# FIND Evaluation of Liming Bio

# StrongStep SARS-CoV-2 Antigen Rapid Test

# External Report

*Version 1.0, [16 December 2022]*

## Copyright and use of the report



## 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 | 16 December 2022 | First release |

## 1 Product Info:

| | |
|---|---|
| Manufacturer name | Nanjing Liming Bio-products Co. Ltd |
| Test name | StrongStep SARS-CoV-2 Antigen Rapid Test |
| Product code(s) | 500200 |
| Pack size(s) | 20 tests/box |
| Contents of kit | Sealed foil pouch with test device, dilution buffer vials, extraction tubes, packs of swabs, saliva collection funnel, workstation, package insert |
| Equipment and consumables required, but not provided | PPE, timer |
| Product storage (temperature range) | 2-30℃ |
| Shelf-life (months) | 24 |
| 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: | 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 Liming Bio 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 Liming Bio among all negatives by the reference method and reported as a percentage.<br>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 | **South Africa** | **Peru** |
|---|---|---|
| Location of clinical site(s) (city, town) | Cape Town | Lima |
| Health care level of site(s) | Hospital testing | Community Testing Clinic |
| Study period (date to date) | 21 April to 8 August 2022 | 20 July to 30 September 2022 |
| 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.<br>Provided informed consent | Adults with acute respiratory illness who meets WHO case definition of a COVID-19 suspected case presenting to temporary testing locations around clinical sites.<br>Provided informed consent |
| Sample type, antigen test | Nasal, saliva | Nasal, saliva |
| Reference PCR method | Abbott Alinity m SARS-CoV-2 Assay,<br>Seegene Allplex™ 2019-nCoV Assay | 2019-nCoV TaqMan RT-PCR Kit (Norgen Biotek Corp) |
| Sample type, PCR test | Nasopharyngeal swab | Nasopharyngeal swab |

# 4 Results:

## 4.1 Study cohort

| Country | South Africa | Peru |
|---|---|---|
| Total N (valid PCR results) | 142 | 187 |
| Age [mean (min-max), N] | 33.2 (18-92), 142 | 383 (18-85), 187 |
| Gender [%F, (n/N)] | 52.8% (67/142) | 70.1% (131/187) |
| Symptoms present [%Yes, (n/N)] | 100% (142/142) | 100% (187/187) |
| Hospitalized (n, % Yes) | Not applicable | Not applicable |
| Days from symptom onset [median (Q1-Q3); N] | 3, (2-3), 142 | 4, (3-5), 187 |
| Days < 0-3 (n, %) | 116, 82% | 88, 47% |
| Days 4-7 (n, %) | 23, 16% | 96, 51% |
| Days 8+ (n, %) | 3, 2% | 3, 2% |
| Positivity [%, (n/N)] | 42.2%, (60/142) | 30%, (57/187) |
| PCR Ct [median (Q1-Q3); N] | 21, (17-27), 39[1] | 18.7, (15.3-29), 57 |
| Ct > 33 (n, %) | 4, 10% | 7, 12% |
| Ct > 30 (n, %) | 6, 15% | 13, 23% |
| Ct > 25 (n, %) | 14, 36% | 18, 32% |

[1] Ct values not available for 21 IDs

### 4.2 Estimation of Clinical Performance

| | South Africa | |
|---|---|---|
| **Country** | **Nasal** | **Saliva** |
| Clinical Sensitivity (95% CI), N | 61.7% (49, 72.9), 60 | 21.7% (13.1, 33.6), 60 |
| Sensitivity days ≤7, N | 61% (48.3, 72.4), 59 | 22% (13.4, 34.1), 59 |
| Sensitivity Ct ≤ 33, N | 74.3% (57.9, 85.8), 35 | 31.4% (18.6, 48), 35 |
| Sensitivity Ct ≤ 25, N | 88% (70, 95.8), 25 | 32% (17.2, 51.6), 25 |
| Clinical Specificity (95% CI), N | 98.8% (93.3, 99.8), 81 | 100% (95.5, 100), 82 |
| Invalid rate (%, n/N) | 0% (0/142) | 0% (0/142) |
| | | |
| | **Peru** | |
| **Country** | **Nasal** | **Saliva** |
| Clinical Sensitivity (95% CI), N | 84.2% (72.6, 91.5), 57 | 64.9% (51.9, 76), 57 |
| Sensitivity days ≤7, N | 83.9% (72.2, 91.3), 56 | 66.1% (53, 77.1), 56 |
| Sensitivity Ct ≤ 33, N | 90% (78.6, 95.7), 50 | 68% (54.2, 79.2), 50 |
| Sensitivity Ct ≤ 25, N | 100% (91, 100), 39 | 71.8% (56.2, 83.5), 39 |
| Clinical Specificity (95% CI), N | 65.4% (56.9, 73), 130 | 61.5% (53, 69.5), 130 |
| Invalid rate (%, n/N) | 0% (0/187) | 0% (0/187) |