**STUDY TITLE**

**Analytical Performance Report for Specimen Stability Study**

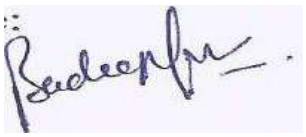
**DOCUMENT NUMBER**

**APR-07/IM/GRA/002**

**Revision No. 00**

**STUDY ARTICLE**

**MERISCREEN COVID-19 Antigen Detection Test**

| **Report Approvals:** |
|---|
| **Prepared by:** |
| Name: Ms. Vandana S Rohit<br>Signature:<br>  <br>Date: 01.10.2020<br>Designation: Jr. Executive - Quality Assurance |
| **Reviewed by:** |
| Name: Mr. Pradeep Kumar<br>Signature:<br>  <br>Date: 01.10.2020<br>Designation: DGM - Research and Development |
| **Approved by:** |
| Name: Mr. Ram Kanoje<br>Signature:<br>  <br>Date: 01.10.2020<br>Designation: Head – Quality Assurance |

## Table of contents

## 1. Report synopsis

**Table 1: Report synopsis**

| | |
|---|---|
| **Name of sponsor/company:**<br>**Meril Diagnostics Pvt. Ltd.**<br>Second Floor, D1 – D3, Meril Park,<br>Survey No. 135/2/B & 174/2,<br>Muktanand Marg,<br>Chala, Vapi – 396191<br>Gujarat, India. | |
| **Trade name of device:** MERISCREEN COVID-19 Antigen Detection Test | |
| **Measurand:** SARS-CoV-2 antigen | |
| **Title of study:**<br>Specimen Stability Study | |
| **Study site(s) location: In-House**<br>Meril Diagnostics Pvt. Ltd.<br>Second Floor, D1 – D3, Meril Park,<br>Survey No. 135/2/B & 174/2,<br>Muktanand Marg,<br>Chala, Vapi – 396191<br>Gujarat, India. | |
| **Name and contact information of individual responsible for the study:** | |
| Mr. Pradeep Kumar,<br>DGM – R&D | Mr. Ram Kanoje,<br>Head - QA |
| **Study commencement date:**<br>30.09.2020 | **Study completion date:**<br>01.10.2020 |
| **Study Objective:**<br>To identify the effect of Storage nasopharyngeal swab specimen stability on MERISCREEN COVID-19 Antigen detection test. | |
| **Study Design:**<br>COVID-19 antigen positive nasopharyngeal swab specimens and COVID-19 negative nasopharyngeal swab specimens shall be stored at 2-8 °C upto 28 hrs. and tested with MERISCREEN COVID-19 Antigen Detection test for 0 hrs (initial testing), 3 hrs,6 hrs, 9 hrs, and 24 hrs, 28 hrs to evaluate the specimen stability. | |

## 2. List of abbreviation and Definitions of terms

1. Diagnostic specificity: As per Common Technical Specification (CTS), 27th November 2009, Diagnostic Specificity is defined as the probability that the device gives a negative result in the absence of the target marker.
2. 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
3. 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
4. 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
5. 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
6. RA : Regulatory Affairs
7. COVID : Corona Virus Disease
8. Measurand : SARS-COV-2 antigen
9. NPA: Negative predictive value

## 3. Purpose/Objective & Scope

**Purpose / Objective:**

The purpose of the study is to identify the effect of storage specimen stability on MERISCREEN COVID-19 Antigen detection test.

**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 protocol 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 Specimen Stability Study of MERISCREEN COVID-19 Antigen Detection Test
- MERISCREEN COVID-19 Antigen Detection Test pack insert

## 5. Introduction

Specimen Stability is defined by the International Standards Organization (ISO) as the capability of a specimen sample to retain the initial property of a measured constituent for a period of time within specified limits when the sample is storage under defined conditions.

## 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:

1. Individually packed test devices with desiccant
2. Extraction solution
3. Extraction tube
4. Disposable dropper cap

5. Sterilized nasopharyngeal swab for sample collection
6. Product 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

The detail of materials used in the study are mentioned below:

- **MERISCREEN COVID-19 Antigen Detection Test :**

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

**Test sample :**COVID-19 Antigen Positive or Negative Samples

## 9. Operator of assay

Detail of Operator who has performed the study are mentioned below:

**Name of the Operator:** Ms. Nehali Patel

**Designation:** Sr.Officer - R & D

## 10. Study design

Two nasopharyngeal swab specimen Covid-19 antigen positive fresh collected in Extraction Tube and Five COVID-19 Antigen negative fresh nasopharyngeal swab specimen were utilized in this study and these specimens were tested with MERISCREEN COVID-19 Antigen Detection test on 0 hours i.e, 0 hrs testing. After 0 hrs testing, these samples were stored at low temperature (2-8°C) for 3 hrs, 6 hrs, 9 hrs, 24 hrs and 28 hrs tested as per the pack-insert instruction at the interval of three hours.

