General IVD Emergency Use Authorization (EUA)/Pre-EUA Template

This template provides the Food and Drug Administration’s (FDA) current recommendations concerning what data and information should be submitted in support of a pre-EUA or an EUA request for in vitro diagnostic devices (IVDs) for emerging pathogens during an applicable section 564 declared emergency. The validation recommendations also apply to a test offered as described in an enforcement discretion policy during an applicable section 564 declared emergency.

As described in the FDA guidance document entitled “Validation of Certain In Vitro Diagnostic Tests for Emerging Pathogens During a Section 564 Declared Emergency,” FDA is providing this template to help IVD manufacturers provide recommended validation data and other information to FDA, but alternative approaches can be used.

This template reflects FDA’s current thinking on the topic, and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* means that something is suggested or recommended, but not required. For more information about EUAs in general, please see the FDA guidance document entitled “[Emergency Use Authorization of Medical Products and Related Authorities](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities).”

Manufacturers of IVDs interested in requesting an EUA are encouraged to submit a pre-EUA to engage discussions with FDA early, when not all validation studies are completed. A pre-EUA can be submitted *prior to* or *during* an applicable 564 declaration before submitting an EUA request. A pre-EUA can only transition to an EUA request if there is a current applicable 564 declaration. IVD manufacturers can submit a Pre-EUA or an EUA request to CDRH-IVD-EUA@fda.hhs.gov.

General IVD EUA/Pre-EUA Template

# BACKGROUND

1. **Applicant Name:**

Please enter the official applicant’s name.

1. **Applicant Address:**

Please enter the applicant’s address.

1. **Application Primary Correspondent:** Name; Phone Number; Email address
2. **Application Secondary Correspondent:** Name; Phone Number; Email address
3. **Device Name:**

Please enter the proprietary, abbreviated, and/or established name of the device.

1. **Measurand:** Specific nucleic acid sequences from the genome **OR** specific antigen(s) from the pathogen.

Please specify the targeted gene(s) or antigen(s), if applicable.

1. **Regulatory History:**
	1. **Device:**

The device name is not cleared, CLIA waived, approved, or subject to an approved investigational device exemption.

*If the device has been previously reviewed, please provide the submission number, or type N/A:* Previous submission number, if applicable

* 1. **Applicant:**

*If the applicant has previous experience with FDA:*

Please provide the submission number(s) and/or type(s) of interactions.

1. **Intended Use Population(s)** (please check all that apply)**:**

[ ]  Patients suspected of infection by a healthcare provider (i.e., presently showing symptoms or symptomatic)

[ ]  Individuals with or without signs or other reasons to suspect infection (i.e., for screening )

[ ]  Other: Please describe.

1. **Notification reference number (if applicable):** Please enter notification reference number.

|  |
| --- |
| **FOR FDA USE:** **Regulatory Information:** Panel Code:to be completed by FDA;Review Group:to be completed by FDA; Product Code:to be completed by FDA**Unmet Need Addressed:** to be completed by FDA**Approved/Cleared Alternative Products:** to be completed by FDA**Risks and Benefits:** to be completed by FDA |

# MAIN TEMPLATE

## PRODUCT INFORMATION

1. **Device Type:** Choose an item.
2. **Proposed Intended Use:**

Please provide your proposed Intended Use statement.

1. **Prescription Use/Non-Prescription Use:** Choose an item.
2. **Device is intended for use in the following settings:** Choose an item.[ ]  Other: Describe intended setting.
3. **Device Technology:** Choose an item.[ ]  Other\* Please describe.
4. **Specimen Type(s):** Please describe.
5. **Instruments Required:**

Please list the instruments employed/required to perform the test, including software, cameras, smart phones, mobile applications, operating systems, and automated extraction instruments, if applicable.

1. **Test Targets:**

**Oligonucleotides:**

Please list any oligonucleotide sequences and include a description of the analyte target(s) (e.g., gene/genomic region name and nucleotide sequence of the full amplified region(s) detected), if applicable.

