FIND Evaluation of Joysbio (Tianjin) Biotechnology Co., Ltd. SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) External Report

Version 1.0, 11 February 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	11 February 2021	Initial version

1 Product info

Manufacturer name	Joysbio (Tianjin) Biotechnology Co., Ltd.
Test name	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)
Product code(s)	COV-AG-20/G10313
Pack size(s)	20 tests / kit – version used
Contents of kit	Test device, desiccant, buffer, extraction tube, specimen sampling swabs
Equipment and consumables required, but not provided	Positive and negative control swab (optional) PPE, Timer, Biohazard container
Product storage (temp. range)	2-30°C
Shelf-life (months)	24 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 Joysbio 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 Joysbio SARS-CoV-2 Antigen Rapid 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.
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	**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)	4-13 January 2021
Study cohort inclusion/exclusion	Adults 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. Provided informed consent
Sample type, antigen test	Anterior Nares (AN, Nasal) swab
Reference PCR method	Cobas SARS-CoV-2 (Roche Diagnostics Inc) (n=216) Xpert Xpress SARS-CoV-2 (Cepheid) (n=1) TaqPath™ COVID-19 CE IVD RT PCR Kit (Thermo Fisher Scientific) (with Nimbus Presto Extraction instrument) (n=48)
Sample type, PCR test	Nasopharyngeal swab

4 Results

4.1 Study Cohort

Country	**Switzerland**
Total N (valid PCR results)	265

Age [mean (min-max), N]	36.3 (16-80), 265
Gender [%F, (n/N)]	47.5%, (265/265)
Symptoms present[1] [%Yes, (n/N)]	88.6%, (39/44)
Hospitalized (n, % Yes)	Not available
Days from symptom onset[1] [median (Q1-Q3); N]	2 (1-3.5); 31
Days < 0-3 (n, %)	23, 74%
Days 4-7 (n, %)	8, 26%
Days 8+ (n, %)	0, 0%
Positivity [%, (n/N)]	17%, (44/265)
PCR Ct [median (Q1-Q3); N]	26.6 (22.3-30); 44
Ct > 33 (n, %)	6, 14%
Ct > 30 (n, %)	10, 23%
Ct > 25 (n, %)	21, 48%

[1]*Note: data on symptom onset only available for individuals who tested PCR positive.*

4.2 Estimation of clinical performance

Country	**Switzerland**
Clinical Sensitivity (95% CI), N	70.5% (55.8, 81.8), 44
Sensitivity days ≤7, N	74.2% (56.8, 86.3), 31
Sensitivity Ct ≤ 33, N	78.9% (63.7, 88.9), 38
Sensitivity Ct ≤ 25, N	91.3% (73.2, 97.6), 23
Clinical Specificity (95% CI), N	99.1% (96.8, 99.8), 221
Invalid rate (%, n/N)	0%, 0/265

4.2.1 Estimation of analytical performance

	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent	Supplier-reported LOD
Analytical Sensitivity	**1.0 x 10^2 pfu/ml** ~ 1.42 x 10^2 $TCID_{50}$/ml	**1.0 x 10^2** pfu/ml	**2.18 x10^5 copies/ml** applied to test	1.6 x 10^2 $TCID_{50}$/ml ~ 1.12 x 10^2 **pfu/ml**

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

4.3 Ease of use

Joysbio	[TBC] out of 100	TBC operators, Switzerland