## 11. Test samples:

Positive or Negative Samples shall be Collected from Shri Vinoba Bhave Civil Hospital, Selvasa

## 12. Test procedure

### 12.1 Test procedure of MERISCREEN COVID-19 Antigen Detection Test as per the pack insert:

The evaluation of 02 nos of positive sample and 10 nos of negative samples was performed with MERISCREEN COVID-19 Antigen Detection Test by the following sequence:

1. Bring the specimen and test components to room temperature if refrigerated or frozen.
2. Place the test 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 atleast 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 3 drops(100µl) into the sample well.
7. Interpret the test result at the end of 15 minutes.Do not read the result after 30 minutes.

### 12.2 Interpretation of Results:

1. 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.
2. Negative result: If only the Control (C) band is developed, the test indicates that the result is negative.
3. Invalid result: If no Control(C) band is developed, then the assay is invalid regardless of colour development on Test (T) band. 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 results should be matched with results of initial testing for each of the intervals of the study.

## 14. Results and data analysis

Total of 02 nos of COVID-19 antigen positive or 05 nos of negative COVID-19 antigen samples were tested with MERISCREEN COVID-19 Antigen Detection test.

Evaluation plan with respect to the planned numbers of samples, tested samples, invalid or rejected results is mentioned in below table:-

**Result and Data Analysis**

**Table:- 3.1 Testing at 0 hrs:**

| Sr. No. | Sample ID | Specimen Type | Test Start Time | Test End Time | Result (0 hrs) | | Background Clearance Time |
|---|---|---|---|---|---|---|---|
| | | | | | C | T | |
| 1 | COVAGP037 | Nasopharyngeal swab | 00:00 | 20:00 | 4+ | 4+ | 12 min |
| 2 | COVAGP038 | Nasopharyngeal swab | 00:02 | 20:02 | 4+ | 3+ | 10 min |
| 3 | COVAGN131 | Nasopharyngeal swab | 00:04 | 20:04 | 4+ | 0 | 11 min |
| 4 | COVAGN132 | Nasopharyngeal swab | 00:06 | 20:06 | 4+ | 0 | 12 min |
| 5 | COVAGN133 | Nasopharyngeal swab | 00:08 | 20:08 | 4+ | 0 | 12 min |
| 6 | COVAGN134 | Nasopharyngeal swab | 00:10 | 20:10 | 4+ | 0 | 10 min |
| 7 | COVAGN135 | Nasopharyngeal swab | 00:12 | 20:12 | 4+ | 0 | 12 min |

**Table:- 3.2 Testing at 3 hrs:**

| Sr. No. | Sample ID | Specimen Type | Test Start Time | Test End Time | Result (3 hrs) | | Background Clearance Time |
|---|---|---|---|---|---|---|---|
| | | | | | C | T | |
| 1 | COVAGP037 | Nasopharyngeal swab | 00:08 | 20:08 | 4+ | 4+ | 10 min |
| 2 | COVAGP038 | Nasopharyngeal swab | 00:11 | 20:11 | 4+ | 3+ | 11 min |
| 3 | COVAGN131 | Nasopharyngeal swab | 00:16 | 20:16 | 4+ | 0 | 11 min |
| 4 | COVAGN132 | Nasopharyngeal swab | 00:19 | 20:19 | 4+ | 0 | 14 min |
| 5 | COVAGN133 | Nasopharyngeal swab | 00:22 | 20:22 | 4+ | 0 | 13 min |
| 6 | COVAGN134 | Nasopharyngeal swab | 00:25 | 20:25 | 4+ | 0 | 13 min |
| 7 | COVAGN135 | Nasopharyngeal swab | 00:28 | 20:28 | 4+ | 0 | 12 min |

