Statement of Work (SOW)

1. INTRODUCTION:

The Winchester Engineering and Analytical Center (WEAC) has a critical need for Mask Synthetic Blood Penetration Tester to be used in mission critical regulatory analyses and research & development projects for FDA. A Mask Synthetic Blood Penetration Tester can be used to evaluate the penetration and splash resistance property of medical face masks by the impact of a small, fixed volume of a high-velocity stream of synthetic blood or other liquid body fluids. This machine will help to determine the synthetic blood penetration of materials or certain materials used in medical face masks under different test pressures. Mask Blood Penetration tester will be required for evaluating protective garments and materials used for several critical projects at WEAC including but not limited to, analytical test protocols development and optimization for post-regulatory mask testing using ASTM 1862 test methodology and research and development activities pertaining to COVID-19 Research Project recently funded for evaluating protective fabric against penetration of respiratory fluids. To complete these mission critical regulatory and research projects successfully, we will need a Mask Synthetic Blood Penetration Tester.

Without this equipment, the FDA will not benefit from the capability to increase, and rapid and accurate analytical capability brought with this equipment for testing regulatory samples and research and development efforts at WEAC.

2. BACKGROUND:

A Mask Synthetic Blood Penetration Tester is necessary for evaluating the safety of face masks for penetration of blood or other body fluids in support of regulatory testing program of FDA. Mask Synthetic Blood Penetration Tester will readily support regulatory analysis of engineering samples done by WEAC. In addition, COVID-19 research project for protective garment testing against respiratory fluids will be highly benefited through this equipment having available in house as it will further help advance the research and development activities that support the FDA's public health mission at WEAC.

3. SCOPE:

Winchester Engineering and Analytical Center (WEAC) requires one Mask Synthetic Blood Penetration Tester to support the development of analytical test protocol for mask testing for assessing the safety of these PPE, regulatory analysis of engineering samples as well as research and development activities for currently ongoing COVID-19 research project for evaluating the effectiveness of Protective garment materials against respiratory droplets containing virus-like particles.

4. REQUIREMENTS:

The contractor shall provide the minimum technical requirements for **a** Mask Synthetic Blood Penetration Tester as follows:

- Shall have ability to conduct the tests of standards for at least ASTM 1862 and ASTM F2100
- Shall be able to generate different pressure controls to deliver at least 2ml of liquid in volume.

- Instrument shall use a gas source that can provide (ranging from 19-21Kpa) pressure to continuously pressurize the sample without being limited by the space of the test site
- Fabric Specimen shall be able to mount at a distance of at least 300mm between the emission point.
- Shall be able to simulate various pressures (10.6kPA, 16kPa and 21.3kPa) and velocities (450cm/S, 550cm/2, 635cm/s)
- Liquid velocity sprayed on the specimen shall be accurate and repeatable
- Shall have a plate/reservoir to contain the liquid being tested from splashing around
- System shall have a digital display with touch screen controller with settable observation timer with accuracy ± second, that is convenient to use during entire testing process
- Instrument shall have a pressure gauge to display pressure which can be adjusted
- Pressurized medium used shall be compressed air.
- Electrical Utility requirement shall match the following specification: 120VAC, 10Amp, 1 phase, 50/60Hz
- Unit shall be compact and shall be able to install in a small bench space with approximate dimension of 2 X1 X 1 meters (L x W x H).
- Manual/instructional documentation for operation shall be included
- The components and/or equipment shall be a newly manufactured, not used, and refurbished, or previously used for demonstration.
- The entire system shall be warranted for parts and labor for a minimum of 12 months from date of formal government acceptance. The warranty shall include unlimited telephone/e-mail support for questions regarding operation.

5. DELIVERABLES:

Description	Quantity	Delivery Date
Mask Synthetic Blood Penetration Tester	1	Within 1 month of contract award date
Shipping costs	1	

6. DELIVERY POINT:

ORA/Winchester Engineering and Analytical Center
Attn: Jayaleka J. Amarasinghe
109 Holton St.
Winchester, MA, 01890

7. PLACE OF PERFORMANCE:

U.S. FDA Winchester Engineering and Analytical Center
109 Holton Street, Winchester, MA 01890

8. PERIOD OF PERFORMANCE

The Period of Performance begins the date of contract award execution and continues for one year from the date of formal government acceptance.

9. **Quotation Instructions:**

All quotes are due by e-mail to Nina Montgomery, Nina.Montgomery@fda.hhs.gov on or before September 22, 2023 at 10:00 am (Eastern Standard Time).