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

Version 1, 23 November 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	23 November 2021	

1 Product info:

Manufacturer name	Premier Medical Corporation Private Limited.
Test name	• Sure Status® COVID-19 Antigen Card Test – Nasal Swab • Sure Status® COVID-19 Antigen Card Test – Nasopharyngeal Swab
Product code(s)	• SS03-NS-P25 (Nasal) • SS03P25 (NP)
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.
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.

3 Evaluation details

Country of collaborator	United Kingdom
Location of clinical site(s) (city, town)	Liverpool John Lennon Airport, United Kingdom
Health care level of site(s)	Drive through testing centre
Study period (date to date)	14 October – 16 September 2021
Study cohort inclusion/exclusion	Inclusion: • 18 years or older, who are undergoing testing for COVID-19 • Symptomatic for COVID-19 • Provided informed consent Exclusion: • Asymptomatic • Younger than 18 years
Sample type, antigen test	Nasal swab
Reference PCR method	TaqPath™ COVID-19 CE-IVD RT-PCR Kit (ThermoFisher Scientific)
Sample type, PCR test	Nasopharyngeal swab

4 Results

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

Country	UK
Total N (valid PCR results)	370
Age [mean (min-max), N]	43 (18-81), 370
Gender [%F, (n/N)]	57%, (211/370)
Symptom's present [%Yes, (n/N)]	100%, (370/370)

Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	2 (1-3), 369
Days < 0-3 (n, %)	304, 82%
Days 4-7 (n, %)	56, 15%
Days 8+ (n, %)	9, 2%
Positivity [%, (n/N)]	33%, (121/370)
PCR Ct [median (Q1-Q3); N]	18.5 (15.3-23.2), 121
Ct > 33 (n, %)	6, 5%
Ct > 30 (n, %)	8, 7%
Ct > 25 (n, %)	22, 18%

4.2 Estimation of clinical performance

Country	UK	
	Nasal swab	Nasopharyngeal swab
Clinical Sensitivity (95% CI), N	82.6 (74.9, 88.4), 121	81.8 (74, 87.7), 121
Sensitivity days ≤7, N	82.5 (74.7, 88.3), 120	81.7 (73.8, 87.6), 120
Sensitivity Ct ≤ 33, N	86 (78.4, 91.2), 114	85.1 (77.4, 90.5), 114
Sensitivity Ct ≤ 25, N	93.9 (87.3, 97.2), 98	91.8 (84.7, 95.8), 98
Clinical Specificity (95% CI), N	99.2 (97, 99.8), 243	98.8 (96.5, 99.6), 248
Invalid rate (%, n/N)	1.6% (6/370)	0.3% (1/370)
Positive percent agreement – nasal/NP (95% CI), N	94.1% (87.8, 97.3), 102	NA
Negative percent agreement – nasal/NP (95% CI), N	96.3% (93.2, 98), 267	NA