STUDY TITLE

Repeatability and Reproducibility Study

DOCUMENT NUMBER

APR-04/IM/GRA/002

Revision No. 00

STUDY ARTICLE

MERISCREEN COVID-19 Antigen Detection Test

Report Approvals:

Prepared By:

Name: Ms. Vandana S Rohit

Signature:

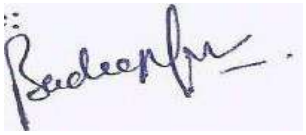
Date: 29.09.2020

Designation: Jr. Officer - Quality Assurance

Reviewed By:

Name: Mr. Pradeep Kumar

Signature:



Date: 29.09.2020

Designation: DGM - Research and Development

Approved By:

Name: Mr. Ram Kanoje

Signature:

Date: 29.09.2020

Designation: Head - Quality Assurance

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1. Report Synopsis

Table 1: Report Synopsis

Name of sponsor/company: **Meril Diagnostics Pvt. Ltd.** Second Floor, D1 – D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi – 396191 Gujarat, India.	
Trade name of device: MERISCREEN COVID-19 Antigen Detection Test	
Measurand: SARS-CoV-2 antigen	
Title of study: Repeatability and Reproducibility	
Study site(s) location: In-House Meril Diagnostics Pvt. Ltd. Second Floor, D1 – D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi – 396191 Gujarat, India.	
Name and contact information of individual responsible for the study:	
Mr. Pradeep Kumar DGM – R&D	Mr. Ram Kanoje, Head - QA
Study commencement date: 25.09.2020	**Study completion date:** 29.09.2020
Study Objective: The objective of this study is to evaluate the repeatability and reproducibility of the MERISCREEN COVID-19 Antigen Detection Test assay kit to be used for qualitative determination of COVID-19 Antigen in nasopharyngeal swab from human.	
Study Design: COVID-19 positive samples were tested in replicated of three with same lot to evaluate the repeatability and Inter-lot variability were assessed with three lots and inter-operator, inter-day and within-run reproducibility were assessed with one lot of MERISCREEN COVID-19 Antigen Detection Test.	
Statistical methods: 95% confidence interval method was used to analyze the Repeatability and Reproducibility of the MERISCREEN COVID-19 Antigen Detection Test Kit.	

2. List of abbreviation and Definitions of terms

- Precision (of measurement): As per EP15 – A2, Volume 25, Precision (of measurement) is defined as the closeness of agreement between independent test results obtained under stipulated conditions; **NOTE**: Precision is not typically represents as a numerical value but is expressed quantitatively in terms of imprecision – the standard deviation (SD) or the coefficient of variation (CV%) of the results in a set of replicate measurements.
- Repeatability (of results of measurements): As per EP15 – A2, Volume 25, Repeatability (of results of measurements) is defined as the closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement
- It is the extreme measures of precision, determines the agreement of inter user variability, inter lot variability and inter day variability of test kit with same positive and negative sample sets.
- Repeatability conditions: As per EP15 – A2, Volume 25, Repeatability conditions is defined as the conditions where independent test results are obtained with the same method on identical test material in the same laboratory by the same operator using the same equipment within a short interval of time.
- Reproducibility : Reproducibility is the closeness of the agreement between the results of measurements of the same measurand carried out with the same methodology described in the corresponding scientific evidence.
- Run: As per EP15 – A2, Volume 25, Run is defined as an interval within which the trueness and precision of a testing system are expected to be stable, but cannot be greater than 24 hours.
- Trueness (of measurement): As per EP15 – A2, Volume 25, Trueness (of measurement) is defined as the closeness of agreement between the average value obtained from a large series of test results and an accepted reference value.
- Within-laboratory precision: As per EP15 – A2, Volume 25, it is defined as the precision over a defined time and operators, within the same facility and using the same equipment. Calibration and reagents may vary.
- Diagnostic sensitivity: As per Common Technical Specification (CTS), 27th November 2009, Diagnostic Sensitivity is defined as the probability that the device gives a positive result in the

presence of the target marker.

