# **RADx Fast Track Program: High Performance COVID-19 Rapid Tests**

*This document is intended only as a preview for prospective applicants. It is* ***not*** *a submission form. To submit an application, you may:*

* *Use our* [*online submission tool*](https://colab.secure-platform.com/a/solicitations/111/home)*.*
* *Download our accessible Excel application form for enhanced accessibility.*

*More detailed instructions are provided in the online submission tool and the Excel application form. For additional accessibility assistance please email* [*info.radx@poctrn.org*](mailto:info.radx@poctrn.org)*.*

*Unless specifically requested, your responses must be text-only. Please do not include links to websites or other materials.*

## **Section 1: Applicant Information**

**Project Title** – Short answer (This is a required field)

**Abstract** – Please provide a brief description of the problem and solution being addressed (50 words or less) – Comment box (This is a required field)

**Name of organization, institution, or company** (if submitted by group of individuals not associated with an organization, institution, or company enter “Team”) - Short answer (This is a required field)

**Organization/Group website** (Respond with N/A if needed) (This is a required field)

**Prior work with RADx?** – Select one (This is a required field)

* Yes
* No

**If yes, please explain the prior work done with RADx**. Include previous RADx application number(s) as appropriate – Comment box (This is a required field)

**Point of Contact Given (first) name** – Short answer (This is a required field)

**Point of Contact Family (last) name** – Short answer (This is a required field)

**Point of Contact Title at organization, institution, or company (as applicable)** – Short answer (This is a required field)

**Point of Contact Preferred e-mail** – Short answer (This is a required field)

**Point of Contact Preferred phone number** – Short answer (This is a required field)

### **Demographics**

The following questions are to help us understand the responses we are getting so we can improve our outreach. They have no impact on our assessment of your application

**Country** – Short answer (This is a required field)

**State or U.S. Territory** (If outside the U.S., please respond with N/A) – Short answer (This is a required field)

**Organization/ Group Type** - Select all the apply (This is a required field)

* Academic
* Non-Profit Lab/CRO
* Start-up (<1 year)
* Small business (<50 employees)
* Mid-size business (between 50 and 250 employees)
* Large business (>250 employees)
* Independent Team
* Other (please specify) – Short answer

Where did you learn of this solicitation? – Select all that apply (This is a required field)

* Direct from a POCTRN Center/NIH faculty member
* E-mail Blast
* Newsletter
* Website
* Referral
* Other (please specify)

***The application continues on the following page.***

## **Section 2: Project Details**

**Solution Summary** - Provide a brief solution overview (200 words or less) - Comment box (This is a required field)

**Technical Characteristics** - Briefly describe technical characteristics of the solution and how the technology compares to current, best-in-class OTC technologies. (200 words or less) – Comment box (This is a required field)

**Sample type** – Select all that apply (This is a required field)

* Anterior Nares (AN)
* Blood (BL)
* Nasal mid-turbinate (NMT)
* Nasal, non-specific (NS)
* Nasopharyngeal (NP)
* Nasopharyngeal wash/aspirate or nasal wash/aspirate (NW)
* Oropharyngeal (OP)
* Saliva/oral secretion (SA)
* Sputum (SP)
* Other (please specify)

### **Key Performance Parameters**

**Sensitivity** – Short answer (This is a required field)

**Specificity** – Short answer (This is a required field)

**Level of detection** – Short answer (This is a required field)

**Time to run a test** – Short answer (This is a required field)

**Production cost of the test** – Short answer (This is a required field)

**Production cost of the instrument** (if applicable) – Short answer (This is a required field)

**Prior Work and Current Status** - Describe the current status of your proposed solution and any additional information you would like reviewers to consider. (750 words or less) – Comment box (This is a required field)

**Maturity of the Solution**

**Regulatory Status** - Provide an overview of regulatory status (FDA and CLIA approvals) (200 words or less) – Comment box (This is a required field)