 **Antibodies:**

Antibodies used in your test, including whether they are polyclonal or monoclonal, and catalog numbers and manufacturer name if commercially available, as applicable.

**Amino Acid Sequences:**

Specific amino acid sequence(s) (including amino acid position numbers relative to the target) of the immunogen used to generate the antibodies used in your test to detect the antigen(s), if applicable.

 **Immunogen Generation Description:**

How the immunogen was generated (e.g., synthetic peptide, recombinant protein, etc.), if applicable.

 **Epitope Description:**

If known, including whether the epitope is linear or conformational, recognized by the antibodies used in your test to detect to the virus antigen(s).

1. **Test Steps:**

Please describe, in order, the test steps required to perform the test, including instrument(s) and/or the details and steps for ordering and processing home collection kits, as applicable.

1. **Controls Required:**

Included with the Test Kit:

| **Control** | **Description** | **Requirement** | **How it works** | **Where it is used** | **Frequency of use** |
| --- | --- | --- | --- | --- | --- |
| **Positive** | Provide description  | Describe need | Describe how the control is expected to work | Describe where the control is used | Describe the frequency of use |
| **Negative** | Provide description  | Describe need | Describe how the control is expected to work | Describe where the control is used | Describe the frequency of use |
| **Extraction** | Provide description  | Describe need | Describe how the control is expected to work | Describe where the control is used | Describe the frequency of use |
| **Internal** | Provide description  | Describe need | Describe how the control is expected to work | Describe where the control is used | Describe the frequency of use |

NOT included with the Test Kit:

Any controls that are required, but not included with the test kit; description of the control, recommended sources of the material, the need for the control, how it works, where in the test is it used, and the frequency of use.

1. **Test Result Reporting *(Home Use and Home Collection):***

Please describe how you will ensure all users of the test can report results to public health and/or other authorities to whom reporting is required, in accordance with local, state, and federal requirements. Please note whether identified information will be sent to local public health authorities and/or if de-identified information will be sent to CDC. For home collection kits, please describe how test results will be communicated to the healthcare provider and/or home user.

1. **Partnering Laboratories (*Home Collection Only*):**

| **Laboratory** | **Diagnostic Test** | **Lab Testing Capacity** **(Per day or week)** |
| --- | --- | --- |
| Lab Name, Address, Phone Number, CLIA # | Diagnostic Test Name and Test Developer, Submission # if EUA request submitted, Link to EUA if already authorized |  |

1. **Laboratory Manufacturers:**

| **Name and CLIA #** | **Address** | **Contact Info (Phone number and Email)** |
| --- | --- | --- |
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## MANUFACTURING INFORMATION

***FDA recommends that you confirm your agreement with the following statement to help facilitate authorization in the event FDA determines it is appropriate to authorize the candidate test:***

 [ ] Yes [ ] No *The* device name *has been validated using only the components referenced in this submission and will not be changed after authorization without prior concurrence from FDA (e.g., through an authorized Predetermined Change Control Plan (PCCP) or authorization of a supplemental EUA request).*

1. **Manufacturing Location:**

Please list the manufacturing location name and contact information.

1. **FDA Registration Number**: Please enter FDA registration number, or N/A, if not applicable.
2. **Quality System:** e.g., 21 CFR 820 or ISO 13485
3. **Packager:** Please include the name of the packager, if applicable (e.g., material may be bottled and kitted by [packager name]).
4. **Manufacturing and Testing Capabilities**

Total time required to perform all steps of the test (e.g., extraction setup and run, detection setup, run and result analysis): Please describe, if applicable.

Number of patient tests that can be performed per day (8hr shift): Using a 1 instrument setup (e.g., 1 extraction instrument, 1 PCR instrument, etc.) and 1 trained laboratory user, if applicable.

