Updated 6/13/2025

Question #	Question	Response
1	Will a list of potential BSL-3/BSL-4 laboratories be provided to facilitate collaboration for this opportunity, or are applicants expected to identify and engage suitable partners independently?	BARDA can work with you to fill in any gaps in your product development plan during negotiations and can point you to contract research organizations (CROs) that can assist with materials, animal studies, and facilities for working with BSL-3/4 pathogens. Additionally, the RRPV hosts the Collaboration Database on the Members Only Website where members can view the capabilities of other organizations for the purpose of establishing collaborative partnerships. Offerors can also send a one-pager capability statement to rrpv@ati.org, and it will be uploaded to the Teaming page on the Members Only Website specifically for the DxR2 RPP.
2	Please provide more information on the expected or desired use cases for these tests.	BARDA's preferred requirement is for products that are point-of-care and remote-use capable during a PHE scenario. However, well-justified use cases that call for clinical laboratory instruments and testing, including high volume testing and similar options, may be acceptable. Products that more closely align with BARDA's goals will be considered more competitive.
3	Will the tests be for screening applications or for symptomatic/"high risk of exposure" patients?	Please ensure your proposal includes clear intended use statements and/or concepts of operation. Specific uses/applications may vary depending on the clinical and operational need to address and respond to an emergency, which could be intentional or naturally occurring. In short, both may apply if well justified, keeping in mind that products are IVDs and must use results to inform patient treatment and not be used for surveillance, e.g., environmental testing, animal testing, or the like.
4	Among the many sample types mentioned in CDC guidance for biothreat Dx, which are of most interest to BARDA for this solicitation? Are any sample types acceptable, as long as they are mentioned in CDC guidance?	There is no general preference for sample type. Choice of proposed sample should be clinically justified for each pathogen. If Standard of Care (SOC) (or proposed improvements over SOC) necessitate the use of multiple sample types, then your product would be more competitive if it is able to address those various sample types.

5	Will BSL-3 testing and material be provided by the government for this effort? How should this be handled in proposals?	When building out the statement of work and budget, you may come across some difficult development tasks to address if you've not previously worked in the biothreat test space. For example, you may require a critical reagent or test specimen materials, or you may not be able to scope out the regulatory path for clinical validation because there is no FDA guidance. One option is that you leave those tasks in the SOW as TBD. If your product and proposal are selected, BARDA will work with you to fill in any gaps in your product development plan during negotiations or project execution, based on BARDA needs and proposed solution. The program team has provided this level of support in the past and we have provided access to government furnished material (GFM), e.g., reagents or test specimens, or facilitated access to CROs that can assist with materials, animal studies, logistics, and facilities required to work with BSL-3 and BSL-4 pathogens.
6	Do subcontractors also need to be RRPV member?	No, subcontractors do not have to be RRPV members. However, we encourage them to apply for membership.
7	What is the TRL requirement?	Ideally, BARDA would prefer mature platforms. These would include platforms that are commercially available and have been approved through the appropriate FDA clearance. The assay for the biothreat test can be at a lower TRL, including starting from scratch since there is no requirement for feasibility data for the biothreat test target. The key factor for the more competitive proposals is that your product/platform is mature and your manufacturing capability is mature, as described in your proposal. Preferred product capabilities are described in the solicitation in Section 2.5.
8	Description says "maintain domestic test manufacturing facilities" - are companies with development and manufacturing capabilities OUS allowed to submit proposals? Would transfer of manufacturing capacity to the US be in scope?	Yes, you may submit if your manufacturing occurs outside of the US (OUS). Domestic test manufacturing is a preferred capability, and not an absolute requirement, at this time. Domestic production will make your proposal more competitive. OUS manufacturing must occur in a nation that is considered 'friendly' and is in good standing. Nations of concern are subject to change if needed to align to updates in USG priorities, policies, or laws. Please note that onshoring of manufacturing will not be funded as part of the base program. The base program remains focused on rapid biothreat assay development, regulatory clearance, and a manufacturing capacity study.