**Performance Testing** - Provide an overview of performance testing done to date (200 words or less) - Comment box (This is a required field)

**Implementation and Production** - Provide a summary of your implementation and production plans (including projected monthly production capacity) (200 words or less) - Comment box (This is a required field)

**Other Information -**Provide other relevant information including handling variants, accessibility for individuals with disabilities, support for telemedicine and communications of results, platform and/or multiplexing capabilities, avoidance of common supply chain issues, addressing unmet needs of traditionally underserved and underprivileged populations, and scalability of production. (750 words or less) – Comment box (This is a required field)

**Support requested from RADx** ***-*** Please select any areas where you require major support to meet milestones – Select all that apply (This is a required field)

* + Clinical verification
  + Access to samples
  + Regulatory
  + Quality
  + Commercialization
  + Digital Support
  + Manufacturing
  + Supply Chain
  + Distribution
  + No support needed
  + Other

***The application continues on the following page.***

## **Section 3: Work Package Details and Team**

We are **not** asking for detailed work plans - that will come later. Describe the results of the work you expect to complete in discrete "Deliverables" or outputs of your work.  If you are selected, we will work with you to finalize plans, including access to needed resources. Work Package #1 is intended to address high-risk barriers to success, which, when successfully resolved, will enable Work Package #2, which will focus on implementation.

### **Work Package #1**

**Budget** – Please indicate your expected direct budget (including labor and all expenses with full Federal OH rates) – Short answer (This is a required field)

**Duration** – What is the expected duration of WP #1 (in weeks) – Short answer (This is a required field)

**Deliverables** (200 words or less) – Comment box (This is a required field)

### **Work Package # 2**

**Budget** – Please indicate your expected direct budget (including labor and all expenses with full Federal OH rates) – Short answer (This is a required field)

**Duration** – What is the expected duration of WP #2 (in weeks) – Short answer (This is a required field)

**Deliverables** (200 words or less) – Comment box (This is a required field)

### **Key Team Members**

**Overview of Team and Environment** - Please provide an overview of the team members and why they collectively have the expertise and access to resources to be successful in achieving a deployable solution. (200 words or less) – Comment box (This is a required field)

#### **Key Team Members**

Please describe up to 5 team members, individuals, or organizations. (This document previews the questions in this segment. In response forms, identical segments are provided to allow for additional team members -up to 5 – to be reported.) (One key team member must be reported)

**Team Member Name** – Short answer (This is a required field)

**Role on Team** – Short answer (This is a required field)

**Level of Effort** – Short answer (This is a required field)

**Relevant Experience** (up to 200 words) – Comment box (This is a required field)

**Current or most recent position** - Include start and end dates, title and position description - Comment box (This is a required field)

**Past position #1** - Include start and end dates, title and position description – Comment box (This is a required field)

**Past position #2** - Include start and end dates, title and position description – Comment box (This is a required field)

##### **Diversity, Equity, and Inclusion**

**Gender Identity Demographic Data Collection Options:** How do you identify?(Select One)

* Cisgender Man - A man and was assigned the male sex at birth
* Transgender Man - A man who was assigned the female sex at birth
* Cisgender Woman - A woman who was assigned the female sex at birth
* Transgender Woman - A woman who was assigned the male sex at birth
* Non-binary - A person who does not exclusively identify as a man or a woman, whose gender identity is outside the gender binary
* I do not wish to disclose
* Prefer to self-describe (please specify)

**Ethnicity:** Are you of Hispanic or Latino descent? (Select one)

* Yes
* No
* I do not wish to disclose

**Race Demographic Data Collection Options:** Regardless of your answer to the prior question, please check one or more of the following groups in which you consider yourself to be a member: (Mark all that apply):

* American Indian or Alaskan Native - A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment
* Asian - A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
* Black or African American - A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" can be used in addition to "Black or African American."
* Native Hawaiian or Other Pacific Islander - A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
* White - A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
* I do not wish to disclose
* Another race or ethnicity not listed above (please specify)

