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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/](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

<table>
<thead>
<tr>
<th>Document Version</th>
<th>Date</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>11 February 2021</td>
<td>Initial release</td>
</tr>
</tbody>
</table>
### 1 Product info:

<table>
<thead>
<tr>
<th>Manufacturer name</th>
<th>Abbott Rapid Diagnostics Jena GmbH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test name</td>
<td>Panbio COVID-19 Ag Rapid Test Device Nasal</td>
</tr>
<tr>
<td>Product code(s)</td>
<td>41FK11 (nasal version evaluated), 41FK21 (nasal, contains 2D barcode), 41FK10 (nasopharyngeal)</td>
</tr>
<tr>
<td>Pack size(s)</td>
<td>25 tests per kit</td>
</tr>
<tr>
<td>Contents of kit</td>
<td><strong>41FK11</strong> Test device (individually in a foil pouch with desiccant), buffer, extraction tubes, extraction tube caps, positive control swab, negative control swab, sample collection swab (Nasal swab), quick reference guide, Instructions for Use</td>
</tr>
<tr>
<td></td>
<td><strong>41FK10</strong> Test device (individually in a foil pouch with desiccant), buffer, extraction tubes, extraction tube caps, positive control swab, negative control swab, sample collection swab (Nasopharyngeal swab), quick reference guide, Instructions for Use</td>
</tr>
<tr>
<td>Equipment and consumables required, but not provided</td>
<td>Personal Protective Equipment per local recommendations (i.e. gown/lab coat, face mask, face shield/eye goggles and gloves), Timer, Biohazard container</td>
</tr>
<tr>
<td>Product Storage (temperature range)</td>
<td>2-30 °C.</td>
</tr>
<tr>
<td>Shelf-life (months)</td>
<td>12 months</td>
</tr>
<tr>
<td>Manufacturing site (country)</td>
<td>South Korea</td>
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### 2 Study details:

<table>
<thead>
<tr>
<th>Study design:</th>
<th>Prospective diagnostic accuracy study to demonstrate the equivalency of nasal swab to nasopharyngeal swab for COVID-19 antigen RDTs, using consecutive enrolment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index assays:</td>
<td>Novel lateral flow format tests that detect recombinant SARS-CoV-2 antigens used with nasal swab as sample type.</td>
</tr>
<tr>
<td>Reference method:</td>
<td>Results of the index test are compared to the routine, diagnostic RT-PCR result, which is used for clinical management. Comparability between nasal swab Ag RDT results and nasopharyngeal swab Ag RDT results was also analysed.</td>
</tr>
<tr>
<td>Limit of detection:</td>
<td>Not conducted. See Panbio COVID-19 Ag, nasopharyngeal swab report.</td>
</tr>
<tr>
<td>--------------------</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td>Clinical Performance:</td>
<td>Sensitivity was calculated as the proportion of true positive results detected by Panbio COVID-19 RDT nasal 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 Panbio COVID-19 RDT nasal among all negatives by the reference method, and reported as a percentage. Positive and negative percent agreement between the two sample types was also calculated as the proportion of nasal swab positive/negative among all positive/negative by nasopharyngeal swab by Panbio COVID-19 RDT, 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.</td>
</tr>
<tr>
<td>Ease of use</td>
<td>Not conducted. See Panbio COVID-19 Ag, nasopharyngeal swab report.</td>
</tr>
</tbody>
</table>

3 Evaluation details

<table>
<thead>
<tr>
<th>Country of collaborator</th>
<th>Germany</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location of clinical site(s) (city, town)</td>
<td>Heidelberg</td>
</tr>
<tr>
<td>Health care level of site(s)</td>
<td>Drive-in testing Center</td>
</tr>
<tr>
<td>Study period (date to date)</td>
<td>15 December 2020 to 19 January 2021</td>
</tr>
<tr>
<td>Study cohort inclusion/exclusion</td>
<td>Adults able to ambulate, at high risk for SARS-CoV-2 according to clinical suspicion, and meeting suspect definition of the Department of Public Health Provided informed consent</td>
</tr>
<tr>
<td>Sample type, antigen test</td>
<td>Nasal Mid-Turbinate (NMT, Nasal) and Nasopharyngeal (NP)</td>
</tr>
</tbody>
</table>
| Reference PCR method | • LightMix® Modular SARS-CoV (COVID19) E-gene (Tib Molbiol)  
  o N = 266  
• Allplex 2019-nCov Assay (Seegene Inc)  
  o N = 13  
• Abbott RealTime SARS-CoV-2 (Abbott Molecular, Inc)  
  o N = 3 |
| Sample type, PCR test | Nasopharyngeal (NP) |
4 Results

4.1 Study cohort

<table>
<thead>
<tr>
<th>Country</th>
<th>Germany</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total N (valid PCR results)</td>
<td>281</td>
</tr>
<tr>
<td>Age [mean (min-max), N]</td>
<td>42.92 (18-81)</td>
</tr>
<tr>
<td>Gender [%F, (n/N)]</td>
<td>52.1%, (146/280)</td>
</tr>
<tr>
<td>Symptoms present [%Yes, (n/N)]</td>
<td>46.2%, (130/279)</td>
</tr>
<tr>
<td>Hospitalized (n, % Yes)</td>
<td>Not available</td>
</tr>
<tr>
<td>Days from symptom onset [median (Q1-Q3); N]</td>
<td>3 (1-5); 126</td>
</tr>
<tr>
<td>Days &lt; 0-3 (n, %)</td>
<td>86, 68%</td>
</tr>
<tr>
<td>Days 4-7 (n, %)</td>
<td>290, 23%</td>
</tr>
<tr>
<td>Days 8+ (n, %)</td>
<td>11, 9%</td>
</tr>
<tr>
<td>Positivity [%, (n/N)]</td>
<td>16% (44/281)</td>
</tr>
<tr>
<td>PCR Ct [median (Q1-Q3); N]</td>
<td>21.7 (18.5-25.9); 44</td>
</tr>
<tr>
<td>Ct &gt; 33 (n, %)</td>
<td>2, 5%</td>
</tr>
<tr>
<td>Ct &gt; 30 (n, %)</td>
<td>6, 14%</td>
</tr>
<tr>
<td>Ct &gt; 25 (n, %)</td>
<td>13, 30%</td>
</tr>
</tbody>
</table>

4.2 Estimation of clinical performance

<table>
<thead>
<tr>
<th>Country</th>
<th>Germany</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal swab</td>
<td>Nasopharyngeal swab</td>
</tr>
<tr>
<td>Clinical Sensitivity (95% CI), N</td>
<td>86.4% (73.3, 93.9), 44*</td>
</tr>
<tr>
<td>Sensitivity days ≤7, N</td>
<td>97% (84.7, 99.5), 33</td>
</tr>
<tr>
<td>Sensitivity Ct ≤ 33, N</td>
<td>90.5% (77.9, 96.2), 42</td>
</tr>
<tr>
<td>Sensitivity Ct ≤ 25, N</td>
<td>96.8% (83.8, 99.4), 31</td>
</tr>
<tr>
<td>Clinical Specificity (95% CI), N</td>
<td>99.2% (97, 99.8), 237</td>
</tr>
<tr>
<td>Invalid rate (%n, n/N)</td>
<td>0%, 0/281</td>
</tr>
<tr>
<td>Positive percent agreement – nasal/NP (95% CI), N</td>
<td>88.1% (75, 94.8), 42</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Negative percent agreement – nasal/NP (95% CI), N</td>
<td>99.2% (97, 99.8), 239</td>
</tr>
</tbody>
</table>

*Note: 44/44 positives were tested using TibMolbiol.*