**Table:- 3.3 Testing at 6 hrs:**

| Sr. No. | Sample ID | Specimen Type | Test Start Time | Test End Time | Result (6 hrs) | | Background Clearance Time |
|---|---|---|---|---|---|---|---|
| | | | | | C | T | |
| 1 | COVAGP037 | Nasopharyngeal swab | 00:05 | 20:05 | 4+ | 4+ | 12 min |
| 2 | COVAGP038 | Nasopharyngeal swab | 00:09 | 20:09 | 4+ | 3+ | 14 min |
| 3 | COVAGN131 | Nasopharyngeal swab | 00:13 | 20:13 | 4+ | 0 | 13 min |
| 4 | COVAGN132 | Nasopharyngeal swab | 00:15 | 20:15 | 4+ | 0 | 15 min |
| 5 | COVAGN133 | Nasopharyngeal swab | 00:18 | 20:18 | 4+ | 0 | 12 min |
| 6 | COVAGN134 | Nasopharyngeal swab | 00:22 | 20:22 | 4+ | 0 | 11 min |
| 7 | COVAGN135 | Nasopharyngeal swab | 00:26 | 20:26 | 4+ | 0 | 11 min |

**Table:- 3.4 Testing at 9 hrs:**

| Sr. No. | Sample ID | Specimen Type | Test Start Time | Test End Time | Result (9 hrs) | | Background Clearance Time |
|---|---|---|---|---|---|---|---|
| | | | | | C | T | |
| 1 | COVAGP037 | Nasopharyngeal swab | 00:14 | 20:14 | 4+ | 4+ | 13 min |
| 2 | COVAGP038 | Nasopharyngeal swab | 00:17 | 20:17 | 4+ | 3+ | 11 min |
| 3 | COVAGN131 | Nasopharyngeal swab | 00:21 | 20:21 | 4+ | 0 | 15 min |
| 4 | COVAGN132 | Nasopharyngeal swab | 00:25 | 20:25 | 4+ | 0 | 14 min |
| 5 | COVAGN133 | Nasopharyngeal swab | 00:28 | 20:28 | 4+ | 0 | 11 min |
| 6 | COVAGN134 | Nasopharyngeal swab | 00:31 | 20:31 | 4+ | 0 | 14 min |
| 7 | COVAGN135 | Nasopharyngeal swab | 00:34 | 20:34 | 4+ | 0 | 15 min |

**Table:- 3.5 Testing at 24 hrs:**

| Sr. No. | Sample ID | Specimen Type | Test Start Time | Test End Time | Result (24 hrs) | | Background Clearance Time |
|---|---|---|---|---|---|---|---|
| | | | | | C | T | |
| 1 | COVAGP037 | Nasopharyngeal swab | 00:05 | 20:05 | 4+ | 4+ | 11 min |
| 2 | COVAGP038 | Nasopharyngeal swab | 00:08 | 20:08 | 4+ | 3+ | 10 min |
| 3 | COVAGN131 | Nasopharyngeal swab | 00:14 | 20:14 | 4+ | 0 | 10 min |
| 4 | COVAGN132 | Nasopharyngeal swab | 00:17 | 20:17 | 4+ | 0 | 14 min |
| 5 | COVAGN133 | Nasopharyngeal swab | 00:21 | 20:21 | 4+ | 0 | 13 min |
| 6 | COVAGN134 | Nasopharyngeal swab | 00:26 | 20:26 | 4+ | 0 | 11 min |
| 7 | COVAGN135 | Nasopharyngeal swab | 00:30 | 20:30 | 4+ | 0 | 13 min |

**Table:- 3.6 Testing at 28 hrs:**

| Sr. No. | Sample ID | Specimen Type | Test Start Time | Test End Time | Result (28 hrs) | | Background Clearance Time |
|---|---|---|---|---|---|---|---|
| | | | | | C | T | |
| 1 | COVAGP037 | Nasopharyngeal swab | 00:06 | 20:06 | 4+ | 4+ | 13 min |
| 2 | COVAGP038 | Nasopharyngeal swab | 00:07 | 20:07 | 4+ | 3+ | 12 min |
| 3 | COVAGN131 | Nasopharyngeal swab | 00:14 | 20:14 | 4+ | 0 | 12 min |
| 4 | COVAGN132 | Nasopharyngeal swab | 00:17 | 20:17 | 4+ | 0 | 12 min |
| 5 | COVAGN133 | Nasopharyngeal swab | 00:23 | 20:23 | 4+ | 0 | 11 min |
| 6 | COVAGN134 | Nasopharyngeal swab | 00:26 | 20:26 | 4+ | 0 | 11 min |
| 7 | COVAGN135 | Nasopharyngeal swab | 00:35 | 20:35 | 4+ | 0 | 13 min |

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

**Remarks :**

The test interpretation time for COVID-19 Antigen detection test was 20 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

## 15. Conclusion

Based on the results and data analysis, it is concluded that “stored nasopharyngeal swab sample at 2-8°C up to 24 hours can be used for testing.