**Disability:** How do you describe your disability/ability status?

* I have a disability or have a history/record of having a disability
* I do not have a disability and do not have a history/record of having a disability
* I do not wish to disclose

**Veteran Status:** Do you identify as having military or veteran status?

* Yes
* No
* I do not wish to disclose

***The application continues on the following page.***

## **Section 4: IVD Innovation Cycle Checklist**

The remainder of the application consists of multiple-choice items that ask you to characterize the status of your project through the lens indicated at the beginning of each section (Headings 3). Responses in this section are not required, but they will help reviewers understand your project’s status and needs, so we ask that you complete them to the best of your ability.

### **Characterize the status of your insights into unmet needs and available solutions.**

#### **Clinical**

Unmet need statement

* Not started
* Partial
* Completed

Disease characterization

* Not started
* Partial
* Completed

#### **Business**

Needs screening and selection

* Not started
* Partial
* Completed

Existing solutions characterized

* Not started
* Partial
* Completed

#### **Regulatory**

Regulatory familiarization

* Not started
* Partial
* Completed

#### **Technology**

State-of-the-Art Summary

* Not started
* Partial
* Completed

***The application continues on the following page.***

### **Characterize the solution’s potential to meet unmet needs, and your progress toward selecting, describing, evaluating this idea.**

#### **Clinical**

**Envisioned benefit statement**

* Not started
* Partial
* Completed

**Feedback from 5+ clinical stakeholders**

* Not started
* Partial
* Completed

**Identify appropriate target(s) to be detected**

* Not started
* Partial
* Completed

**Workflow scenario**

Not started

Partial

Completed

#### **Business**

**Competitive landscape**

* Not started
* Partial
* Completed

**Envisioned Value Proposition**

* Not started
* Partial
* Completed

**Key stakeholders identified**

* Not started
* Partial
* Completed

**Market map and segmentation**

* Not started
* Partial
* Completed

**Reimbursement familiarization**

* Not started
* Partial
* Completed

#### **Regulatory**

**Comparables identified**

* Not started
* Partial
* Completed

**Medical device determination**

* Not started
* Partial
* Completed

#### **Technology**

**Core components of kits/reagents identified**

* Not started
* Partial
* Completed

**Hypothesis and experimental design**

* Not started
* Partial
* Completed

**Idea screening and selection**

* Not started
* Partial
* Completed

**Institutional IP disclosure**

* Not started
* Partial
* Completed

**Paper prototype**

* Not started
* Partial
* Completed

***The application continues on the following page.***

### **Characterize the status of your solution’s Proof of Concept (PoC) – key component concepts validated in models and value proposition tested.**

#### **Clinical**

**Feedback from clinical stakeholders in 5+ settings**

* Not started
* Partial
* Completed

**Target outcomes**

* Not started
* Partial
* Completed

**Updated need statement and workflow scenario**

* Not started
* Partial
* Completed

#### **Business**

**Business protection model**

* Not started
* Partial
* Completed

**Competing solutions characterized**

* Not started
* Partial
* Completed

**Preliminary Path-to-Payment plan**

* Not started
* Partial
* Completed

**Preliminary value proposition**

* Not started
* Partial
* Completed

**Stakeholder map**

* Not started
* Partial
* Completed

#### **Regulatory**

**Design control system in place**

* Not started
* Partial
* Completed

**Preliminary indications for use**

* Not started
* Partial
* Completed

**Preliminary regulatory classification**

* Not started
* Partial
* Completed

**Preliminary regulatory pathways (LDT or device)**

* Not started
* Partial
* Completed

**Preliminary risk and hazard analysis**

* Not started
* Partial
* Completed

#### **Technology**

**Demonstration results**

* Not started
* Partial
* Completed

**Key assay components identified**

* Not started
* Partial
* Completed

**Key hardware/device component PoC prototype**

* Not started
* Partial
* Completed

**Preliminary Freedom to Operate (FTO) Assessment**

* Not started
* Partial
* Completed

**Updated institutional IP disclosure**

* Not started
* Partial
* Completed

***The application continues on the following page.***

### **Characterize the status of your solution’s Proof of Feasibility (PoF) – feasibility of the whole solution demonstrated in models and in feedback from stakeholders.**

