FIND Evaluation of Uniogen Oy, GenomEra® SARS-CoV-2, Flu A/B + RSV 2.0 assay External Report

Version 1.0 [6 November 2023]

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Evaluation process – private sector engagement

FIND 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; ease-of-use of the test and instrument robustness; the manufacturing and distribution capacity of the supplier; and the supplier-reported clinical and analytical performance.

Document history

Document version	Date	Comment
1.0	6 November 2023	Initial release

1 Product Information:

Manufacturer name	Uniogen Oy
Test name	GenomEra® SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit
Product code(s)	CDX-160-01-100
Pack size(s)	100 tests per kit
Contents of kit	Test chips, package insert, extraction columns, waste tubes, sample elution tubes, chip holder, procedure card
Equipment and consumables required, but not provided	Transport media and sterile swabs for specimens, PCR microtubes, Fast Gene High Speed Mini centrifuge, vortex, micropipettes, filter-blocked tips, powderless gloves, GenomEra® CDX System
Product storage (temperature range)	2-8°C
Shelf-life (months)	12 months
Manufacturing site (country)	Finland

2 Study details:

Study design:	Prospective diagnostic evaluation study in an independent site to determine the accuracy of COVID-19 point-of-care (POC) molecular assays
Index assay:	GenomEra® SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit as a RT-PCR test able to detect separately SARS-CoV-2, Flu A/B + RSV RNA
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 the GenomEra® SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit, 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 the GenomEra® SARS-CoV-2, Flu A/B + RSV 2.0 Assay Kit, 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	Uganda
Location of clinical site(s) (city, town)	Mulago National Referral Hospital, Kiruddu National Referral Hospital, Butabika National Referral Hospital and Kawempe National Referral Hospital
Health care level of site(s)	National Referral Hospitals
Study period (date to date)	January 2023 to May 2023
Study cohort inclusion/exclusion	Inclusion criteria - Adult individuals (≥18 years of age) with symptoms suggesting plausible COVID-19 infection (as per WHO or national clinical case definitions) - Individuals who have voluntarily given written consent to participate in this study or who have given their written consent for their specimen to be used for future research studies - Individuals able to provide the specimens required for the study Exclusion criteria - Individuals on oxygen therapy - Individuals with recent history of excessive nose bleeds - Individuals with hemodynamic instability as determined by their treating physician - Individuals already enrolled in other clinical studies, where similar respiratory specimens are collected on the same day
Sample type, index test	Nasal swab
Reference PCR method	RT-PCR Cobas® SARS-CoV-2
Sample type, reference test	Nasopharyngeal swab

4 Results:

4.1 Study cohort

Country	**Uganda**
Total N (valid PCR results)	261
Age [mean (min-max), N]	35.9 (18-85), 261
Gender [%F, (n/N)]	50.2%, (131/261)
Symptoms present [%Yes, (n/N)]	100%, (261/261)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	4 (3-4); 261
Days < 0-3 (n, %)	125, 47.9%
Days 4-7 (n, %)	131, 50.2%
Days 8+ (n, %)	5, 1.9%
Positivity [%, (n/N)]	47.9%, (125/261)
PCR Ct [median (Q1-Q3); N]	29 (27.6-31.1); 125
Ct > 33 (n, %)	12, 9.6%
Ct > 30 (n, %)	47, 37.6%
Ct > 25 (n, %)	118, 94.4%

4.2 Estimation of Clinical Performance

Country	**Uganda**
Clinical Sensitivity (95% CI), N	67.9% (58.7, 75.8), 112
Sensitivity days ≤7, N	66.7% (57.3, 74.9), 108
Sensitivity Ct ≤ 33, N	71.6% (62.2, 79.4), 102
Sensitivity Ct ≤ 25, N	85.7% (48.7, 97.4), 7
Clinical Specificity (95% CI), N	97.3% (92.3, 99.1), 110
Invalid rate [% (n/N)]	14.9% (39/261)

4.2.1 Estimation of analytical performance

- Supplier-reported LOD

Template / target analyte	LoD (in original specimen)
First WHO International Standard for SARS-CoV-2 RNA	500 IU/mL
NATtrol™ SARS-CoV-2	1429 copies/mL

- First WHO International Standard for SARS-CoV-2 RNA (NIBSC code: 20/146) (SARS-CoV-2/England/02/2020)
- NATtrol™ SARS-CoV-2 Stock, Cat.# NATSARS(COV2)-ST (Zeptometrix, Buffalo, USA) (USA-WA1/2020, NR-52281)

The standards were spiked in various concentrations into pooled negative nasopharyngeal patient samples collected in eSwab transport medium (Copan, Brescia, Italy). The limit of detection (LoD) was defined as the lowest standard concentration per sample which could be reproducibly distinguished from negative samples with 95 % confidence.

- Verified LOD

Variant (lineage)	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent
Omicron (BA.5)	**1.0 x10^{-8} pfu/ml** ~ 1.41x 10^{-8} $TCID_{50}$/ml	**1.0 x10^{-8} pfu/ml**	**3.0 x10^{1} genome copies/ml** applied to test

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