- True Positive: As per Common Technical Specification (CTS), 27th November 2009, a specimen known to be positive for the target marker and correctly classified by the device
- False Negative: As per Common Technical Specification (CTS), 27th November 2009, a specimen known to be positive for the target marker and misclassified by the device
- False Positive: As per Common Technical Specification (CTS), 27th November 2009, a specimen known to be negative for the target marker and misclassified by the device
- True Negative: As per Common Technical Specification (CTS), 27th November 2009, a specimen known to be negative for the target marker and correctly classified by the device
- COVID : Corona Virus Disease
- Measurand : SARS-CoV-2 Antigen
- SARS-Cov-2 : Severe Acute Respiratory Syndrome - Corona Virus - 2

3. Purpose/Objective & Scope

Purpose / Objective:

The objective of this study is to evaluate the repeatability and reproducibility of the MERISCREEN COVID-19 Antigen Detection Test assay kit to be used for qualitative determination of COVID-19 Antigen in nasopharyngeal swab from human.

Scope:

The scope of this Report is applicable for MERISCREEN COVID-19 Antigen Detection Test assay kit performance only.

4. References

- EN 13612:2002 Performance evaluation of In-Vitro diagnostic medical devices
- Common Technical Specification (CTS), 27th November 2009 - COMMON TECHNICAL SPECIFICATION (CTS) as defined in EUROPEAN COMMISSION DECISION 2009/886 amending decision 2002/364/EC
- GHTF/SG1/N063:2011 Summary Technical Documentation (STED) for demonstrating conformity to the Essential Principles of Safety and Performance of In-Vitro diagnostics medical devices

- EP12 – P, Vol. 20, No. 15 – User Report for evaluation of qualitative test performance; Approved guideline.
- PQDx_018v2 30 June 2014, Instructions for Compilation of a Product Dossier – Prequalification of In Vitro Diagnostics Programme.
- Analytical Performance Protocol for Reproducibility Study of MERISCREEN COVID-19 Antigen Detection Test
- MERISCREEN COVID-19 Antigen Detection Test pack insert

5. Introduction

Measurement repeatability is defined as the measurement precision under a set of conditions of measurement that included the same measurement procedure, same operators, same measuring system, same operating conditions, same location and replicate measurements on the same or similar objects over a short period of time. Repeatability information can be useful for troubleshooting purposes.

User variability (inter-operator): it is conducted by three different users on same lot of test kit on same day with same positive and negative sample sets.

Lot to lot variability (inter-lot): it is conducted on three different lots of test kit by single user on same day with same positive and negative sample sets.

Day to day variability (inter-day): it is conducted on two consecutive days on single lot of test kit by single user with same positive and negative sample sets.

In this study, evaluation of Repeatability and Reproducibility Study of MERISCREEN COVID-19 Antigen Detection Test shall be performed under defined conditions of storage and handling.

6. Intended use of the device

COVID-19 Antigen Detection Test is a rapid immunochromatographic assay kit for the qualitative detection of SARS-CoV-2 antigen in nasopharyngeal swab from human.

7. Device description and principle of the method

7.1 Device Description:

MERISCREEN COVID-19 Antigen Detection Test Kit contains following components.

1. Individually packed test devices with desiccant
2. Extraction solution
3. Extraction tube
4. Disposable dropper cap
5. Sterilized nasopharyngeal swabs for sample collection
6. Package Insert

7.2 Principle of the method:

MERISCREEN COVID-19 Antigen Detection Test is an immunoassay kit for rapid and qualitative determination of SARS-CoV-2 infection from swab specimens. Monoclonal anti-SARS-CoV-2 antibody is coated on the test line region. Antigens of SARS-CoV-2 in the specimens react with the anti-SARS-CoV-2 monoclonal antibody-coupled gold conjugate and form antigen-antibody complex followed by reaction with anti-SARS-CoV-2 monoclonal antibodies immobilized in the test line. This complex migrates on the membrane, where it will be captured by the monoclonal anti-SARS-CoV-2 antibody. A colored test line would be visible in the result window if SARS-CoV-2 antigens are present in the specimen. The intensity of colored test line will vary depending upon the amount of SARS-CoV-2 antigen present in the specimen. If SARS- CoV-2 antigens are not present in the specimen, then no line appears in the test line. The control band is used for procedural control and should always appear if the test procedure is performed correctly.

