

## FIND Evaluation of Boditech Medical, Inc.

### iChroma COVID-19 Ag Test

### External Report

*Version 1.0, 23 February 2021*

#### **Copyright and use of the report**

Copyright in this report is the property of FIND (or controlled by FIND). You are free to share, copy and redistribute the material in any medium or format provided that:

- (i) attribution: you must give appropriate credit to FIND and indicate if changes were made, you may do so in any reasonable manner, but not in any way that suggests that FIND endorses you or your use;
- (ii) non-commercial: you may not use the report for commercial purposes; and
- (iii) no derivatives: if you remix, transform, or build upon the materials or report, you may not distribute the modified materials or report unless with express authorization from FIND.

Presentation of data on our website does not impact any data ownership rights and FIND is not responsible for any use by any third party of these data. Data sources are provided.

#### **Evaluation process – private sector engagement**

FIND, the global alliance for diagnostics, 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 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	23 February 2021	Initial release

## 1 Product info:

Manufacturer Name	Boditech Medical, Inc.
Test name	iChroma COVID-19 Ag Test
Product code(s)	CFPC-115
Pack size(s)	25 tests/kit
Contents of kit	Cartridge, detector tube, extraction buffer, nozzle, ID chip, instructions for use
Equipment and consumables required, but not provided	PPE, Timer, Biohazard container
Product Storage (temperature range)	2-30°C
Shelf-life (months)	20 months
Manufacturing site (country)	Korea

## 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 iChroma COVID-19 Ag 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 iChroma COVID-19 Ag Test among all negatives by the reference method, and reported as a percentage.

	The 95% confidence intervals were calculated in order 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)	21 to 29 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	Nasopharyngeal swab
Reference PCR method	Cobas SARS-CoV-2 (Roche Diagnostics Inc) (n=35) Cobas SARS-CoV-2 & Influenza A/B (Roche Diagnostics Inc) (n=197)
Sample type, PCR test	Nasopharyngeal swab

### 4 Results

#### 4.1 Study cohort

<b>Country</b>	Switzerland
Total N (valid PCR results)	232
Age [mean (min-max), N]	36.3 (16-76), 232
Gender [%F (n/N)]	55.6% (129/232)

Symptoms present <sup>1</sup> [%Yes (n/N)]	92.7% (38/41)
Hospitalized (n, % Yes)	Not available
Days from symptom onset [median (Q1-Q3); N]	1.5 (1-3); 32
Days < 0-3 (n, %)	26, 81%
Days 4-7 (n, %)	5, 16%
Days 8+ (n, %)	1, 3%
Positivity [%, (n/N)]	17.7%, (41/232)
PCR Ct [median (Q1-Q3); N]	22.7 (18.9-28.9); 39
Ct > 33 (n, %)	3, 8%
Ct > 30 (n, %)	7, 18%
Ct > 25 (n, %)	17, 44%

<sup>1</sup>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	73.2% (58.1, 84.3), 41
Sensitivity days ≤7, N	83.9% (67.4, 92.9), 31
Sensitivity Ct ≤ 33, N	83.3% (68.1, 92.1), 36
Sensitivity Ct ≤ 25, N	95.5% (78.2, 99.2), 22
Clinical Specificity (95% CI), N	100% (98, 100), 191
Invalid rate (% , n/N)	0% (232/232)

### 4.2.1 Estimation of analytical performance

	Lowest dilution detected	Verified LOD concentration	Viral copy equivalent	Supplier-reported LOD
<b>Analytical Sensitivity</b>	<b>1.00 x 10<sup>4</sup> pfu/ml ~ 1.43 x 10<sup>4</sup> TCID<sub>50</sub>/ml</b>	1.66 x 10 <sup>3</sup> pfu/ml	<b>2.6 x 10<sup>6</sup> copies/ml</b> applied to test	87 TCID <sub>50</sub> /ml ~ 4.8 X 10 <sup>3</sup> copies / test

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

TBC	TBC out of 100	TBC operators, Switzerland
-----	----------------	----------------------------