Updated 11/17/2025		
Question #	**Question**	**Response**
1	The solicitation states: "The mNGS-based assay must utilize existing sequencing reagents and either an existing sequencing platform or a platform in development that is TRL 5 or greater." We understand this to mean that only the sequencing platform and reagents must be TRL 5 or greater. Is this correct? If other components of the system are lower TRLs (i.e., TRL 4) does the offeror remain eligible?	This is correct; only the sequencing platform and sequencing reagents need to be TRL5, other components can be lower. However, keep in mind, feasibility data and other information asked for in the RPP should be included if you choose to submit.
2	2.8 It is anticipated that anything delivered under this proposed effort would be delivered to the Government with unlimited data rights as defined in the RRPV Base Agreement unless otherwise specified in Attachment 1, Abstract, and agreed to by the Government. Does this mean we will lose all our IP rights on the technology developed under an awarded grant? What about background IP that will be brought in? Or will this be specified under the award agreement?	**From the RRPV Base Agreement:** **9.1.1** Ownership. The Project Awardee shall retain ownership of each Subject Invention throughout the world, unless (i) Project Awardee shall have notified the OTAO, through the CMF, that Project Awardee does not intend to retain ownership of such Subject Invention in accordance with of this Article, (ii) Project Awardee fails to disclose such Subject Invention to the OTAO, through the CMF, in accordance with terms defined herein, or (iii) Project Awardee fails to file a patent application for such Subject Invention in accordance with the terms of this Agreement, in which case ownership shall vest with the Government. **9.1.2** With respect to any Subject Invention made under a Project Award in which the Project Awardee retains title, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. For clarity, this license does not include the right to use or allow others to use the Subject Invention for commercial purposes.

3	I read all entities are eligible for funding, and thus a US partner with the consortium is not required. Have any grants in the past been awarded to non-US consortia? Or is US partnership preferential and thus in reality, required after all?	Submission and award is open to all RRPV members, regardless of location, unless specifically excluded in the RPP. Selection decisions will be made based on the evaluation criteria listed in the RPP.
4	Will BSL-3 and above or high-containment facilities be required as a part of the manufacturing for this project?	If your proposal includes pathogens that might require BSL-3 or higher, relevant facilities will need to be described. If a proposer has difficulty finding these types of facilities, the US government may be able to assist in finding facilities that are compatible with a proposer's needs. However, please not that BARDA is not requesting a clearance of a diagnostic that has all possible human pathogens from any sample type as the intended use. The goal is to have an FDA-cleared metagenomic next-generation sequencing diagnostic capability for known viral and bacterial pathogens that can be rapidly adapted to novel or emerging threats and multiple clinical sample types.
5	When the proposals are submitted for phase 1, would the prime, along with their subcontractors, submit a single, consolidated document?	Yes, responses should be a comprehensive solution and include any necessary team members proposed by the prime organization
6	Is there a proposed timeline for when proposals will be invited to phase 2?	The anticipated timeline is January 2026, subject to change.
7	Do you need to be an accepted member of the consortium to get a portal account? Do I need to wait to be accepted to make an account	Yes, your application must be approved prior to requesting portal access

8	Is the submission made via RRPV website or BDR portal?	Submissions must be made via the RRPV BDR Portal
9	Pathogenic fungi?	Out of scope Fungal targets may be included as part of a cost-share where the offeror funds the fungal portion, but the focus of the proposal is for bacteria and viral pathogens.
10	If we are focused on Fungal Pathogens, would this still be accepted? (not specifically mentioned)	Out of scope Fungal targets may be included as part of a cost-share where the offeror funds the fungal portion, but the focus of the proposal is for bacteria and viral pathogens.
11	What number of samples is considered medium-to-high throughput?	For the offeror to define based on their system specifications.
12	If the platform technology works on LFA test against clinical samples but have not been used toward mNGS for enrichment, can we still apply?	Unable to provide a response without additional clarification of question.
13	Since the main goal of this solicitation is for an IVD assay, can the offer be using a new sequencing platform that has yet to obtain IVD status?	"The mNGS-based assay must utilize existing sequencing reagents and either an existing sequencing platform or a platform in development that is TRL 5 or greater."
14	Where can I find the list of pathogens that are of interest to BARDA?	Biothreat agents of interest include (listed alphabetically): *Bacillus anthracis* (anthrax), botulinum neurotoxin (botulism), *Burkholderia mallei* (glanders) and *Burkholderia pseudomallei* (melioidosis), filoviruses (Ebola disease and Marburg disease), *Francisella tularensis* (tularemia), *Rickettsia prowazekii* (epidemic typhus), Variola virus (smallpox; orthopox genus virus assays acceptable), and *Yersinia pestis* (plague). BARDA is also interested in diagnostics for pandemic influenza and bacterial pathogens that identify the pathogen(s) and their resistance or susceptibility to relevant antibiotics.