Current manufacturing capacity (number of diagnostic tests or home collection kits manufactured per 7 days for US distribution): Please describe.

Surge manufacturing capacity: Approximate maximum number of tests that could be manufactured per week, including approximate timeframe to increase to surge capacity.

1. **Distribution:**

Authorized Distributors:

| **Name** | **Address** | **Contact Info (Phone number and Email)** |
| --- | --- | --- |
|  |  |  |
|  |  |  |

1. **Device Components:**

Components Included with the Test/Home Collection kit:

| **Kit Components & Other Materials/****Information** | **Main Reagents Composition/****Matrix** | **Concentration/****Quantity/Volume** | **Manufacturer** | **Catalog #** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
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Components Required but NOT Included with the Device:

List all components and other materials/information (e.g., instruments, reagents, smartphones, timer, disposable gloves, eye protection) not included with the device that must be supplied by the user to perform the test, with specific supplier names and catalog numbers or other identifiers for obtaining the components. Please include here all specific consumables that were validated for use with your device, that are not interchangeable with other products and that are needed to guarantee device performance as established in the EUA validation studies.

Research Use Only (RUO) Components:

Please specify any instruments or other components of your device which are labeled as research use only (RUO), or are otherwise not labeled with the statement “For In Vitro Diagnostic Use”, or associated symbol.

Does the test use an RUO instrument that will be distributed to more than one lab? [ ] Yes [ ] No

1. **Software and Mobile/Web Applications:**

*Section V.B(13) of Guidance*

Does the proposed device contain device software functions? [ ]  Yes [ ]  No

Has the software been previously cleared/approved by FDA? [ ]  Yes [ ]  No

If Yes, please include previous submission number where the software has been cleared or approved: Please include previous submission number, if applicable.

 If No, please provide the following:

 Software Documentation Level[[1]](#footnote-2): [ ]  Basic [ ]  Enhanced

Software Validation: [ ]  Validation complete [ ]  Developed per GMPs

If software validation is complete:

[ ]  Provide detailed study protocol(s)

[ ]  Provide detailed study report(s)

Does the software contain any external wired and/or wireless communication interfaces?[[2]](#footnote-3):

[ ] Yes [ ] No

If Yes: [ ]  Provide cybersecurity evaluation

Provide a software update plan:

Please describe how this plan covers mobile application updates, algorithm updates, and web application updates that may impact the performance or safe reporting of the device.

1. **Basic Safety and Essential Performance:**

*Section V.B(14) of Guidance*

Does the device have electrical components previously cleared/approved by FDA? [ ] Yes [ ] No

If Yes, please include previous submission number where the electrical testing has been cleared/approved: Please include previous submission number, if applicable.

If No, please indicate if the basic safety requirements were evaluated according to International Electrotechnical Commission (IEC) 60601-1 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance)? [ ] Yes [ ] No

If No, please include a summary of the standard utilized, or alternate methodologies:

Please describe the alternate EMC testing methodologies utilized or indicate “not applicable” if this is a home collection device.

1. **Electromagnetic Compatibility (EMC) Testing:**

*Section V.B(15) of Guidance*

Is the device electrically-powered or have functions or sensors that are implemented using electrical or electronic circuitry previously cleared/approved by FDA? [ ]  Yes [ ]  No

If Yes, please include previous submission number where the software has been cleared/approved: Please include previous submission number, if applicable.

If No, please indicate if EMC testing was performed according to the test levels in International Electrotechnical Commission (IEC) 60601-1-2? [ ]  Yes [ ]  No

If No, please include a summary of the standard utilized, or alternate methodologies, including a test plan, test report, acceptance criteria, and risk analysis to support your approach:

Please describe the alternate EMC testing methodologies utilized or indicate “not applicable” if this is a home collection device.

