

FIND Evaluation of Acon Biotech (Hangzhou) Co. Ltd
Flowflex SARS-CoV-2 Antigen Rapid Test
External Report
Version 1.0, 9 June 2021

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Evaluation process – private sector engagement

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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	9 June 2021	Initial release

1 Product info:

Manufacturer name	Acon Biotech (Hangzhou) Co. Ltd.
Test name	Flowflex SARS-CoV-2 Antigen Rapid Test
Product code(s)	L031-11815
Pack size(s)	25 tests per kit
Contents of kit	Test cassettes, positive control swab, negative control swab, disposable swabs, specimen collection guide, extraction buffer tubes, package insert.
Equipment and consumables required, but not provided	PPE, timer
Product storage (temperature range)	2-30°C
Shelf-life (months)	24 months
Manufacturing site (country)	China

2 Study details: (NOTE: will be the same for all reports)

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 Flowflex SARS-CoV-2 Antigen Rapid 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 Flowflex SARS-CoV-2 Antigen Rapid Test

	<p>among all negatives by the reference method and reported as a percentage.</p> <p>The 95% confidence intervals were calculated to assess the level of uncertainty introduced by sample size, using the Wilson's score method.</p>
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3 Evaluation details (NOTE: if multiple sites, info per site)

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)	19 April 2021 – 1 June 2021
Study cohort inclusion/exclusion	<p>Individuals (age 16+) 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.</p> <p>Provided informed consent</p>
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)	279
Age [mean (min-max), N]	34.4 (16-77), 279
Gender [%F, (n/N)]	55.2%, (154/279)
Symptoms present ¹ [%Yes, (n/N)]	95.3%, (61/64)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	2 (1-2), 52 ²
Days < 0-3 (n, %)	45, 87%

Days 4-7 (n, %)	6, 12%
Days 8+ (n, %)	1, 2%
Positivity [%, (n/N)]	23%, (63/279)
PCR Ct [median (Q1-Q3); N]	21 (19.2-24.8), 63
Ct > 33 (n, %)	5, 8%
Ct > 30 (n, %)	6, 10%
Ct > 25 (n, %)	15, 24%

¹ Note: data on symptom onset only available for individuals who tested PCR positive, or false positive by antigen RDT.

² symptom onset date missing for 12 samples.

4.2 Estimation of clinical performance

Country	Switzerland
Clinical Sensitivity (95% CI), N	92.1% (82.7, 96.6); 63
Sensitivity days ≤7, N	92.2% (81.5, 96.9); 51
Sensitivity Ct ≤ 33, N	98.3% (90.9, 99.7); 58
Sensitivity Ct ≤ 25, N	100% (92.6, 100); 48
Clinical Specificity (95% CI), N	99.5% (97.5, 99.9); 216
Invalid rate (% , n/N)	0% (0/216)

4.3 Estimation of analytical performance

	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent	Supplier-reported LOD
Analytical Sensitivity	5.0 x10¹ pfu/ml ~ 7.05 x 10 ¹ TCID ₅₀ /ml	5.0 x10¹ pfu/ml	6.8 x10³ copies/ml applied to test	1.6 x10² TCID₅₀/ml ~ 1.13 x10² pfu/ml

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