#### **Clinical**

**Feedback from users in 20+ settings**

* Not started
* Partial
* Completed

**Updated need and workflow descriptions**

* Not started
* Partial
* Completed

**Updated target outcomes**

* Not started
* Partial
* Completed

#### **Business**

**Business advisory board**

* Not started
* Partial
* Completed

**Development plan**

* Not started
* Partial
* Completed

**Feedback from 5+ economic buyers**

* Not started
* Partial
* Completed

**Key relationships identified**

* Not started
* Partial
* Completed

**Preliminary business model**

* Not started
* Partial
* Completed

**Preliminary supply chain strategy**

* Not started
* Partial
* Completed

**Secure Access to Core IP**

* Not started
* Partial
* Completed

#### **Regulatory**

**Draft essential requirements checklist**

* Not started
* Partial
* Completed

**Draft instructions for use**

* Not started
* Partial
* Completed

**Draft product claims**

* Not started
* Partial
* Completed

**Institutional approval request(s)**

* Not started
* Partial
* Completed

**Submission pathway defined**

* Not started
* Partial
* Completed

#### **Technology**

**Essential experiment results**

* Not started
* Partial
* Completed

**Intellectual property assessment**

* Not started
* Partial
* Completed

**Key in-sourcing plans**

* Not started
* Partial
* Completed

**Preliminary BOM and Manufacturing-QMS Plan**

* Not started
* Partial
* Completed

**Provisional IP filing**

* Not started
* Partial
* Completed

**User/Product requirement document (URD/PRD)**

* Not started
* Partial
* Completed

**“Works Like” and “Looks Like” prototypes**

* Not started
* Partial
* Completed

***The application continues on the following page.***

### **Characterize the status of your solution’s Proof of Value (PoV) – the potential of the solution to work and create value for all stakeholders.**

#### **Clinical**

**Animal/first in/with man experiments**

* Not started
* Partial
* Completed

**Clinical trial endpoints**

* Not started
* Partial
* Completed

**Feedback from 5+ KOLs**

* Not started
* Partial
* Completed

**Feedback from 50+ clinical stakeholders**

* Not started
* Partial
* Completed

**Medical advisory board**

* Not started
* Partial
* Completed

#### **Business**

**Feedback from 10+ economic buyers**

* Not started
* Partial
* Completed

**Incorporation and founders agreement**

* Not started
* Partial
* Completed

**Initial seed investment**

* Not started
* Partial
* Completed

**Investor-ready business plan**

* Not started
* Partial
* Completed

**Key management team committed**

* Not started
* Partial
* Completed

**Key relationships formalized**

* Not started
* Partial
* Completed

#### **Regulatory**

**Application regulatory authority submitted**

* Not started
* Partial
* Completed

**Clinical Investigation approval(s)**

* Not started
* Partial
* Completed

**Electronic Protected Health Information (ePHI) plans**

* Not started
* Partial
* Completed

**Essential requirements checklist**

* Not started
* Partial
* Completed

**Quick reference guide**

* Not started
* Partial
* Completed

#### **Technology**

**cGMP compliant pilot manufacturing process**

* Not started
* Partial
* Completed

**Essential technical experiments results**

* Not started
* Partial
* Completed

**IP search report**

* Not started
* Partial
* Completed

**Key in-sourcing requirements committed**

* Not started
* Partial
* Completed

**“Works like, Looks like, Made-like” prototypes**

* Not started
* Partial
* Completed

***The application continues on the following page.***

### **Characterize the status of your solution’s initial clinical trials (ICT) – regulated production of protypes and collection of clinical and economic data.**