8. Equipment and Materials

To assess the reproducibility of MERISCREEN COVID-19 Antigen Detection Test, Inter-lot, Inter-operator, Inter-day and within-run studies were performed. The details of materials used in the above mentioned studies for evaluating the reproducibility of MERISCREEN COVID-19 Antigen Detection Test are mentioned below:

1. Repeatability Study:

One lot is utilized for this study. Details of the lot is mentioned below:

Lot No. : MRD131 **Mfg. Date:** 2020/09 **Exp. Date:** 2021/08

2. Inter-Lot Study:

Three lots were used for this study. Details of these lots are mentioned below:

i. **Lot No. :** MRD131 **Mfg. Date:** 2020/09 **Exp. Date:** 2021/08

ii. **Lot No. :** MRD132 **Mfg. Date:** 2020/09 **Exp. Date:** 2021/08

iii. **Lot No. :** MRD133 **Mfg. Date:** 2020/09 **Exp. Date:** 2021/08

3. Inter-Operator Study:

One lot is utilized for this study. Details of the lot is mentioned below:

Lot No. : MRD131 **Mfg. Date:** 2020/09 **Exp. Date:** 2021/08

4. Inter-Day Study:

One lot is utilized for this study. Details of the lot is mentioned below:

Lot No. : MRD131 **Mfg. Date:** 2020/09 **Exp. Date:** 2021/08

5. Within-run Study:

One lot is utilized for this study. Details of the lot is mentioned below:

Lot No. : MRD131 **Mfg. Date:** 2020/09 **Exp. Date:** 2021/08

Test Specimens:

For evaluating the repeatability and reproducibility of the kit, studies were performed with the following samples:

- COVID-19 Positive Sample
- COVID-19 Negative sample

9. Operator of assay

To assess the reproducibility of MERISCREEN COVID-19 Antigen Detection Test, Inter-lot,Inter-operator, Inter-day and within-run studies were performed. The details of operators who had performed the above mentioned studies for evaluating the reproducibility of MERISCREEN COVID-19 Antigen Detection Test are mentioned below:

1. Repeatability Study:

This study was performed by one operator. Details are mentioned below:

Name of the Operator: Ms. Nehali Patel

Designation: Sr. Officer - R&D

2. Inter-Lot Study:

This study was performed by one operator. Details are mentioned below:

Name of the Operator: Ms. Nehali Patel

Designation: Sr. Officer- R&D

3. Inter-Operator Study:

This study was performed by three operators. Details are mentioned below:

Table 2: Details of Operators

	Operator 1	**Operator 2**	**Operator 3**
Name of the Operator	Ms. Nehali Patel	Ms. Rupali Yadav	Mr. Kardam Dave
Designation	Sr. Officer - R&D	Executive - R&D	Sr.Manager - R&D

4. Inter-Day Study:

This study was performed by one operator. Details are mentioned below:

Name of the Operator: Ms. Nehali Patel

Designation: Sr. Officer - R&D

5. Within-run Study:

This study was performed by one operator. Details are mentioned below:

Name of the Operator: Ms. Nehali Patel,

Designation: Sr. Officer - R&D

10. Study design

Repeatability assess intra-assay variability between replicates tested with the same lot and operator and Reproducibility assess the inter-assay variability between operators, lots and days.

To evaluate Repeatability of MERISCREEN COVID-19 Antigen Detection Test, Positive Sample and Negative sample were tested in replicates of three (03) with one lot of MERISCREEN COVID-19 Antigen Detection Test assay kit by same operator on same day.

To evaluate Reproducibility of MERISCREEN COVID-19 Antigen Detection Test, Inter-lot, Inter-Operator, Inter-day and within-run studies were performed.

1. Inter-Lot Study:

The study was performed with Three lots of MERISCREEN COVID-19 Antigen Detection Test (Details of lots mentioned above in section 8) by one operator (Details of operator mentioned above in section 9). Test was performed with an COVID-19 Positive Sample and negative samples. The tests were carried out at the same time i.e., on same day, same run. Results obtained from all the three lots were compared.

2. Inter-Operator Study:

The study was performed with One lot of MERISCREEN COVID-19 Antigen Detection Test (Details of lots mentioned above in section 8) by three operators (Details of operator mentioned above in section 9). Test was performed with an COVID-19 Positive Sample and negative samples. The tests were carried out at the same time i.e., on same day, same run. Results obtained from all the three operators were compared.

3. Inter-Day Study:

The study was performed with One lot of MERISCREEN COVID-19 Antigen Detection Test (Details of lots mentioned above in section 8) by one operator (Details of operator mentioned above in section 9). Test was performed with an COVID-19 Positive Sample and negative samples. The tests were carried out on the span of two days. The tests were carried out on same time but on two consecutive days. Results obtained on two days were compared.