9	Is a single biomarker target acceptable or multiplexed panel of biomarkers expected?	It is acceptable to identify multiple markers to target one specific pathogen for the purpose of increasing sensitivity and specificity. Multiplex 'panel' products focusing on multiple biothreats in one test are also acceptable and may be more competitive depending on the intended use. However, if funding is not available for an expanded panel and the likely complex clinical studies, the product panel would need to be flexible to scale down to what is in scope. Another option would be cost sharing. See question 14.
10	Some of the pathogens highlighted within the biothreat list require CAT 4 laboratories. Is BARDA able to help with access to some facilities or is it up to the applicant to prepare that in the plan?	If you do not have a CRO selected already, BARDA can work with you during negotiations to begin to identify those organizations. Please refer to question 5 above for more details.
11	How strict is the 30 min sample-to-answer requirement? For example, can the assay be <1 hr?	Similar to other aspects of the RPP, this is not an absolute requirement. A product that meets the 30-minute sample-to-answer criterion will be more competitive than one that does not. However, it does not preclude one that does not, especially if that proposal is stronger in other criteria.
12	Should BSL-3/4 testing if requested through GFM be included in the budget estimate?	See question 5 above.
13	How should the term 'previously cleared commercially available' be interpreted? Specifically, would an IVD that was CE-marked and legally marketed in the past—but is no longer available due to commercial decisions—still qualify under this definition?	Yes, this is acceptable. Regulatory clearance can occur within or without the preferred capabilities and still be considered. The closer a proposal aligns to the preferred capabilities, the more competitive it is.
14	How many assays should be developed and priced: "2. Address biothreat test development of glanders, botulism toxin (BoNT), tularemia, typhus, smallpox, OR plague." Can you provide guidance?	Specifically, the proposal should address development of one assay/panel. Multiplexing may be a strength. However, realize that funding may not be available to address the full multiplexed panel. See question 9.
15	Will enabling technology development be competitive in this RPP? e.g. an on-demand, point of use reagent production platform	It depends. Please refer to the basic requirements of the RPP where the final product must be an in vitro diagnostic device that detects biothreats. Companies with enabling technologies or products that do not meet these requirements alone could partner to incorporate these into an IVD product/platform. For companies interested in partnering, the RRPV hosts the Collaboration Database on the Members Only Website where members can view the capabilities of other organizations for the purpose of establishing collaborative partnerships. Offerors can also send a one-pager

		capability statement to rrpv@ati.org, and it will be uploaded to the Teaming page on the Members Only Website specifically for the DxR2 RPP.
16	Is there a cap to the requested amount of money per proposal? or would $10 million per award be expected?	While there is no specified cap, please note that funds are limited and intended to be used to make multiple awards. BARDA requests that proposers cost their proposals out accurately. Budgets should realistically reflect resources needed to accomplish your proposed scope of work and achieve stated metrics for success.
17	Is single target or multi-target panel preferred?	See questions 9 and 14 above.
18	Is there a COGs requirement for the proposed biothreat product(s)?	No, there is not a COGs requirement. However, the lower the cost the more competitive your proposal could potentially be. Proposals should provide COGs at multiple scales, e.g. 10,000; 1,000,000; 10,000,000
19	Is there a desired range for product ASP?	No, there is not a ASP requirement. However, the lower the ASP the more competitive your proposal could potentially be. Proposed products should be competitively priced with existing commercial products. For remote/OTC-capable molecular products, BARDA's preference is to fund lower-cost platforms that would be price-competitive for home-use (e.g., <$20/test).
20	Is the period of performance limited to 3 years?	This is not a firm requirement. This is an estimate based upon what is seen for similar projects. However, please keep in mind that a goal of this program is to demonstrate rapid development and manufacture of biothreat tests.
21	Do we need to quantify the pathogen levels? Or does qualitative tests like lateral flow devices qualify?	Qualitative tests are acceptable.
22	Can a partnership or consortium of two entities jointly apply, or is the application restricted to a single legal entity?	A team can work together to submit a comprehensive proposal. Typically, one organization will submit the proposal as the awardee, and the other will be considered a subawardee or team member of the awardee. A Project Award will be issued to only one organization.
23	Would proposing target disease agents beyond/other than/in addition to those in the list provided be viewed as favorable?	While you may allude to this possibility in your proposal, this capability is not within the parameters of the RPP. Your proposal should focus on at least one of the biothreat pathogens that are listed.