1. **Interpretation of Results:**

Interpretation required to determine if results are positive or negative for the presence of the target analyte: [ ]  Cutoff [ ]  Raw data review [ ]  Algorithm/calculation

Test Controls:

| **Control** | **Expected Results**  | **Acceptance Criteria** | **Measured Values for Valid & Invalid Controls** | **Actions if Invalid Control**  |
| --- | --- | --- | --- | --- |
| **Positive** | Describe expected results | Provide acceptance criteria | Describe, as applicable | Actions user should take |
| **Negative** | Describe expected results | Provide acceptance criteria | Describe, as applicable | Actions user should take |
| **Extraction** | Describe expected results | Provide acceptance criteria | Describe, as applicable | Actions user should take |
| **Internal** | Describe expected results | Provide acceptance criteria | Describe, as applicable | Actions user should take |

Examination and Interpretation of Patient Specimen Results:

Please describe when clinical specimen test results should be assessed and outline the criteria for test validity.

Interpretation of Numeric Test values:

Clearly indicate how to interpret numeric test values (if applicable) as positive or negative for presence of the target analyte. If applicable, indicate how to identify indeterminate/inconclusive/equivocal/invalid results.

Combinations of Test Values:

When applicable, provide a table clearly describing the possible combinations of test result values for target analyte(s) and the controls, and how they should be combined into a final interpretation of the result for your test. If the test produces indeterminate/inconclusive/equivocal/invalid result or a result that will be used as part of a CDC recommended testing algorithm, please indicate what follow-up testing/process should be conducted, if applicable.

## PERFORMANCE EVALUATION

1. **Clinical Performance Evaluation**

*Section V.A of Guidance*

[ ]  Provide detailed study protocol and report, including any deviations to the protocol during the conduct of the study.

[ ]  Provide complete study line data (e.g., Ct values for NAAT tests for both the candidate and comparator) in Excel-compatible format

[ ]  Provide detailed study design for post-authorization clinical studies, as applicable.

 Comparator Test Name: Please describe.

 [ ]  Comparator test used per cleared, approved, or authorized instructions for use

 [ ]  Comparator test not cleared, approved, or authorized or modified instructions for use

 [ ]  Not applicable for contrived specimen testing

Specimens: Specimen types tested: Please describe. [ ]  Fresh [ ]  Frozen

Number of natural negative specimens: Please describe.

Number of natural positive specimens: Please describe.

Number of contrived positive specimens: Please describe.

Results:

Please describe.

Positive percent agreement (PPA): XX/XX = XX.XX% (95% CI = XX.XX – XX.XX%)

Negative percent agreement (NPA): XX/XX = XX.XX% (95% CI = XX.XX – XX.XX%)

Low positive clinical specimens among all positive specimens (as determined by the comparator test): XX/XX = XX.XX%

Clinical Performance Evaluation Results:

|  |  |  |
| --- | --- | --- |
|  | **Comparator Test** |  |
| Detected | Not Detected | **Total** |
| **Candidate Test** | Detected | XX | XX | XX |
| Not Detected | XX | XX | XX |
|  | **Total** | XX | XX | XX |

 Is the device intended for Point-of-Care (POC) testing? [ ]  Yes [ ]  No

If Yes, please provide the following additional studies:

1. **Performance around LoD *(Supplemental POC Testing Specimens[[3]](#footnote-4))***

*Section VI.C of Guidance*

[ ]  Provide detailed study protocol

[ ]  Provide complete study line data in Excel-compatible format

Performance around LoD Results (POC):

|  |  |  |
| --- | --- | --- |
| **Operator #. and Site #** | **Low positive specimens near cut-off** **(<2X LoD)** | **Negative specimens** |
| **Number of Tests Interpreted Correctly/Total** | **% Concordance with Expected Result** | **Number of Tests Interpreted Correctly/Total** | **% Concordance with Expected Result** |
|  |  |  |  |  |
|  |  |  |  |  |

1. **Limit of Detection (LoD) (Analytical Sensitivity)**

*Section V.B(1) of Guidance*

[ ]  Provide detailed study protocol

[ ]  Provide complete study line data in Excel-compatible format

Lowest detectable concentration of virus at which approximately 95% of all (true positive) replicates test positive (LoD): Please describe.

