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

Version 1.1, 18 August 2021

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	27 April 2021	

1.1	18 August 2021	10 samples from Germany excluded – tests were not stored appropriately Additional data from Apollo Hospital in New Delhi added to the India dataset

1 Product info:

Manufacturer name	Premier Medical Corporation Private Limited.
Test name	Sure Status® COVID-19 Antigen Card Test
Product code(s)	SS03P25
Pack size(s)	25 tests per kit
Contents of kit	Test device pouch (including test device and desiccant), nasopharyngeal swab, reaction 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 that detect recombinant 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. The 95% confidence intervals were calculated to assess the level of uncertainty introduced by sample size, using the Wilson score method.
Ease of use	A System usability survey and ease of use questionnaire assessing the quality of the test, test preparation, ease of test execution, procedure time, ease of result interpretation, storage conditions and perceived settings of use was completed by operators and a final score out of 100 was calculated.

3 Evaluation details

Country of collaborator	Germany	India
Location of clinical site(s) (city, town)	1. Heidelberg (HD) 2. Berlin	1. Chennai 2. Delhi
Health care level of site(s)	1. Heidelberg: Drive-in testing Center 2. Berlin: Ambulatory testing clinic of Charité – University Hospital	Tertiary care Hospital
Study period (date to date)	1. HD: 26 Feb – 25 Mar 2021 2. Berlin: 11 Feb – 24 Mar 2021	1. Chennai: 3 Dec 2020 – 23 Apr 2021 2. Delhi: 31 Dec 2020 – 15 March 2021
Study cohort inclusion/exclusion	Adults able to ambulate and meeting suspect definition of the Department of public health Provided informed consent	Inclusion: Adults presenting to Apollo Hospital Centers volunteering for study. Exclusion: • Hemodynamic instability as determined by the treating physician • Patient unable to cooperate with respiratory sample collection

		• Patient unable to give informed consent • Recent history of excessive nose bleeds.
Sample type, antigen test	Nasopharyngeal (n=512) or mid-turbinate (n=1) or oropharyngeal (n=17) swabs	Nasopharyngeal (n=994) or combined nasopharyngeal/oropharyngeal (n=3) swab
Reference PCR method	• LightMix® Modular SARS-CoV (COVID19) E-gene (Tib Molbiol) ○ N = 229 • Cobas SARS-CoV-2 (Roche Diagnostics Inc) ○ N = 53 • Tib Molbiol or Cobas (all PCR neg and therefore Ct values not collected) ○ N=181	TaqPath COVID-19 Combo Kit (Thermo Fisher)
Sample type, PCR test	1. HD: Nasopharyngeal swabs (oropharyngeal if NP contraindicated) 2. Berlin: Combined nasopharyngeal/oropharyngeal swabs	Nasopharyngeal (n=523) or combined nasopharyngeal/oropharyngeal (n=474) swab

4 Results

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

Country	Germany	India
Total N (valid PCR results)	519	997
Age [mean (min-max), N]	38.8 (18-79), 519	41.8 (1-88), 997
Gender [%F, (n/N)]	48.7%, (251/515)[1]	31% (309/996)[4]
Symptoms present [%Yes, (n/N)]	64%, (329/514)[2]	16.2% (162/997)
Hospitalized (n, % Yes)	Not applicable	Not applicable
Days from symptom onset [median (Q1-Q3); N]	2 (1-4), 328[3]	5 (2 -7), 68[5]
Days < 0-3 (n, %)	225, 69%	27, 40%

Days 4-7 (n, %)	77, 23%	26, 38%
Days 8+ (n, %)	26, 8%	15, 22%
Positivity [%, (n/N)]	19%, (100/529)	18%, (105/600)
PCR Ct [median (Q1-Q3); N]	20.3 (17.5, 23.7), 100	19 (16.5-25), 103[6]
Ct > 33 (n, %)	4, 4%	0, 0%
Ct > 30 (n, %)	9, 9%	5, 5%
Ct > 25 (n, %)	20, 20%	22, 21%

[1] Gender not available for n=4, [2] Symptoms data not available for n=5, [3] Symptom onset not available for n=1, [4] Gender not available for n=1, [5] Symptom onset not available for n=94, [6] Ct value not available for n=2

4.2 Estimation of clinical performance

Country	Germany	India
Clinical Sensitivity (95% CI), N	91% (83.8, 95.2), 100	78.5% (70.6, 84.7), 130
Sensitivity days ≤7, N	96.2% (89.3, 98.7), 78	75.9% (57.9, 87.8), 29
Sensitivity Ct ≤ 33, N	93.8% (87, 97.1), 96	74.8% (65.6, 82.2), 103
Sensitivity Ct ≤ 25, N	97.5% (91.3, 99.3), 80	87.7% (78.7, 93.2), 81
Clinical Specificity (95% CI), N	97.1% (95.1, 98.4), 419	99.8% (99.2, 99.9), 867
Invalid rate (%, n/N)	0% (0/519)	0% (0/997)
Defective rate (%, n/N)	9.7% (58/600)[1]	0% (0/600)

[1] Note: 600 total tests were received, and 58 swabs were noted to be unsterile or contaminated and therefore could not be used.

4.2.1 Estimation of analytical performance

	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent	Supplier-reported LOD
Analytical sensitivity	**2.5 x10^2 pfu/ml** ~ 3.53 x 10^2 $TCID_{50}$/ml	**2.5 x10^2 pfu/ml**	**5.97 x10^5 copies/ml** applied to test	**52.5 pfu/ml** ~75 TCID50/ml

Note: viral dilution was applied directly to the test cassette, not to the provided swab

4.3 Ease of use

SureStatus COVID-19 Antigen Card Test	85 out of 100	5 operators, 1 country