# FIND Evaluation of Premier Medical Corporation Pvt. Ltd Sure Status® COVID-19 Antigen Card Test- Nasal Swab External Report

*Version 1, 17 April 2022*



**Evaluation process – private sector engagement**

FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis around the world. It works closely with the private and public sectors and receives funding from donors and some of its industry partners. It has internal fire walls, policies and processes to protect it against any undue influence in its work or the publication of its findings.

More information on our policy and guidelines for working with private sector partners can be found here: https://www.finddx.org/policies/

For the COVID-19 response, FIND has commissioned independent evaluations of in vitro diagnostics following an Expression of Interest (EOI) process available on FIND's website by which all test submissions were scored according to their regulatory status and time to market; the manufacturing and distribution capacity of the supplier; and the supplier-reported clinical and analytical performance.

**Document history**

| Document version | Date | Comment |
|---|---|---|
| 1.0 | 17 April 2022 | First release |

## 1 Product info:

| | |
|---|---|
| Manufacturer name | Premier Medical Corporation Private Limited. |
| Test name | Sure Status® COVID-19 Antigen Card Test - Nasal swab |
| Product code(s) | SS03-NS-P25 |
| Pack size(s) | 25 tests per kit |
| Contents of kit | Test device pouch (including test device and desiccant), nasal swab, prefilled extraction buffer buffer vial with nozzle, extraction buffer bottle, instructions for use |
| Equipment and consumables required, but not provided | PPE, timer, biohazardous waste container |
| Product storage (temperature range) | 4-30°C |
| Shelf-life (months) | 24 months |
| Manufacturing site (country) | India |

## 2 Study details:

| | |
|---|---|
| Study design: | Prospective diagnostic evaluation studies across multiple, independent sites to determine the accuracy of COVID-19 antigen RDTs, using consecutive enrolment. Interim analyses are performed at 25% and 50% enrolment, and the evaluation is stopped if tests do not meet 95% specificity. Presence of symptoms, date of symptom onset and hospitalization status is collected for all enrolled participants. |
| Index assays: | Novel lateral flow format tests with monoclonal antibodies to detect SARS-CoV-2 antigens. |
| Reference method: | Results of the index test are compared to the routine, diagnostic RT-PCR result, which is used for clinical management. |
| Limit of detection: | Verification of analytical sensitivity, i.e. Limit of detection, was performed at the Liverpool School of Tropical Medicine in which standardized serial dilutions of cultured viral isolate were prepared. Proprietary swab provided in the kit was soaked in viral dilution series. Dilutions were tested in triplicate and the LOD was defined as the last dilution where all repeats were interpreted as positive. |
| Clinical performance: | Sensitivity was calculated as the proportion of true positive results detected by Sure Status® COVID-19 Antigen Card Test among all positives by the reference method and reported as a percentage. |

| | |
|---|---|
| | Specificity was calculated as the proportion of true negative specimens, identified as negative by Sure Status® COVID-19 Antigen Card Test among all negatives by the reference method, and reported as a percentage.<br>The 95% confidence intervals were calculated to assess the level of uncertainty introduced by sample size, using the Wilson score method. |

## 3 Evaluation details

| | |
|---|---|
| Country of collaborator | Switzerland |
| Location of clinical site(s) (city, town) | University Hospital of Geneva |
| Health care level of site(s) | Community Testing Clinic |
| Study period (date to date) | 25 February – 15 March 2022 |
| Study cohort inclusion/exclusion | Adults in community meeting Department of Public Health definition of a suspected COVID-19 case and being tested for SARS-CoV-2 part of routine medical care.<br>Provided informed consent |
| Sample type, antigen test | Nasal Swab |
| Reference PCR method | Cobas SARS-CoV-2 (Roche Diagnostics Inc) |
| Sample type, PCR test | Nasopharyngeal swab |

## 4 Results

### 4.1 Study Cohort (NOTE: if multiple sites, one column per site/country)

| **Country** | Switzerland |
|---|---|
| Total N (valid PCR results) | 200 |
| Age [mean (min-max), N] | 36.2 (16-75), 200 |
| Gender [%F, (n/N)] | 49%, (98/200) |

| | |
|---|---|
| Symptoms present [%Yes, (n/N)]* | 99%, (99/100) |
| Hospitalized (n, % Yes) | Not applicable |
| Days from symptom onset [median (Q1-Q3); N] | 2 (1-3), 92 |
| Days < 0-3 (n, %) | 71, 77% |
| Days 4-7 (n, %) | 11, 12% |
| Days 8+ (n, %) | 10, 11% |
| Positivity [%, (n/N)] | 51%, (102/200) |
| PCR Ct [median (Q1-Q3); N] | 22.2 (19.2-27.1), 102 |
| Ct > 33 (n, %) | 7, 7% |
| Ct > 30 (n, %) | 12, 12% |
| Ct > 25 (n, %) | 39, 38% |

*Note: data on symptom and onset for Switzerland only available for individuals who test PCR positive

### 4.2 Estimation of clinical performance

| Country | Switzerland |
|---|---|
| Clinical Sensitivity (95% CI), N | 68.4%, (58.6, 76.7), 98 |
| Sensitivity days ≤7, N | 74.4%, (63.7, 82.7), 78 |
| Sensitivity Ct ≤ 33, N | 72.8%, (63, 80.9), 92 |
| Sensitivity Ct ≤ 25, N | 83.9%, (72.8, 91), 62 |
| Clinical Specificity (95% CI), N | 98.9%, (94.3, 99.8), 95 |
| Invalid rate (%, n/N) | 3.5%, 7/200 |