15	Can you please clarify cost sharing - is it required or is not?	Cost sharing is encouraged, but not required.
16	Does the scope require submission of a 510k or De Novo package to the FDA by the end of the 36 month PoP or is just a strategy toward clearance required?	The scope requires 510(K) or de novo submission/clearance and the PoP is negotiable
17	When are awards expected to be made?	The expected award date is Q2 of CY26, subject to change.
18	Did I hear it correctly that the proposed assay should already be FDA approved or accepted? Or just that this should be the outcome after 36 months?	The desired outcome is 510(K) or de novo submission/clearance within 36 months.
19	How is the solicitation RRPV RPP-26-09 related to the BARDA solicitation BAA-23-100-SOL-00004 and specifically AOI 7.4.1 and will they cause any conflict or overlap in any way ?	The RRPV RPP-26-09 is similar to the BARDA solicitation BAA-23-100-SOL-00004, however, there is a difference in the minimum TRL required. Offerors can submit to both or either solicitation if their submissions are sufficiently different. If the submissions are the same, then only one award may be applicable.
20	Would a targeted metagenomic assay for agnostic pathogen detection be in scope of this solicitation? (I.e. A universal approach that is not whole genome sequencing)	If the chemistry of the assay has to be altered to add additional pathogen targets, then it would be out of scope.
21	Can BARDA please clarity what they mean by "must utilize existing sequencing reagents"? For example, does this mean off-the-shelf reagents or would established reagents for a platform in development be acceptable?	Established reagents for a platform in development would be acceptable if the platform was TLR 5 or higher.

22	"Section 1.3 of the RPP states, "The purpose of this RPP is to support the advanced development, clinical evaluation, and FDA clearance of mNGS-based diagnostic assays for viral and bacterial pathogen detection." Slide 20 of the Proposers Day conference slides states, "The FDA cleared mNGS test for known pathogens". Slide 25 of the Proposers Day conference slides states, "Strategy to achieve FDA 510(k) Clearance/de novo Approval for targeted pathogens". Can BARDA confirm that the RPP requirements expected to be met during the period of performance include BOTH, 1.) the generation of all analytical and clinical performance data, AND 2.) submission of a final FDA 510(k) Clearance or de novo Approval package/application to the FDA, NOT just a "strategy" to achieve FDA 510(k) Clearance/de novo Approval?	The final milestone will be achieving 510(k) clearance/de novo approval.
23	"Section 1.3 of the RPP states, "The purpose of this RPP is to support the advanced development, clinical evaluation, and FDA clearance of mNGS-based diagnostic assays for viral and bacterial pathogen detection." Slide 20 of the Proposers Day conference slides states, "The FDA cleared mNGS test for known pathogens". Slide 25 of the Proposers Day conference slides states, "Strategy to achieve FDA 510(k) Clearance/de novo Approval for targeted pathogens". Can BARDA confirm that the RPP requirements for the generation of analytical and clinical performance data must include data for the detection of at least one viral AND at least one bacterial pathogen?	Abstract submissions must include feasibility data demonstrating that at least one DNA virus, one RNA virus and one bacterial pathogen nucleic acids can be adequately extracted and analyzed from at least one (1) specimen type at a clinically-relevant concentration.
23	How does BARDA define medium-to-high throughput, per the RPP?	For the offeror to define based on their system specifications.

24	The RPP anticipates unlimited data rights unless otherwise specified/approved. For Stage 1, should Offerors explicitly list any proposed restricted rights in the Abstract's Data Rights Assertions table, even if details could be further negotiated at Stage 2?	Yes, any proposed restricted rights should be identified within the Abstract.
25	The Quad Chart calls for "major goals/milestones by Project Year; Proposed Funding (Rough Order of Magnitude estimate)." Please confirm whether the Government intends the Proposed Funding (ROM) to be presented by Project Year on the Quad Chart, paired to the year-specific milestones, with a project-total ROM also shown? If per-year ROM is not desired, we will provide a single project-total ROM on the Quad Chart.	Offerors should provide an overall rough order of magnitude (ROM) for the work and any pertinent assumptions.
26	The Abstract template includes a "Budget Estimation" section. Should the Abstract provide ROM by Project Year, or may Offerors provide a bottom-line ROM plus key assumptions?	Offerors should provide an overall rough order of magnitude (ROM) for the work and any pertinent assumptions.
27	For the bacterial component of the RPP, does 16S metagenomics suffice, or is there an expectation that gyrB/rpoB or antibiotic resistance genes are also included?	If mNGS of the 16S is sufficient to identify the bacterium and the chemistry does not change when adding a new pathogen, then that is acceptable. It is also preferred to include antibiotic resistance genes that are associated with the bacteria that are detected and reported.