

## Target Product Profile: Point of Care/CLIA-Waived and OTC/At-Home Use Pathogen Diagnostics

| Attribute                             | Minimal   | Ideal   |
|---------------------------------------|---|---|
| <b>Intended use</b>                   | <ul style="list-style-type: none"> <li>Rapid detection of infectious diseases;<br/><a href="https://aspr.hhs.gov/PHEMCE/Pages/Priority-Threats.aspx">https://aspr.hhs.gov/PHEMCE/Pages/Priority-Threats.aspx</a></li> </ul>   | <ul style="list-style-type: none"> <li>Rapid detection of specific disease/condition</li> </ul>   |
| <b>Target population being tested</b> | <ul style="list-style-type: none"> <li>General population to make informed decisions about health or during periods of heightened disease threats</li> </ul>  | <ul style="list-style-type: none"> <li>General population with special emphasis on underserved and resource limited areas</li> </ul>  |
| <b>Use setting</b>                    | <ul style="list-style-type: none"> <li>Home, remote-use, community centers, urgent care, mobile units, ER.</li> </ul>   | <ul style="list-style-type: none"> <li>Home, remote-use, community centers, urgent care, mobile units, ER.</li> </ul>   |
| <b>Product description</b>            | <ul style="list-style-type: none"> <li>Small, hand-held meter and disposable test strip</li> <li>Meter price &lt;\$10</li> <li>Disposable test price &lt;\$0.50</li> <li>Multiplexing capability for 2 to 4, including controls</li> <li>Ease of use: simple intuitive procedure with minimal training</li> <li>Ease of scale-up and manufacturing</li> <li>Battery operated meter</li> <li>Packaging: minimal, moisture proof and lightweight</li> <li>Product readily accessible through local distribution channels</li> <li>Shelf life – 3 months at RT and RH &lt; 50%               <ul style="list-style-type: none"> <li>Shelf life – transportation at ~ 60° C, for 24 hours, RH 60%</li> <li>No change in performance when exposed to direct sunlight for more than 1 hour</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>No meter required</li> <li>Disposable test price &lt; \$0.50</li> <li>Multiplexing 4 to 6+ including controls</li> <li>Ease of use: simple intuitive procedure with minimal training</li> <li>Results visualization and data transfer using smart phone</li> <li>Scalable production using locally sourced material</li> <li>No power requirement</li> <li>Packaging: moisture proof, lightweight and biodegradable.</li> <li>Available in multiple local languages, with pictorial instructions for non-literate users</li> <li>Shelf life – 24 months at RT at and RH &lt;80%               <ul style="list-style-type: none"> <li>Shelf life – transportation at ~ 60° C, for 24 hours, RH 80%</li> </ul> </li> </ul> |
| <b>Performance characteristics</b>    | <ul style="list-style-type: none"> <li>Sensitivity: &gt; 90% for influenza / &gt; 95% for biothreats</li> <li>Specificity: &gt; 95% for influenza / &gt; 98% for biothreats</li> <li>Sensitivity and specificity comparable to FDA approved methods, gold standard, and/or ability to detect targets within the diagnostic window of opportunity.</li> <li>Time to result: &lt; 30 mins</li> <li>Sample type(s): Easy to collect samples (capillary blood, saliva, nasal swabs)</li> <li>Prevention of sample contamination of the meter</li> <li>Sample processing: minimal</li> <li>Four or fewer steps from sample to answer</li> </ul>  | <ul style="list-style-type: none"> <li>Sensitivity: &gt;95% for the target analyte(s)</li> <li>Specificity: &gt;98%</li> <li>Sensitivity and specificity compared to FDA approved methods</li> <li>Time to result &lt; 10 mins</li> <li>Sample type(s): Easy to collect samples (finger-stick blood, urine, saliva, nasal swabs)</li> <li>Ability to process multiple specimen types</li> <li>Sample processing: none</li> <li>Two steps from sample to answer</li> <li>Performance unaffected by high temperatures (40° C) and relative humidity (&gt;85%) for 24 months</li> </ul>  |

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|-------------------------------|--|--|
|                               | <ul style="list-style-type: none"> <li>• Performance unaffected by high temperatures (40° C) and relative humidity (&gt;85%) for 12 months</li> <li>• No cold chain storage</li> </ul>                                       | <ul style="list-style-type: none"> <li>• No cold chain storage</li> </ul>  |
| <b>Safety</b>                 | <ul style="list-style-type: none"> <li>• Must not use toxic materials in test or in sample prep</li> <li>• Safe for handling in non-laboratory settings</li> <li>• Safely disposable and/or easily decontaminated</li> </ul> | <ul style="list-style-type: none"> <li>• Must not use toxic materials in test or in sample prep</li> <li>• Safe for handling in non-laboratory settings</li> <li>• Safely disposable and/or easily decontaminated</li> </ul> |
| <b>User experience</b>        | <ul style="list-style-type: none"> <li>• Simple, intuitive use</li> <li>• Clear instructions for valid use</li> <li>• Results are easily interpretable</li> </ul>  | <ul style="list-style-type: none"> <li>• Simple, intuitive use</li> <li>• Clear visual readout</li> <li>• Results are easily interpretable</li> </ul>  |
| <b>Regulatory and quality</b> | <ul style="list-style-type: none"> <li>• CE mark and/or FDA clearance/approval</li> <li>• CLIA-waived or CLIA-waivable</li> <li>• ISO 13485 certification and batch –to-batch consistency</li> </ul>                         | <ul style="list-style-type: none"> <li>• CE mark and FDA clearance/approval</li> <li>• CLIA-waived or CLIA-waivable</li> <li>• ISO 13485 certification and batch-to-batch consistency</li> </ul>                             |
| <b>Competitive landscape</b>  | <ul style="list-style-type: none"> <li>• Lateral flow devices</li> </ul>   | <ul style="list-style-type: none"> <li>• Lateral flow devices, POC molecular tests</li> </ul>  |