24	Will this be a 510K approval? Or will there be a way to expedite approval with BARDA support?	Yes, the product must adhere to a FDA 510k approval/De Novo process. There is no possible expedited process available.
25	Is there an opportunity for a guaranteed procurement commitment from the USG following FDA approval, or would purchases be made on an as-needed basis?	BARDA cannot make any guarantees regarding this.
26	Our company submitted a proposal to the DXR2 issued in 2024 and after numerous rounds of negotiation was eventually put into the basket in April of 2025. Will previous basket proposals such as this one be considered in the 2025 RRPV solicitation?	Only proposals submitted in response to RRPV-25-06-DxR2 will be considered.
27	Is it possible to re-submit a modified basket proposal, that is changed to address reasons for the proposal being put into the "basket" with the addition of cost sharing?	Yes it is possible. However, proposals submitted should best address the requirements identified in RRPV-25-06-DxR2.
28	Is it acceptable to submit 2 different proposals that are substantially different?	Yes
29	The Technical Proposal Template requires resumes or CVs for key personnel, limited to three pages each. Is this requirement limited to the technical team, or should we also include resumes for key personnel from other departments, such as regulatory, manufacturing, clinical, or commercial teams?	The key personnel section of the technical proposal requires resumes for management and technical personnel. The principal investigator should also be identified.
30	The Technical Approach section requires subsections on Background and Technical Maturity, including a commercialization strategy. Given that this is a government-funded development project with no guaranteed procurement, how critical are these subsections in the evaluation process? Are reviewers prioritizing technical feasibility and regulatory readiness over background context or commercialization plans?	Technical maturity, proposed intended use, clinical utility, and regulatory readiness are very important. Company background and commercialization strategy are helpful to tell your story but are not critical since it is not expected that proposers will have backgrounds/experience with biothreat test development and commercialization.
31	Along the same line, will the government provide the product requirements during	In addition to product requirements listed in Section 4.2 of the solicitation, proposals should include well-justified intended uses / concepts of operation, including target product profiles and key performance metrics (e.g., LoD,

	negotiations, or are the "market requirements" for the offeror to identify?	clinical sensitivity). If selected, USG will work with the offeror to finalize product requirements and metrics of success during negotiations.
32	"4.1. Introduction For scheduling and pricing purposes, Offerors should assume that some elements of the Base Period may occur concurrently to support cost and schedule savings; however, an agreement modification will be required to begin an option period." (Page 9, Section 4.1 (Introduction)) • Is BARDA anticipating offerors to address the cost and schedule savings in their basic phase technical and cost proposal? Or is this notifying offerors BARDA anticipates the savings, but will address those in the proposal for the option, if applicable?	Offerors are required only to address (SOW, budget) for the base period at this time.
33	Could BARDA please clarify the anticipated timing and conditions under which Option I (Maintain Warm-Base Surge Capacity) might be exercised? Will it likely be during the Base Period or after? (Page 9, Section 4.2 (Overview))	Options may be considered after the offeror achieves success on biothreat test development and subsequent FDA clearance.
34	Could BARDA please clarify the anticipated timing and conditions under which Option II (Manufacturing Capacity Modifications) might be exercised? (Page 10, Section 4.2 (Overview))	Options may be considered after the offeror achieves success on biothreat test development and subsequent FDA clearance.
35	Could BARDA/ATI please provide details on what compliance screening elements most frequently cause proposals to be eliminated or returned for additional clarification? (Page 12, Section 5.1 (Compliance Screening))	The compliance screening is performed to ensure that proposals comply with the prescribed templates and that key information (total cost, period of performance, teaming, etc.) is consistent throughout the technical proposal, cost proposal, and BDR submission forms. Proposals that do not contain all of the required elements in the RPP or contain inconsistent details across documents are returned to the offeror for revision.
36	Given that most of the biological targets are BSL-3, should bidders have a partner with BSL-3 capabilities?	See question 5 and 10 above.
37	Should the assay proposed be focused on naturally occurring or deliberate forms of the threat?	Both.

