Desired Platform Attributes: ASSURE

ASsay development for Superior Understanding of Response and Efficacy

Attribute	Minimal	Optimal[1]
Platform Characteristics	• Measures immune responses elicited by vaccines and/or infection to provide a comprehensive immune profile in complement to standard serology (e.g., cell-mediated, mucosal) • Sample-sparing technologies that reliably operate with reduced sample volumes. • Multiplexing measurement of biomarkers or other immune features • Moderate-throughput workflows with partial automation	• Maximizes utility by allowing multiple assay types to be run from a single sample • Modular and scalable multiplexing system rapidly reconfigurable across pathogens or vaccines • Establishment of non-traditional correlates of protection to clinically relevant endpoints • Fully automated, and high throughput, singular system • Analysis (AI/ML) of multiplexed outputs
Intended Use[2]	• Inform on immune status (including protection, waning, or lack of immunity) due to pathogen exposure or vaccination • Inform on vaccine efficacy (to complement serology • Applicable to pathogens relevant to public health emergency medical countermeasures enterprise (PHEMCE) priority threats.	• Support regulatory path and licensure for any vaccine (e.g. new Correlates of Protection)
Target Use Setting	• Central labs, research labs, clinical labs	• Adaptable to decentralized settings, point-of-collection labs, or near-patient testing environments
Sample collection and processing	• Simplified workflows that preserve sample stability and integrity, and cell viability and function. • Compatible with minimally invasive sample collection (capillary blood, dried blood spot, mucosal fluids) and minimal sample preparation (e.g., partially automated)	• Small volume sampling (e.g., < 50 µL) • Fully automated sample preparation
Sample type[3]	• Compatibility with at least one of the following: whole blood, serum,	• Compatibility with more than 1 sample types of the following: whole blood,

[1] Acceptable attributes are expected to be met in addition to the characteristics listed under desirable attributes.
[2] For pathogens relevant to BARDA's mission space with a special interest for influenza.
[3] Including human samples from biorepositories and commercial providers or samples from individuals enrolled in vaccine clinical trials or observational trials for BARDA-relevant pathogens.

	plasma, PBMC, fixed cells, dried blood spots, mucosal secretions (e.g., respiratory tract, salivary, lacrimal, or mammary gland, stool)	dried blood spots, serum, plasma, PBMC, mucosal secretions (e.g., respiratory tract, salivary, lacrimal, or mammary gland, stool)
Performance, throughput, and time to results	• Turnaround time relevant to the clinical use case (hours to one day). • Ability to scale to moderate number of patient samples	• Same day or <24-hour results • Ability to process thousands of samples per run or batch
Reagent Storage	• Reagents stable under standard lab conditions (e.g., –80°C, -20°C or 4°C)	• Long-term stable, lyophilized, or room-temperature reagents
Sensitivity and specificity	• Proof-of-concept reproducibility • Fit for purpose analytical sensitivity and specificity • Defined performance metrics consistent with commercial and regulatory considerations	• High sensitivity and specificity, low background, and minimal cross-reactivity
Regulatory readiness	• Early stage, research use only or investigational use • Requires some initial validation	• Comprehensive analytical and clinical validation to support FDA pre-submission engagement for a diagnostic, or to support LDT qualification • Robust validation plan, bridging strategy to regulatory assays, qualification for correlates, and alignment with regulatory expectations (e.g., ICH, FDA) for clinical adoption