Specimen make-up: (e.g., live virus, inactivated virus, natural genomic DNA/RNA, synthetic DNA/RNA, etc.):

Please describe.

LoD study results:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Target Level** | **Valid tested replicates** | **Target** **Analyte 1****Positive** | **Target** **Analyte 2****Positive** | **Internal Control****Positive** | **Results****based on interpretation algorithm** |
| **Mean Ct** | **Detection Rate** | **Mean Ct** | **Detection Rate** | **Mean Ct** | **Detection Rate** | **Detection Rate** |
| Preliminary LoD | e.g., cp/µL | e.g., 3-5 |  | n/N |  |  |  |  |  |
| Confirmatory LoD | e.g., cp/µL | e.g., 20 |  | n/20 |  |  |  |  |  |

1. **Inclusivity (Analytical Reactivity)**

*Section V.B(2) of Guidance*

Monitoring Plan Strategy:

Please provide a summary of your strategy to monitor new and emerging viral mutations and variants that could impact test performance on an ongoing basis; please include your assessment strategy for the impact on the performance of your diagnostic test over time.

Monitoring Access Points:

Please describe where you plan to access monitoring information (e.g., sequence databases such as GISAID).

Monitoring Frequency:

Please describe the frequency of monitoring.

Strategy to Choose Targeted Amplification Regions, and Specific Oligonucleotide Regions:

Please describe your proposed strategy.

Mutations and/or variants have been identified as prevalent and/or clinically significant: [ ]  Yes [ ]  No

If Yes:

[ ]  Provide a detailed risk assessment of whether mutations and/or variants are critical to the test design.

[ ]  If critical to test design, provide evaluation of impact on test performance with both clinical evaluation and LoD studies using wet testing with a clinical sample with the mutation (if available).

[ ]  If a decrease in test performance is observed, provide an assessment whether the known and potential benefits of the test continue to outweigh the know and potential risks.

1. **Cross-Reactivity (Analytical Specificity)**

*Section V.B(3) of Guidance*

[ ]  Provide detailed study protocol

[ ]  Provide complete study line data in Excel-compatible format

All relevant non-target microorganisms that were evaluated: Please describe.

 [ ]  *In Silico* Analysis:

Click or tap here to enter text.

WetTesting:

[ ]  Cross-Reactivity Results:

| **Microorganism, Strain, Accession Number** | **Concentration** | **Replicates Negative / # of Replicates Tested** |
| --- | --- | --- |
|  |   |  |
|  |   |    |

1. **Microbial Interference Studies**

*Section V.B(3) of Guidance*

[ ]  Provide detailed study protocol

[ ]  Provide complete study line data in Excel-compatible format

[ ]  Microbial Interference Results:

| **Microorganism, Strain, Accession Number** | **Concentration** | **Replicates Positive / # of Replicates Tested** |
| --- | --- | --- |
|  |   |  |
|  |   |    |

1. **Endogenous/Exogenous Interference Substances Studies**

*Section V.B(4) of Guidance*

[ ]  Provide detailed study protocol

[ ]  Provide complete study line data in Excel-compatible format

Does the test use extraction methods **not** previously cleared/approved by FDA as part of a premarket submission or does the test not use an extraction procedure at all? [ ]  Yes [ ]  No

If No,

Please provide justification here, if relevant.