4. Within-run Study:

The study was performed with One lot of MERISCREEN COVID-19 Antigen Detection Test (Details of lots mentioned above in section 8) by one operator (Details of operator mentioned above in section 9). Test was performed with an COVID-19 Positive Sample and negative samples.

The tests were carried out on two runs on a same day. Study of first run was carried out in morning and Second run was carried out after noon of same day. Results obtained from two runs were compared.

Testing of MERISCREEN COVID-19 Antigen Detection Test was summarized in below table:

Table 3: Testing Scheme of Repeatability and Reproducibility

Testing Parameter					
Parameters	**Criteria**				
	No. of Lots	**No. of operators**	**No. of Days**	**No. of Runs**	**No. of Samples**
Inter-lot	3	1	1	1	2 nos. Positive Sample 10 nos. Negative sample 2 Positive Control
Inter-operator	1	3	1	1	
Inter-day	1	1	2	1	
Within-run	1	1	1	2	
Repeatability	1	1	1	1	1 nos. Positive Sample 2 nos. Negative sample 1 nos. Positive Control

At the completion of all these studies, Results of all studies were compared and hence the repeatability and reproducibility of the MERISCREEN COVID-19 Antigen Detection Test was evaluated.

11. Test samples:

As mentioned in section 10, and an COVID-19 antigen positive control, COVID-19 Positive Sample and negative samples were tested with MERISCREEN COVID-19 Antigen DetectionTest for each Inter-lot, Inter-operator, Inter-day, Within-run and Repeatability study.

12. Test procedure

Repeatability and Reproducibility of MERISCREEN COVID-19 Antigen Detection Test was evaluated by Inter-lot, Inter-Operator, Inter-day and within-run studies with 10 nos. COVID-19 negative samples, 2 nos. of Positive Sample and 2 nos. of Positive control. Testing scheme of the studies is mentioned in section 11. Testing of MERISCREEN COVID-19 Antigen Detection Test was done as per the procedure outline in MERISCREEN COVID-19 Antigen Detection Test pack insert.

Assay Setup:

SAMPLE COLLECTION AND STORAGE:

1. Sample to be tested should be obtained and handled by standard methods for their collections.
2. Nasopharyngeal swab specimen: To collect nasopharyngeal specimen, carefully insert the sterile swab into the nostril that presents the most secretion under visual inspection.Using gentle rotation, push the swab till resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab against the nasal wall for 2-3 times, hold for few seconds and remove slowly.
3. All Samples should be tested as soon as early they are prepared. If necessary, they may be stored at 2-8°C for up to 24 hours or at -20°C for longer periods.

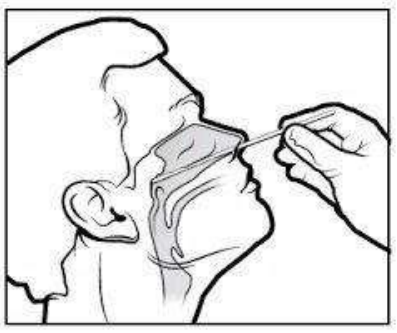

Fig. Nasopharyngeal swab collection

TEST PROCEDURE:

1. Bring the specimen and test components to room temperature if refrigerated or frozen.
2. Place the device on a clean, flat surface.
3. Fill the Extraction tube with Extraction solution up to the buffer line.
4. Insert the nasopharyngeal swab sample into the extraction solution, then mix the swab for 8 to 10 times.
5. Remove the swab while pressing against the solution tube in order to extract most of the specimen.
6. Place the dropper cap and add 4 drops (100 µl) into the sample well.
7. Interpret the test results at the end of 20 minutes. Do not read the results after 30 minutes.

INTERPRETATION OF THE RESULTS:

1. Negative result: If only the Control (C) band is developed, the test indicates that the result is negative.
2. Positive result: If Control(C) and Test (T) bands are developed, the test indicates for the presence of antigens to SARS-CoV-2 in the sample.The result is positive.
3. Invalid result: If no Control(C) band is developed, then the assay is invalid regardless of colour development on Test (T) band as indicated below. Repeat the assay with a new device.

13. Acceptance criteria

MERISCREEN COVID-19 Antigen Detection Test should give accurate results as per the sample status.

