

# **Rapid Test Development FAQs:**

# Q1. What are Point-of-Use (POU) tests?

- POU tests provide rapid results on-site, bypassing the need for samples to be sent to a centralized laboratory for analysis.

#### Q2. What are the benefits of POU tests?

- Rapid results, improved outcomes, reduced lab dependency, and accessibility in remote settings.

# Q3. Which diseases can POU tests diagnose?

- A wide range of biomarkers related to health issues may be detected to identify various conditions or diseases.

# Q4. What technologies are used in POU tests?

- Lateral flow assays, electrochemical sensors, colorimetric and fluorescence methods, nucleic acid amplification, non-invasive, optical detection techniques etc.

## Q5. What factors matter in developing a POU test?

- The target analyte, intended user (skilled or unskilled), and the environment in which they are used.

## Q6. How do I choose the right platform?

- Decide based on the analyte, user requirements, and geographical constraints.

## Q7. What are the regulatory requirements?



- Depends on the test developed and varies by region (FDA, CE, CDSCO); includes validation, clinical trials, and compliance.

#### Q8. How accurate are POU tests?

- When properly developed, their accuracy should not be less than standard lab tests, while also providing a faster turnaround time.

# Q9. Can POU tests give quantitative results?

- Yes, some can provide precise readings if they are paired with an electronic reader (e.g., glucose meters), while most others are qualitative or semi-quantitative.

### Q10. What is the shelf life of POU tests?

- Depends on the technology and the developer. A well-developed test will be stable at room temperature for 1 to 3 years.

## Q11. What training is needed for POU tests?

- Minimal training for simple tests; advanced platforms may require brief training.

## Q12. Can POU tests work in extreme conditions?

- Yes, many are designed for use in rugged environments and can sustain varying high temperature (37 - 45°C) and humidity conditions.

## Q13. How can POU tests help underserved areas?

- By providing affordable, portable diagnostics for timely care in remote settings.

## Q14. What are the costs of implementing POU diagnostics?

- Includes device, test strips, maintenance, and training—often scalable for budgets.