INFORMATION PAPER

16 March 2020

SUBJECT: Guidance for vendor inquiries regarding USAMRDC COVID-19 Clinical Diagnostics for operational or medical treatment facilities

1. PURPOSE: To provide information and guidance to vendors seeking to partner with the U.S. Army Medical Research and Development Command (USAMRDC) for the development and fielding of clinical diagnostic assays for COVID-19 for operational or medical treatment facilities.

2. The USAMRDC recognizes that unique and innovative products or ideas that have been developed outside the government can help us to accomplish our missions. The New Products and Ideas (NPI) web tool, located at https://mrdc-npi.amedd.army.mil/, provides vendors an opportunity to showcase their products and ideas online and gives us visibility of these new product idea submissions. Our subject matter experts will assess these submissions, evaluate applicability to mission requirements, and provide a disposition to you within 10 business days. No funding is associated with NPI, but it offers a platform for constructive feedback.

3. For vendors seeking to partner with the USAMRDC for the COVID-19 clinical diagnostics the three areas the USAMRDC is seeking diagnostics products are:

a. High-throughput screening/detection/confirmatory (e.g., >400 assays/8 hours).

b. Moderate-throughput screening/detection/confirmatory (e.g., >60 assays/8 hours).

c. Low-complexity point of care (e.g., 1 assay/5-15 minutes).

4. The intent of introduction of these screening platforms and/or assays within a clinical or operational health system is to ensure this action improves patient-related health outcomes and avoids misclassification of the result(s). This is done through assessment of the performance, verification that the platform/assay is performing as the manufacturer intended, and demonstrations that the platform and/or assay meets the needs of the user. As part of our assessment we evaluate the following:

a. Assay Operational Characteristics:

(1) Size and requirements for electricity, water, and waste disposal
(2) Training requirements and ease of use
(3) Specimen matrix utility (plasma, dried blood spot, serum, respiratory specimens etc.)
(4) Use in high/low temperature settings, high humidity

(5) Ancillary equipment required, but not provided by manufacturer
(6) Reagent storage requirements, refrigeration, reagent shelf life

b. Assay Analytical Performance:

(1) Accuracy
(2) Precision/Reproducibility
(3) Sensitivity; Specificity
(4) Limit of Detection
(5) Limit of Quantification
(6) Reportable Range
(7) Linearity
(8) Analytical Measurable Range
(9) Clinical Reportable Range
(10) Methods Comparison – if replacing a platform or assay
(11) Cross contamination – if applicable

5. If you have a product that meets one of the areas in paragraph three and can provide information specified in paragraph four, has your company started and/or completed one of the following U.S. Food and Drug Administration (FDA) processes: Section 513(g); Q-Submission; Section 510(k); Pre-Marketing Approval; or Accelerated Emergency Use Authorization for COVID-19 diagnostics?

6. If you have completed one of FDA process listed in paragraph five, then please submit through the NPI website and our subject matter experts will assess your submission and provide a disposition back to you within 10 working days.