FIND Evaluation of Shenzhen Bioeasy Biotechnology Co. Ltd. 2019-nCoV Ag Rapid Test Kit (Fluorescence) External Report

Version 1.0, 19 January 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	19 January 2021	Initial Release

1 Product info:

Manufacturer name	Shenzhen Bioeasy Biotechnology Co. Ltd.
Test name	Diagnostic Kit for 2019-Novel Coronavirus (2019-nCoV) Ag Test (Fluorescence Immunochromatographic Assay) (Bioeasy) Immunofluorescence Analyser EASY-11
Product code(s)	**YRLF04401025 – version evaluated** YRLF04401050/YRLF04401100 YRLE01105: analyser
Pack size(s)	25 tests/ 50tests/100tests
Contents of kit	Test cards with desiccant in a sealed foil pouch; sample extraction buffer; extraction tube holder; tube; dripper; swab; ID chip; instructions for use
Equipment and consumables required, but not provided	Equipment: Timer, refrigerator (for storage of specimens prior to testing, optional). Consumables: PPE Reagents: Phosphate solution
Product Storage (temperature range)	2-30 °C
Shelf-life (months)	12 months
Manufacturing site (country)	China

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 Bioeasy 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 Bioeasy 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
Location of clinical site(s) (city, town)	1. Heidelberg, Germany 2. Berlin, Germany
Health care level of site(s)	1. Heidelberg: Drive-in testing Center 2. Berlin: Drive-in testing Center
Study period	1. HD: 14 April – 03 May 2020 2. Berlin:14 May – 03 June 2020
Study cohort inclusion/exclusion	Heidelberg and Berlin: Adults able to ambulate and meeting suspect definition of the Department of public health. Provided informed consent
Sample type, antigen test	1. HD: Nasopharyngeal swab (or oropharyngeal swabs if NP was contra-indicated) 2. Berlin: Combined Naso/oropharyngeal swabs Proprietary swab/media provided by Shenzhen Bioeasy

	Note: a second sample was collected for each patient, using the same specimen type as for PCR

Reference PCR method	• Cobas SARS-CoV-2 (Roche Diagnostics Inc);
	  ○ n = 223
	• Abbott *RealTime* SARS-CoV-2 (Abbott Molecular, Inc);
	  ○ n = 5
	• Allplex 2019-nCov Assay (Seegene Inc);
	  ○ n = 343
	• LightMix® Modular SARS-CoV (COVID19) E-gene (Tib Molbiol);
	  ○ n = 158

Sample type, PCR test	1. HD: nasopharyngeal (NP) swabs (or oropharyngeal swabs if NP was contra-indicated) 2. Berlin: combined naso/oropharyngeal swabs

4 Results

4.1 Study cohort

Country	**Germany**
Total N	729
Age [mean (min-max), N]	40 (18.1-92.0); 728
Gender [%F, (n/N)]	47.2% (369/699)
Symptoms present [%Yes, (n/N)]	86.1% (563/654)
Hospitalized (n, % Yes)	Not available
Days from symptom onset [median (Q1-Q3); N]	3 (2-6); 540
Days < 0-3 (n, %)	303 (56.1%)
Days 4-7 (n, %)	132 (24.4%)
Days 8+ (n, %)	105 (19.4%)
Positivity [%, (n/N)]	2.1% (15/729)*
PCR Ct [median (Q1-Q3); N]	23.1 (20.5-30.1); 15
Ct > 33 (n, %)	2 (13.33%)
Ct > 30 (n, %)	4 (26.7%)
Ct > 25 (n, %)	6 (40%)

** 6/15 positives were tested using Roche, 2/15 positives were tested using Seegene and 7/15 positives were tested using TibMolbiol.*

***Note*: Evaluation stopped after preliminary analysis indicated specificity below 97%.**

4.2 Estimation of clinical performance

Country	**Germany**
Clinical Sensitivity (95% CI), N	66.7 (47.7, 84.8); 15*
Sensitivity days ≤7, N	66.7 (39.1, 86.2); 12
Clinical Specificity (95% CI), N	93.1 (91.0, 94.8); 712
Invalid rate (%, n/N)	0.27%, (2/729)

** 6/15 positives were tested using Roche, 2/15 positives were tested using Seegene and 7/15 positives were tested using TibMolbiol.*

Note: Evaluation stopped after preliminary analysis indicated specificity below 97%.

4.2.1 Estimation of analytical performance

	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent	Supplier-reported LOD
Analytical Sensitivity	**5.0×10^3 pfu/ml** ~ 7.14×10^3 $TCID_{50}$/ml	**4.55×10^2** pfu/ml	**6.88×10^5 copies/ml**	Not reported

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

Bioeasy	73 out of 100	8 operators [Germany]