## 16. Enclosure

- Enclosure-1 : Raw data for Specimen stability study

## 17. Amendment history

**Table 2: Amendment history**

| Revision No. | Date | Amendment Description |
|---|---|---|
| 00 | As on approval | Initial Issue |

# Enclosure - 1

| Meril Diagnostics | **Specimen stability Study**<br>**MERISCREEN COVID-19 Antigen Detection Test** | **Doc. No.: RD/LFT/AG/192/07-01** |
|---|---|---|

**Results and Data Analysis**

| | | | | |
|---|---|---|---|---|
| **Product Name:** | MERISCREEN COVID-19 Antigen Detection test | | | |
| **Date of testing:** | **Initiation:** | 30.09.2020 | **Completion:** | 01.10.2020 |
| **Lot No:** | MRD131 | | | |
| **Mfg. Date:** | 2020/09 | | | |
| **Exp. Date:** | 2021/08 | | | |
| **Operators:** | Nehali Patel | | | |

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

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

| | | |
|---|---|---|
| 3 | **Sample ID:** | 02 Nos.of COVID-19 Antigen Positive samples |
| | | 05 Nos.of COVID-19 Antigen Negative Sample |

| | |
|---|---|
| 4 | **Acceptance Criteria:** |
| | COVID-19 Ag Rapid Test should give accurate result as per true sample status. The colored line in the control line region (C) appears. The appearance of test line indicates the presence of SARS-CoV-2 antigen.The colored line in the control line region (C) appears. No line appears in test line region indicates absence of SARS-CoV-2 antigen . |

| | |
|---|---|
| 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. |

**Table 1: Specimen Stability Study**
**Testing at 0 hrs (Initial testing)**

| Sr.No. | Sample ID | Specimen Type | Test Start Time | Test End Time | Result (0 hrs) | | Background Clearance Time |
|---|---|---|---|---|---|---|---|
| | | | | | C | T | |
| 1 | COVAGP037 | nasopharyngeal swab | 00:00 | 20:00 | 4+ | 4+ | 12 min |
| 2 | COVAGP038 | nasopharyngeal swab | 00:02 | 20:02 | 4+ | 3+ | 10 min |
| 3 | COVAGN131 | nasopharyngeal swab | 00:04 | 20:04 | 4+ | 0 | 11 min |
| 4 | COVAGN132 | nasopharyngeal swab | 00:06 | 20:06 | 4+ | 0 | 12 min |
| 5 | COVAGN133 | nasopharyngeal swab | 00:08 | 20:08 | 4+ | 0 | 12 min |
| 6 | COVAGN134 | nasopharyngeal swab | 00:10 | 20:10 | 4+ | 0 | 10 min |
| 7 | COVAGN135 | nasopharyngeal swab | 00:12 | 20:12 | 4+ | 0 | 12 min |

**Table 2: Testing at 3 hrs**

| Sr.No. | Sample ID | Specimen Type | Test Start Time | Test End Time | Result (3 hrs) | | Background Clearance Time |
|---|---|---|---|---|---|---|---|
| | | | | | C | T | |
| 1 | COVAGP037 | nasopharyngeal swab | 00:08 | 20:08 | 4+ | 4+ | 10 min |
| 2 | COVAGP038 | nasopharyngeal swab | 00:11 | 20:11 | 4+ | 3+ | 11 min |
| 3 | COVAGN131 | nasopharyngeal swab | 00:16 | 20:16 | 4+ | 0 | 11 min |
| 4 | COVAGN132 | nasopharyngeal swab | 00:19 | 20:19 | 4+ | 0 | 14 min |
| 5 | COVAGN133 | nasopharyngeal swab | 00:22 | 20:22 | 4+ | 0 | 13 min |
| 6 | COVAGN134 | nasopharyngeal swab | 00:25 | 20:25 | 4+ | 0 | 13 min |
| 7 | COVAGN135 | nasopharyngeal swab | 00:28 | 20:28 | 4+ | 0 | 12 min |

**Table 3: Testing at 6 hrs**

| Sr.No. | Sample ID | Specimen Type | Test Start Time | Test End Time | Result (6 hrs) | | Background Clearance Time |
|---|---|---|---|---|---|---|---|
| | | | | | C | T | |
| 1 | COVAGP037 | nasopharyngeal swab | 00:05 | 20:05 | 4+ | 4+ | 12 min |
| 2 | COVAGP038 | nasopharyngeal swab | 00:09 | 20:09 | 4+ | 3+ | 14 min |
| 3 | COVAGN131 | nasopharyngeal swab | 00:13 | 20:13 | 4+ | 0 | 13 min |
| 4 | COVAGN132 | nasopharyngeal swab | 00:15 | 20:15 | 4+ | 0 | 15 min |
| 5 | COVAGN133 | nasopharyngeal swab | 00:18 | 20:18 | 4+ | 0 | 12 min |
| 6 | COVAGN134 | nasopharyngeal swab | 00:22 | 20:22 | 4+ | 0 | 11 min |
| 7 | COVAGN135 | nasopharyngeal swab | 00:26 | 20:26 | 4+ | 0 | 11 min |

