

Desired Product Attributes (DPA): **Capillary whole blood sample collection and processing device**

Attribute	Essential	Optimal
Intended use	To enable minimally trained users to safely and reliably (self-) collect sufficient volumes of capillary blood for downstream diagnostic needs, while reducing the risk of exposure to a blood borne pathogen, to separate out plasma or serum using the same tool, and to deliver the plasma or serum sample to an (ideally FDA-cleared) antigen or molecular test device or cartridge, and to allow care providers to collect patient samples, and parents to collect samples from children.	To enable minimally trained users to safely and reliably (self-) collect sufficient volumes of capillary blood for downstream diagnostic needs, while reducing the risk of exposure to a blood borne pathogen, to separate out plasma or serum using the same tool and provide complete inactivation of pathogens, and to deliver the resulting sample to an FDA-cleared antigen or molecular test device or cartridge, and to allow care providers to collect patient samples, and parents to collect samples from children.
Use setting	<ul style="list-style-type: none"> Home, clinics, community centers, urgent care, mobile settings 	<ul style="list-style-type: none"> Threshold criteria settings plus remote-use, and resource limited environments, high containment treatment units (increase HCW safety)
Product description - lancet	<ul style="list-style-type: none"> Integrated safety lancet, single button operation Auto-retracting, single-use Microneedles instead of lancet acceptable 	<ul style="list-style-type: none"> Integrated safety lancet with adjustable depth, single button operation A hidden needle/blade, auto-retracting, single use Microneedles instead of lancet acceptable
Product description - biohazard / safety	<ul style="list-style-type: none"> Blood containment – fully enclosed blood path, no exposure to blood drops and any separated blood components. No user contact with blood while handling the device or the sample or while disposing of any of the device components. Blood processing – solution must incorporate a blood separation step to provide serum or plasma, depending on the chosen test. Post use safety – minimal risk of smear/spill/aerosol Sample type – capillary whole blood with serum or plasma separation, if needed 	<ul style="list-style-type: none"> Blood containment – fully enclosed blood path, no exposure to blood drops and any separated blood components. No user contact with blood while handling the device or the sample or while disposing of any of the device components. Limit exposure to blood from the collection site after sample collection. Blood processing – solution must incorporate a blood separation step to provide serum and/or plasma, depending on the chosen test. Blood treatment should result in complete inactivation of bacterial, viral, and fungal pathogens while retaining compatibility with the chosen test. Post use safety – self-sealing, leak proof, pierce proof collection device, remnant blood components rendered safe Sample type – capillary whole blood with serum or plasma separation
Product description - packaging design	<ul style="list-style-type: none"> Packaging – basic box or tube with secondary barrier pouch Visual blood volume indicator Design – suitable for use on adults and pediatric individuals (separate devices or all-in-one solutions for these patient populations are acceptable, based on the target populations listed above) 	<ul style="list-style-type: none"> Packaging – basic box or tube with secondary barrier pouch Auto volume collection, altitude independent. Design – ergonomic for impaired dexterity; suitable for use on adults and pediatric individuals (separate devices or all-in-one solutions for these patient populations are acceptable, based on the target populations listed above)
Product description - COGs (Cost of Goods) and function	<ul style="list-style-type: none"> Unit cost <\$1.00 at scale of 100,000 units Shelf life – 3 months at room temperature Ease of use: simple, intuitive procedure with minimal training Scalable production using locally sourced material All workflow components are integrated 	<ul style="list-style-type: none"> Unit cost < \$0.10 at scale of 100,000 units Shelf life – 24 months at room temperature and <60% relative humidity Ease of use: simple, intuitive procedure with minimal training Scalable production using locally sourced material All workflow components are integrated.
Performance characteristics	<ul style="list-style-type: none"> Sample volume (whole blood) – 500 µl or less Sample volume variability – ± 25% Sample integrity – ≤ 10% hemolysis Pain level – low 	<ul style="list-style-type: none"> Sample volume (whole blood) – 100 µl or less Sample volume variability – ± 10% Sample integrity – ≤ 2% hemolysis Pain level – ultra-low, soft touch lancet
Safety	<ul style="list-style-type: none"> Sharps disposal – included in packaging Contamination risk – very low with design safeguards Biohazard marking – printed instructions 	<ul style="list-style-type: none"> Sharps disposal – included in packaging, tamper proof Contamination risk – near zero with design safeguards, no open surfaces, no open skin wounds, or residual liquid with integrated bandage/wound care Biohazard marking – printed instructions, color coded, universal biohazard symbol
Operator experience	<ul style="list-style-type: none"> Simple, intuitive use Clear instructions for valid use, text with images for self-collection and administration to pediatric individuals 	<ul style="list-style-type: none"> Simple, intuitive use Multilingual, pictorial and low-literacy friendly, for self-collection and administration to pediatric individuals
Regulatory and quality goals for final product	<ul style="list-style-type: none"> FDA clearance/approval CLIA-waivable ISO 13485 certification and batch to batch consistency 	<ul style="list-style-type: none"> FDA clearance/approval (POC + OTC/at-home) CLIA-waived ISO 13485 certification and batch to batch consistency