#### **Clinical**

**Demo feedback from 20+ clinical stakeholders**

* Not started
* Partial
* Completed

**Endpoints achieved in pilot clinical trials**

* Not started
* Partial
* Completed

#### **Business**

**First institutional investment**

* Not started
* Partial
* Completed

**Business resumption plan**

* Not started
* Partial
* Completed

**Feedback from 20+ economic buyers**

* Not started
* Partial
* Completed

**Value quantification**

* Not started
* Partial
* Completed

#### **Regulatory**

**Data requirements confirmation**

* Not started
* Partial
* Completed

**GDPR/HIPAA compliance**

* Not started
* Partial
* Completed

**Pre-submission filed**

* Not started
* Partial
* Completed

**Security and vulnerability certifications**

* Not started
* Partial
* Completed

#### **Technology**

**All in-sourcing requirements achieved**

* Not started
* Partial
* Completed

**cGMPs compliant manufacturing plan**

* Not started
* Partial
* Completed

**Full IP application**

* Not started
* Partial
* Completed

**Updated PRD and experimental validation**

* Not started
* Partial
* Completed

***The application continues on the following page.***

### **Characterize the status of your solution’s Validation of Solution (VoS) – validating that the solution is shown to be effective and of value to all stakeholders.**

#### **Clinical**

**Endpoints achieved in pivotal clinical trials**

* Not started
* Partial
* Completed

**Peer reviewed publication(s) accepted**

* Not started
* Partial
* Completed

#### **Business**

**2nd round of institutional investment**

* Not started
* Partial
* Completed

**Purchasing intent from 10+ buyers**

* Not started
* Partial
* Completed

#### **Regulatory**

**Submission of Technical file to regulatory body**

* Not started
* Partial
* Completed

#### **Technology**

**CGMPs compliant manufacturing process**

* Not started
* Partial
* Completed

**Quality assured process validation (cGMP)**

* Not started
* Partial
* Completed

**Scale-up verification and validation**

* Not started
* Partial
* Completed

***The application continues on the following page.***

### **Characterize the status of your solution’s Approval & Launch (A&L) – institutional and regulatory approval received and sales launch.**

#### **Clinical**

**Specialty medical groups review in place**

* Not started
* Partial
* Completed

**Training materials and support established**

* Not started
* Partial
* Completed

#### **Business**

**Initial sales**

* Not started
* Partial
* Completed

**Regionalization plans**

* Not started
* Partial
* Completed

#### **Regulatory**

**Registration and listing**

* Not started
* Partial
* Completed

**Public coverage and code determination**

* Not started
* Partial
* Completed

#### **Technology**

**Finalized cGMP manufacturing process**

* Not started
* Partial
* Completed

**IP update**

* Not started
* Partial
* Completed

***The application continues on the following page.***

### **Characterize the status of your solution’s Clinical Use (Use) – the solution is used successfully in day-to-day clinical practice.**

#### **Clinical**

**Included in local practice guidelines**

* Not started
* Partial
* Completed

**Peer reviewed publications**

* Not started
* Partial
* Completed

#### **Business**

**New markets launched**

* Not started
* Partial
* Completed

**Profitable sales**

* Not started
* Partial
* Completed

#### **Regulatory**

**Monitoring/inspections**

* Not started
* Partial
* Completed

#### **Technology**

**Improvement plan**

* Not started
* Partial
* Completed

**Key patents issued**

* Not started
* Partial
* Completed

***The application continues on the following page.***

### **Characterize the status of your solution’s Standard of Care (SoC) – recognition that this solution is the standard of care.**

#### **Clinical**

**Recommended by medical specialty**

* Not started
* Partial
* Completed

#### **Business**

**Dominant market share**

* Not started
* Partial
* Completed

**Health economics study**

* Not started
* Partial
* Completed

#### **Regulatory**

**Product Obsolescence Plan**

* Not started
* Partial
* Completed

#### **Technology**

**Component Obsolescence Plan**

* Not started
* Partial
* Completed

***This is the end of the application.***