-up (see comments)

☐ Not approved, requires additional work (see comments)

Comments: _____