38	Each of the individual threats of interest have several different routes of exposure (inhalation, ingestion, bites, cutaneous, wounds). Is there a particular route of exposure that BARDA is most interested in that the assay should be developed for?	There is no general preference, at this time. Proposals should focus on clinically relevant and/or most likely routes of exposure.
39	Is there a preference for the sample type that the assay can test from (nasal swabs, blood, body scabs, pustles, etc.)?	Sample type must be clinically relevant. If there are multiple sample types for a specific pathogen, technologies that can address multiple sample types will be viewed as more competitive. See question 4 above.
40	Would assays for human for exposure assessment (e.g., nasal swabs for aerosol exposure) meet BARDA requirements as a "diagnostic" for the threats on the list that are aerosol risks? Is validating nasal swabs as a diagnostic collection method within scope of the BARDA RRPV DxR2 RPP?	Validating a standalone sample collection method would not be in-scope of the RPP, which seeks to fund in vitro diagnostics that will inform patient care. See question 15 above.
41	Although there is some literature on antigen and DNA levels in the blood and other relevant samples from acutely ill patients for some of the pathogens of interest, there is not a consensus on what is clinically actionable for all pathogens and sample types. Can BARDA provide guidance on expectations around sensitivity or limit of detection requirements for each biothreat agent and sample type, or provide appropriate references or publications?	As part of the proposal, offerors should provide well-justified intended use statements and proposed target product profiles. BARDA encourages discussion of gaps in clinical knowledge/limitations of SOC, particularly in the context of how your proposed product fills a gap. Additionally, offerors should provide their references and data detailing clinical relevance. If selected, BARDA will work with offerors during negotiations to address and finalize analytical metrics of success.
42	Given the short timeframe between the original pre-notice of the solicitation and the release of the RFP, as well as the short time between when answers to questions will be provided and the solicitation due date, can a 3-week extension be provided to the due date? We want to ensure that we can provide the most responsive solution to meet the government's needs.	Amendment 1 was released June 23, 2025 and extends the submission due date to August 4, 2025 at 1PM ET.
43	Are offerors allowed to submit more than one proposal under this RPP?	Yes.

44	Are there specific BARDA Target Product Profiles (TPPs) for point-of-care molecular diagnostics related to this call beyond what is published on https://medicalcountermeasures.gov/barda/tpp? (We've reviewed the current TPPs but want to confirm if there are pathogen-specific or use-case-specific guidance documents aligned to DxR2)	Nothing further except what is mentioned in Section 4.2.
45	Is species-level detection sufficient, or is strain-specific detection required?	At this time, species-level detection is sufficient.
46	Many commercially available isolates are dated — does BARDA have access to more recent samples to support inclusivity assessments?	Possibly. If specific needs for additional isolates are known, please include in the proposal. Details would be determined during negotiations of selected proposals. See question 5 above.
47	Typhus: Should the assay target a specific species (e.g., R. prowazekii) or include coverage of R. typhi and Orientia tsutsugamushi as well?	R. prowazekii
48	Botulism toxin: Can we target the gene responsible for toxin production instead of the toxin itself?	The toxin is preferred; however, the assay must have ultra-high sensitivity to be clinically relevant.
49	Smallpox: Can Vaccinia virus be used as a surrogate in place of Variola virus for both development and validation?	Yes.
50	Can genomic DNA or synthetic material be used as internal and external controls during V&V and QC specification setting?	Yes.
51	Can BARDA advise on specific requirements for clinical trials, or should we direct all questions to FDA?	These will be addressed with FDA. During awarded contracts, BARDA's regulatory team will provide regulatory support.
51 a	How many positive and negative samples are required per pathogen?	This will be addressed with FDA, using available guidance or through formal pre-submissions.
51 b	Can contrived specimens be used in assay validation? If so, what proportion of positive samples can be contrived?	This will be addressed with FDA, using available guidance or through formal pre-submissions.
52	For rare or eradicated pathogens (e.g., smallpox), how can we obtain positive clinical samples? Does BARDA have access to biobanked pathogens, or will they assist in sourcing isolates or samples?	BARDA will assist in sourcing isolates and samples. See questions 5 and 46 above.

52 a	Can samples be sourced from outside of the U.S.?	This will be addressed with FDA, using available guidance or through formal pre-submissions.
53	Are there specific requirements for the comparator or reference method (e.g., must it be FDA-cleared)?	This will be addressed with FDA, using available guidance or through formal pre-submissions.
54	Is BARDA aware of any special considerations or constraints for assays designated as “biothreat agents” beyond a standard 510(k) submission?	Nothing beyond what may be provided in an IFU. It will be a standard 510k/De Novo.