FIND Evaluation of Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit External Report

Version 1.0, 26 April 2021

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Evaluation process – private sector engagement

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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 websitepage 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	26 April 2021	Initial release

1 Product info:

Manufacturer name	Edinburgh Genetics
Test name	ActivXpress+ COVID-19 Antigen Complete Testing Kit
Product code(s)	AG20200905 (**Please note:** this product is no longer distributed; a new product is currently distributed: product code EGCV0101NB)
Pack size(s)	20 test/kit
Contents of kit	Test cassette, sterilized nasopharyngeal swab, extraction reagent in tube dropper
Equipment and consumables required, but not provided	PPE, timer
Product Storage (temperature range)	2-30°C
Shelf-life (months)	12 months
Manufacturing site (country)	United Kingdom

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 ActivXpress+ COVID-19 Antigen 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 ActivXpress+ COVID-19 Antigen 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's score method.

3 Evaluation details

Country of collaborator	Peru
Location of clinical site(s) (city, town)	Universidad Peruana Cayetano Heredia, Lima
Health care level of site(s)	Community Testing Clinic
Study period (date to date)	17 February - 30 March 2021
Study cohort inclusion/exclusion	Adults with acute respiratory illness who meets WHO case definition of a COVID-19 suspected case presenting to temporary testing locations around clinical sites. Provided informed consent
Sample type, antigen test	Nasopharyngeal swab
Reference PCR method	2019-nCoV TaqMan RT-PCR Kit (Norgen Biotek Corp)
Sample type, PCR test	Nasopharyngeal swab

4 Results

4.1 Study cohort

Country	Peru
Total N (valid PCR results)	120
Age [mean (min-max), N]	39.1 (18-68), 120
Gender [%F, (n/N)]	67.7%, (74/120)
Symptoms present [%Yes, (n/N)]	100%, (120/120)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	4 (3-6), 120

Days < 0-3 (n, %)	31, 26%
Days 4-7 (n, %)	74, 62%
Days 8+ (n, %)	15, 12%
Positivity [%, (n/N)]	45%, (54/120)
PCR Ct [median (Q1-Q3); N]	24.1 (20.3-31.2), 54
Ct > 33 (n, %)	10, 19%
Ct > 30 (n, %)	16, 30%
Ct > 25 (n, %)	24, 46%

4.2 Estimation of clinical performance

Country	Peru
Clinical Sensitivity (95% CI), N	61.1% (47.8, 73), 54
Sensitivity days ≤7, N	62% (48.2, 74.1), 50
Sensitivity Ct ≤ 33, N	75% (60.6, 85.4), 44
Sensitivity Ct ≤ 25, N	100% (88.3, 100), 29
Clinical Specificity (95% CI), N	100% (94.5, 100), 120
Invalid rate (%, n/N)	0% (0/120)

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** ~ 3.52 x 10^2 $TCID_{50}$/ml	**2.5 x10^2** pfu/ml	**5.97 x10^5 copies/ml** applied to test	5x10^2 pfu/ml

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