Assessment of the analytical sensitivity of ten lateral flow devices against the SARS-CoV-2 omicron variant

10 Antigen test kits evaluated:
- Panbio™ COVID-19 Ag Rapid Test Device
- NowCheck COVID-19 Antigen test
- Roche SARS-CoV-2 Rapid Antigen Test
- STANDARD™ Q COVID-19 Ag Test
- Sunscreen Diagnostics COVID-19 Antigen Rapid Test Cassette
- VivaDiag™ SARS-CoV-2 Ag Rapid Test
- Wantai SARS-CoV-2 Ag Rapid Test
- Testsea SARS-CoV-2 Antigen Test Kit
- InnoScreen COVID-19 Antigen Rapid Test Device
- LYHER Novel Coronavirus Antigen Test Kit

- Both delta and omicron variants showed similar analytical sensitivity among the testing tools evaluated.
- All testing tools were able to detect delta and omicron variants at 6.50 log_{10} copies/mL (Ct 25.4) and 6.39 log_{10} copies/mL (Ct 25.8) respectively.
- No testing tools were able to detect delta or omicron at 5.23 log_{10} copies/mL (Ct 28.8) and 5.33 log_{10} copies/mL (Ct 28.8) respectively.
- Study was conducted in Australia

Analytical sensitivity of seven SARS-CoV-2 antigen-detecting rapid tests for Omicron variant

7 Antigen test kits evaluated:
- Panbio™ COVID-19 Ag Rapid Test Device
- STANDARD™ Q COVID-19 Ag Test
- Sure Status
- 2019-nCoV Antigen Test
- Beijing Tigsun Diagnostics Co. Ltd.
- Onsite COVID-19 Ag Rapid Test
- Flowflex

- Study was conducted in Switzerland
- Only 3 of the antigen tests used are WHO-EUL approved: Panbio™, STANDARD™, and Sure Status.
- Analytical sensitivity to detect Omicron was lower than other variants in most of the tests evaluated.
- Flowflex showed highest sensitivity for all variants, with omicron being sensitivity being higher than the delta variant.

QUIDEŁ QuickVue At Home OTC COVID-19 Test Sensitivity and Specificity

Test positivity may be affected by the time from the onset of symptoms

Not very sensitive in asymptomatic individuals

Limited data from children
<table>
<thead>
<tr>
<th>Days Since Symptom Onset</th>
<th>Cumulative RT-PCR Positive (+)</th>
<th>Cumulative BinaxNOW COVID-19 Antigen SelfTest Positive (+)</th>
<th>PPA</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12</td>
<td>10</td>
<td>83.3%</td>
<td>51.6% 97.9%</td>
</tr>
<tr>
<td>2</td>
<td>34</td>
<td>28</td>
<td>82.4%</td>
<td>65.6% 93.2%</td>
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<tr>
<td>3</td>
<td>50</td>
<td>41</td>
<td>82.0%</td>
<td>68.6% 91.4%</td>
</tr>
<tr>
<td>4</td>
<td>63</td>
<td>50</td>
<td>79.4%</td>
<td>67.3% 88.5%</td>
</tr>
<tr>
<td>5</td>
<td>78</td>
<td>63</td>
<td>80.8%</td>
<td>70.3% 88.8%</td>
</tr>
<tr>
<td>6</td>
<td>90</td>
<td>75</td>
<td>83.3%</td>
<td>74.0% 90.4%</td>
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<tr>
<td>7</td>
<td>117</td>
<td>99</td>
<td>84.6%</td>
<td>76.8% 90.6%</td>
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<tr>
<td>8 to 10</td>
<td>144</td>
<td>118</td>
<td>81.9%</td>
<td>74.7% 87.9%</td>
</tr>
<tr>
<td>11 to 14</td>
<td>161</td>
<td>126</td>
<td>78.3%</td>
<td>71.1% 84.4%</td>
</tr>
<tr>
<td>All specimens</td>
<td>167</td>
<td>129</td>
<td>77.2%</td>
<td></td>
</tr>
</tbody>
</table>

COVID-19 Tests may have Lower Sensitivity in Vaccinated Individuals with Breakthrough Infections

- Virus shedding is lower among fully or partially vaccinated (mRNA vaccine) healthcare workers with breakthrough infections (pre-Delta) at UCLA winter of 2020-21 (880 infected among 11930 employees, 30% received at least one dose)

- The data for Delta showed that Ct number was similar between infected vaccinated and unvaccinated but the virus titer dropped faster among vaccinated