The performance of inter-lot, inter-Operator, inter-day and within-run studies should be in agreement.

14. Results and data analysis

Positive Sample, Negative sample and Positive Control were tested in replicates of three with single lot of MERISCREEN COVID-19 Antigen Detection Test to evaluate the repeatability of assay. Hence, a total of 9 Test results were generated and results were comparable.

Total of 10 nos. COVID-19 negative sample, 2 nos. of COVID-19 Positive Samples and 2 nos. of Positive Control were tested with MERISCREEN COVID-19 Antigen Detection Test assay kit. The reproducibility of the kit was evaluated by performing Inter-lot study, Inter-operator study, Inter-day Study and Within Run Study. Results of these studies is mentioned in Result and Data of Reproducibility Study.

Inter lot study was performed on three lots of MERISCREEN COVID-19 Antigen Detection Test by single operator. Tests were performed with 10 nos. COVID-19 negative sample, 2 nos. of COVID-19 Positive Samples and 2 nos. of Positive Control. Test results from all three Lots were comparable.

Inter-operator study was performed on single lot of MERISCREEN COVID-19 Antigen Detection Test by three operators. Tests were performed with 10 nos. COVID-19 negative sample, 2 nos. of COVID-19 Positive Samples and 2 nos. of Positive Control. Test results from all three operators were comparable.

Inter-day study was performed on single lot of MERISCREEN COVID-19 Antigen Detection Test by single operator but the test was performed for two consecutive days. Tests were performed with 10 nos. COVID-19 negative sample, 2 nos. of COVID-19 Positive Samples and 2 nos. of Positive Control. Test results from both days were comparable.

Within run study was performed on single lot of MERISCREEN COVID-19 Antigen Detection Test by single operator but the test was performed for two runs of a single day i.e., the tests were

performed before noon and after noon of a day. Tests were performed with 10 nos. COVID-19 negative sample, 2 nos. of COVID-19 Positive Samples and 2 nos. of Positive Control. Test results from both runs were comparable.

Lastly, Test results of all the studies gave comparable results. A total of 152 tests (12 test results from repeatability study, 42 Test results from Inter-Lot study, 42 test results from Inter-operator study, 28 test results from Inter-day study and 28 Test results from Within-run study) were obtained and all the tests gave comparable results. Hence, MERISCREEN COVID-19 Antigen Detection Test showed 100% repeatability and 100% reproducibility.

15. Conclusion

To evaluate Repeatability of MERISCREEN COVID-19 Antigen Detection Test, Positive Sample were tested in replicates of three (03) with one lot of MERISCREEN COVID-19 Antigen Detection Test assay kit by same operator on same day.

To evaluate the reproducibility of MERISCREEN COVID-19 Antigen Detection Test, Inter-lot, inter-Operator, inter-day and within run studies were performed with an COVID-19 Positive Sample, Negative samples and Positive control. The inter-lot study was conducted on three lots of MERISCREEN COVID-19 Antigen Detection Test by single operator. Inter-operator study was conducted on single lot of MERISCREEN COVID-19 Antigen Detection Test by three different operators. Inter-day study was carried out on single lot by single operator for two consecutive days and within-run study was conducted on single lot by single operator on same day but on two runs i.e., tested on before noon and tested on after noon. Results of all these studies were recorded and compared and based on results, 100% Repeatability and 100% Reproducibility concluded for MERISCREEN COVID-19 Antigen Detection Test.

16. Enclosure

- Enclosure-1: Raw data for Repeatability and Reproducibility study

17. Amendment history

Table 14: Amendment history

Revision No.	Date	Amendment Description
00	As on Approvals	Initial Issue

Enclosure - 1

Meril Diagnostics	**Repeatability and Reproducibility Study** **MERISCREEN COVID-19 Antigen Detection Test**	**Doc.No:** **RD/LFT/AG/192/04-01**

Results and Data Analysis

Product Name:	MERISCREEN COVID-19 Antigen Detection Test				
Date of testing:	**Initiation:**	25.09.2020		**Completion:**	29.09.2020
Lot No:	MRD131		MRD132		MRD132
Mfg. Date:	2020/09		2020/09		2020/09
Exp. Date:	2021/08		2021/08		2021/08
Operators:	Nehali Patel				

1	**Sample Source:**	Positive samples collected in Shri Vinoba Bhave Civil Hospital, Selvasa

2	**Tested at:**	Meril Diagnostics Pvt. Ltd., Chala, Vapi, Gujarat, India.