**Table 4: Testing at 9 hrs**

| Sr.No. | Sample ID | Specimen Type | Test Start Time | Test End Time | Result (9 hrs) | | Background Clearance Time |
|---|---|---|---|---|---|---|---|
| | | | | | C | T | |
| 1 | COVAGP037 | nasopharyngeal swab | 00:14 | 20:14 | 4+ | 4+ | 13 min |
| 2 | COVAGP038 | nasopharyngeal swab | 00:17 | 20:17 | 4+ | 3+ | 11 min |
| 3 | COVAGN131 | nasopharyngeal swab | 00:21 | 20:21 | 4+ | 0 | 15 min |
| 4 | COVAGN132 | nasopharyngeal swab | 00:25 | 20:25 | 4+ | 0 | 14 min |
| 5 | COVAGN133 | nasopharyngeal swab | 00:28 | 20:28 | 4+ | 0 | 11 min |
| 6 | COVAGN134 | nasopharyngeal swab | 00:31 | 20:31 | 4+ | 0 | 14 min |
| 7 | COVAGN135 | nasopharyngeal swab | 00:34 | 20:34 | 4+ | 0 | 15 min |

**Table 5: Testing at 24 hrs**

| Sr.No. | Sample ID | Specimen Type | Test Start Time | Test End Time | Result (24 hrs) | | Background Clearance Time |
|---|---|---|---|---|---|---|---|
| | | | | | C | T | |
| 1 | COVAGP037 | nasopharyngeal swab | 00:05 | 20:05 | 4+ | 4+ | 11 min |
| 2 | COVAGP038 | nasopharyngeal swab | 00:08 | 20:08 | 4+ | 3+ | 10 min |
| 3 | COVAGN131 | nasopharyngeal swab | 00:14 | 20:14 | 4+ | 0 | 10 min |
| 4 | COVAGN132 | nasopharyngeal swab | 00:17 | 20:17 | 4+ | 0 | 14 min |
| 5 | COVAGN133 | nasopharyngeal swab | 00:21 | 20:21 | 4+ | 0 | 13 min |
| 6 | COVAGN134 | nasopharyngeal swab | 00:26 | 20:26 | 4+ | 0 | 11 min |
| 7 | COVAGN135 | nasopharyngeal swab | 00:30 | 20:30 | 4+ | 0 | 13 min |

**Table 6: Testing at 28 hrs**

| Sr.No. | Sample ID | Specimen Type | Test Start Time | Test End Time | Result (28 hrs) | | Background Clearance Time |
|---|---|---|---|---|---|---|---|
| | | | | | C | T | |
| 1 | COVAGP037 | nasopharyngeal swab | 00:06 | 20:06 | 4+ | 4+ | 13 min |
| 2 | COVAGP038 | nasopharyngeal swab | 00:07 | 20:07 | 4+ | 3+ | 12 min |
| 3 | COVAGN131 | nasopharyngeal swab | 00:14 | 20:14 | 4+ | 0 | 12 min |
| 4 | COVAGN132 | nasopharyngeal swab | 00:17 | 20:17 | 4+ | 0 | 12 min |
| 5 | COVAGN133 | nasopharyngeal swab | 00:23 | 20:23 | 4+ | 0 | 11 min |
| 6 | COVAGN134 | nasopharyngeal swab | 00:26 | 20:26 | 4+ | 0 | 11 min |
| 7 | COVAGN135 | nasopharyngeal swab | 00:35 | 20:35 | 4+ | 0 | 13 min |

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

**Conclusion :**

From the above result we can concluded that the Specimen sample stable up to 28 hours at 2- 8°C.

| | Prepared By | Reviewed By | Approved By |
|---|---|---|---|
| **Signature** | N.S.Patel | | Pradeep |
| **Date** | 01/10/2020 | 01/10/2020 | 01/10/2020 . |
| **Name** | **Ms. Nehali patel** | **Mr. Kardam Dave** | **Mr. Pradeep Kumar** |
| **Designation** | **Sr. Officer - R&D** | **Sr. Manager - R&D** | **DGM - R&D** |