FIND Evaluation of Coris BioConcept COVID-19 Ag Respi-Strip External Report

Version 1.2, 10 December 2020

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	18 September 2020	Initial release
1.1	3 December 2020	Updated results received from site
1.2	10 December 2020	Updated LOD methodology and results

1 Product info:

Manufacturer Name	Coris BioConcept
Test name	COVID-19 Ag Respi-Strip
Product code(s)	C-1023/TB – version evaluated. C-1323
Pack size(s)	25 tests 250 tests
Contents of kit	Test, buffer, test tube, stopper, instructions for use
Equipment and consumables required, but not provided	Equipment: Timer, refrigerator (for storage of specimens prior to testing, optional). Consumables: PPE Reagents: Negative control
Product storage (temperature range)	4-30 °C.
Shelf-life (months)	*pending*
Manufacturing site (country)	Belgium

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 97% 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:	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 COVID-19 Ag Respi-Strip 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 COVID-19 Ag Respi-Strip 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's 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 and UK**
Location of clinical site(s) (city, town)	1. Heidelberg (Germany) 2. Berlin (Germany) 3. Liverpool (UK)
Health care level of site(s)	1. Heidelberg: Drive-in testing Center 2. Berlin: Ambulatory testing facility of Charité – University Hospital 3. Liverpool: Liverpool University Hospital NHS Foundation (LUHFT)
Study period (date to date)	1. HD: 11-25 May 2. Berlin: 10 Aug; 19-25 Aug 3. Liverpool: 12 May-19 June
Study cohort inclusion/exclusion	1. Germany and Berlin: Adults able to ambulate and meeting suspect definition of the Department of public health. Provided informed consent 2. Liverpool: Adults admitted to LUHFT suspected to have COVID-19 with following symptoms: fever ≥ 37.8C +/- shortness of breath +/- new persistent cough +/- loss of smell OR clinical or radiological evidence of pneumonia. Provided informed consent.
Sample type, antigen test	1. HD: Nasopharyngeal swabs 2. Berlin: Combined naso-/oropharyngeal swab 3. Liverpool: Combined naso-/oropharyngeal swab ESwab™ (modified Amies medium) (Becton, Dickinson and Company)

Reference PCR method	• Allplex 2019-nCov Assay (Seegene Inc) • Cobas SARS-CoV-2 (Roche Diagnostics Inc) • genesig® COVID-19 Real-Time PCR Assay (Primerdesign, Ltd.) • LightMix® Modular SARS-CoV (COVID19) E-gene (Tib Molbiol)
Sample type, PCR test	naso/oropharyngeal swabs

4 Results

4.1 Study Cohort

Countries	**Germany and UK**
Total N	425
Age [mean (min-max); N]	43 (18-89); 424
Gender [% F (n/N)]	61% (255/418)
Symptoms present [%Yes (n/N)]	69.2% (290/419)
Hospitalized [% Yes n/N]	Not available
Days from symptom onset [median (Q1-Q3); N]	3 (1-5); 282
Days < 0-3 [n (%)]	172 (61.0%)
Days 4-7 [n (%)]	75 (26.6%)
Days 8+ [n (%)]	35 (12.4%)
Positivity [%, (n/N)]	1.9% (8/425)
PCR Ct [median (Q1-Q3); N]	23.9 (22.6-28.2); 6
Ct > 33 (n, %)	0 (0%)
Ct > 30 (n, %)	1 (16.7%)
Ct > 25 (n, %)	2 (33.3%)

4.2 Estimation of clinical performance

Countries	**Germany and UK**
Clinical Sensitivity (95% CI); N**	50% (21.5., 78.5); 8

Sensitivity days ≤7; N**	42.9% (15.8, 75.0); 7
Clinical Specificity (95% CI); N**	95.8% (93.4, 97.4); 409
Invalid rate (%, n/N)	1.9% (8/425)

****Note: Evaluation stopped after preliminary analysis indicated specificity below 97%, therefore sensitivity estimate is insufficiently powered.**

4.2.1 Estimation of analytical performance

	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent	Supplier-reported LOD
Analytical Sensitivity	**5 x 10^3 pfu/ml** ~ 7.14 x 10^3 $TCID_{50}$/ml	**1.72 x 10^3 pfu/ml**	**2.61 x 10^6 copies/ml**	7.14 x 10^3 $TCID_{50}$/ml **~ 5 x 10^3 pfu/ml**

Note: verified concentration accounts for volume of dilution that is absorbed onto the swab and then diluted into the proprietary extraction buffer.

4.3 Ease of use

COVID-19 Ag Respi-Strip	48 out of 100	6 operators (Germany) 2 operators (UK)