3	**Sample ID:**	COVID-19 Antigen positive samples

4	**Acceptance Criteria:**
	MERISCREEN COVID-19 Antigen Detection Test should give accurate results as per the sample status. The performance of inter-lot, inter-Operator, inter-day and within-run studies should be in agreement.

5	**Assay Protocol**
	(1) Insert the nasopharyngeal swab sample into the extraction solution,then mix the swab for atlist 10 times .
	(2) Remove the swab while pressing against the solution tube in order to extract most of the specimen.
	(3) Place the dropper cap and add 3 drops(100µl) in the sample well.
	(4) Read the results after 15 minutes. Do not read the results after 30 minutes.

1. Repeatability Study							
Lot No:	**MRD131**						
Sr.No.	**Sample ID**	**Specimen Type**	**Test Start Time**	**Test End Time**	**Result**		**Background Clearance Time**
					C	**T**	
1	NCOVPC-01	nasopharyngeal swab	00:00	20:00	4+	4+	12 min
	NCOVPC-01	nasopharyngeal swab	00:02	20:02	4+	4+	10 min
	NCOVPC-01	nasopharyngeal swab	00:04	20:04	4+	4+	11 min
2	SCOVPC-01	nasopharyngeal swab	00:06	20:06	4+	4+	12 min
	SCOVPC-01	nasopharyngeal swab	00:08	20:08	4+	4+	12 min
	SCOVPC-01	nasopharyngeal swab	00:10	20:10	4+	4+	10 min
3	COVAGP029	nasopharyngeal swab	00:12	20:12	4+	4+	12 min
	COVAGP029	nasopharyngeal swab	00:14	20:14	4+	4+	15 min
	COVAGP029	nasopharyngeal swab	00:15	20:15	4+	4+	15 min
4	COVAGN091	nasopharyngeal swab	00:20	20:20	4+	0	10 min
	COVAGN091	nasopharyngeal swab	00:22	20:20	4+	0	15 min
	COVAGN091	nasopharyngeal swab	00:24	20:24	4+	0	12 min

Observation:	A total of 3 positive sample and one negative sample was tested in replicates of three. Hence a total of 12 tests were run and showed uniform result.

Tested By:	Ms. Nehali Patel
Signature & Date	N.S.Patel 25/09/2020

2. Inter-lot Study	
Lot 1	MRD131
Lot 2	MRD132
Lot 3	MRD133

MERISCREEN COVID-19 Antigen Detection Test							
Sr. No.	Sample ID	Lot 1		Lot 2		Lot 3	
		RESULT		RESULT		RESULT	
		C	T	C	T	C	T
1	NCOVPC-01	4+	4+	4+	4+	4+	4+
2	SCOVPC-01	4+	4+	4+	4+	4+	4+
3	COVAGP031	4+	4+	4+	4+	4+	4+
4	COVAGP032	4+	2+	4+	2+	4+	2+
5	COVAGN101	4+	0	4+	0	4+	0
6	COVAGN102	4+	0	4+	0	4+	0
7	COVAGN103	4+	0	4+	0	4+	0
8	COVAGN104	4+	0	4+	0	4+	0
9	COVAGN105	4+	0	4+	0	4+	0
10	COVAGN106	4+	0	4+	0	4+	0
11	COVAGN107	4+	0	4+	0	4+	0
12	COVAGN108	4+	0	4+	0	4+	0
13	COVAGN109	4+	0	4+	0	4+	0
14	COVAGN110	4+	0	4+	0	4+	0

Observation:	Test results from all three Lots are comparable.

Tested By:	Ms. Nehali Patel
Signature & Date	M.S. Patel 26/09/2020

3. Inter Operator Study	
Operator 1	Ms. Nehali Patel
Operator 2	Ms. Rupali Yadav
Operator 3	Mr. Kardam Dave

MERISCREEN COVID-19 Antigen Detection Test							
Sr. No.	Sample ID	Operator 1 RESULT		Operator 2 RESULT		Operator 3 RESULT	
		C	T	C	T	C	T
1	NCOVPC-01	4+	4+	4+	4+	4+	4+
2	SCOVPC-01	4+	4+	4+	4+	4+	4+
3	COVAGP033	4+	2+	4+	2+	4+	2+
4	COVAGP034	4+	3+	4+	3+	4+	3+
5	COVAGN111	4+	0	4+	0	4+	0
6	COVAGN112	4+	0	4+	0	4+	0
7	COVAGN113	4+	0	4+	0	4+	0
8	COVAGN114	4+	0	4+	0	4+	0
9	COVAGN115	4+	0	4+	0	4+	0
10	COVAGN116	4+	0	4+	0	4+	0
11	COVAGN117	4+	0	4+	0	4+	0
12	COVAGN118	4+	0	4+	0	4+	0
13	COVAGN119	4+	0	4+	0	4+	0
14	COVAGN120	4+	0	4+	0	4+	0

Observation:	Test results from all three operators are comparable.

Tested By:	Ms. Nehali Patel	Ms. Rupali Yadav	Mr. Kardam Dave.
Signature & Date	N.S.Patel 28/09/2020	Yadav 28/09/2020	28/09/2020

4. Inter Day Study	
Day 1	
Day 2	
Lot No:	MRD131

MERISCREEN COVID-19 Antigen Detection Test

Sr. No.	Sample ID	Day 1 RESULT		Day 2 RESULT	
		C	T	C	T
1	NCOVPC-01	4+	4+	4+	4+
2	SCOVPC-01	4+	4+	4+	4+
3	COVAGP029	4+	4+	4+	4+
4	COVAGP030	4+	2+	4+	2+
5	COVAGN091	4+	0	4+	0
6	COVAGN092	4+	0	4+	0
7	COVAGN093	4+	0	4+	0
8	COVAGN094	4+	0	4+	0
9	COVAGN095	4+	0	4+	0
10	COVAGN096	4+	0	4+	0
11	COVAGN097	4+	0	4+	0
12	COVAGN098	4+	0	4+	0
13	COVAGN099	4+	0	4+	0
14	COVAGN100	4+	0	4+	0

Observation:	Test results of Day 1 and Day 2 are comparable.

Tested By:	Ms. Nehali Patel
Signature & Date	N.S.Patel 25/09/2020

5. Within Run Study	
Run 1	Morning
Run 2	After noon

MERISCREEN COVID-19 Antigen Detection Test					
Sr. No.	Sample ID	Run 1		Run 2	
		RESULT		RESULT	
		C	T	C	T
1	NCOVPC-01	4+	4+	4+	4+
2	SCOVPC-01	4+	4+	4+	4+
3	COVAGP035	4+	3+	4+	3+
4	COVAGP036	4+	2+	4+	2+
5	COVAGN121	4+	0	4+	0
6	COVAGN122	4+	0	4+	0
7	COVAGN123	4+	0	4+	0
8	COVAGN124	4+	0	4+	0
9	COVAGN125	4+	0	4+	0
10	COVAGN126	4+	0	4+	0
11	COVAGN127	4+	0	4+	0
12	COVAGN128	4+	0	4+	0
13	COVAGN129	4+	0	4+	0
14	COVAGN130	4+	0	4+	0

Observation:	Test results of run 1 and run 2 are comparable.

Tested By:	Ms. Nehali Patel
Signature & Date	M.S.Patel 29/09/2020

Conclusion:
Repeatability study was perfomed by testing two positive control,one positive samples and one negative sample each in replicates of three. Inter-lot study, Inter-operator study, Inter-day study and within-run study was evaluated using 10 negative samples and 2 Positive sample. Results from these studies are found to be uniform.

Note : C= Control band ; T =Test Band.

Remarks :

The test interpretation time for COVID-19 Ag Rapid test was 15 minutes. The background clearance time was found within 10-15 minutes.

Band intensity criteria:

0, 1+, 2+, 3+ & 4+ = Color band intensity by using WHO color chart Prototype: A

0: Negative, 4+: Strong Positive, 3+: Positive, 2+: Weak Positive, 1+: Faint line and +: Very faint line

	Prepared By	Reviewed By	Approved By
Signature	N.S.Patel	K.P.Dave	Pradeep Kr.
Date	29/09/2020	24/09/2020	29/09/2020
Name	**Ms.Nehali Patel**	**Mr.Kardam Dave**	**Mr. Pradeep Kumar**
Designation	**Sr. Officer - R&D**	**Sr.Manager -R&D**	**DGM - R&D**