If Yes, please provide your endogenous/exogenous interference substances evaluation appropriate for the specimen type intended for use with your candidate test:

[ ]  Endogenous/Exogenous Interference Substance Results:

| **Interfering Substances** | **Active Ingredients** | **Concentration** | **Negative Specimens****Replicates Negative / # Replicates Tested** | **Positive Specimens****Replicates Positive / # Replicates Tested** |
| --- | --- | --- | --- | --- |
|  |   |  |  |  |
|  |   |    |  |  |

1. **High-Dose Hook Effect *(antigen tests)***

*Section V.B(5) of Guidance*

Is your test design susceptible to a high-dose hook effect? [ ]  Yes [ ]  No

If Yes:

[ ]  Provide detailed study protocol

[ ]  Provide complete study line data in Excel-compatible format

[ ]  Indicate the concentration at which performance begins to degrade if observed: provide concentration

If No,

Please provide justification here, if relevant.

1. **Carry-Over/Cross-Contamination**

*Section V.B(6) of Guidance*

Does your device utilize an automated liquid handling system or instrumentation that has not been previously cleared/approved by FDA? [ ]  Yes [ ]  No

If Yes:

[ ]  Provide detailed study protocol

[ ]  Provide complete study line data in Excel-compatible format

1. **Specimen Stability**

*Section V.B(7) of Guidance*

[ ]  Provide detailed study protocol

[ ]  Provide complete study line data in Excel-compatible format

Specimen Stability Results:

| **Time point** | **Storage Condition** | **Total Number** | **# Of Positives** | **# Of Negatives** | **# Of Valid Replicates** | **%****Positives** | **Acceptance criteria met / not met** |
| --- | --- | --- | --- | --- | --- | --- | --- |
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1. **Reagent Stability**

*Section V.B(8) of Guidance*

Have reagent stability studies been completed? [ ] Yes [ ] No

 If Yes, please provide all applicable test protocols and reports

If No, please provide the following information:

Reagent Stability Test Plan**:**

Describe your stability study design which includes but is not limited to: the external positive and negative controls used, number of specimens tested, preparation of specimens, clinical matrix used, number of replicates tested, number of lots tested, testing timeframe, testing temperatures, etc. You should provide a stability plan for the applicable stability studies such as unopened kit shelf-life stability, unopened kit shipping stability, in-use/opened kit stability, inverted stability, and freeze-thaw stability.

1. **Fresh/Frozen Specimens**

*Section V.B(9) of Guidance*

Were both fresh and frozen specimens included in the clinical evaluation and/or does your test include testing of frozen specimens in the intended use? [ ]  Yes [ ]  No

If Yes:

[ ]  Provide detailed study protocol

[ ]  Provide complete study line data in Excel-compatible format

1. **Flex Studies *(POC and Home Use)***

*Section V.B(10) of Guidance*

Conditions evaluated as potential user errors and anticipated environmental stresses:

Please describe

For each flex study:

[ ]  Provide detailed study protocol

[ ]  Provide complete study line data in Excel-compatible format

[ ]  Risk mitigation, as applicable

1. **Usability Studies *(Home Use and Home Collection)***

*Section V.B(11) of Guidance*

What is the intended use population:

[ ]  Adults 18 years of age and older

[ ]  Children 14-17 years of age (child collects and tests (if applicable) specimen with or without assistance from parent)

[ ]  Children 2-13 years of age (child/adult pairs where parent collects and tests (if applicable) specimen from child)

[ ]  Other:

Please describe.

Did participants in the study perform the specimen collection and testing (if applicable) using **ONLY** the quick reference instructions (e.g., written for lay users at no higher than a 7th grade reading level, limited to 1 to 2 pages and includes pictures and diagrams to facilitate use by a lay user)? [ ]  Yes [ ]  No

If Yes:

[ ]  Provide detailed study protocol

[ ]  Provide complete study line data in Excel-compatible format

[ ]  Provide version of instructions utilized in study

[ ]  Provide summary of test results

1. **User Comprehension Studies *(Home Use and Home Collection)***

*Section V.B(11) of Guidance*

 [ ]  Provide detailed study protocol

[ ]  Provide complete study line data in Excel-compatible format

[ ]  Provide version of instructions utilized in study

[ ]  Provide summary of test results

Is the test intended for Home Collection? [ ]  Yes [ ]  No, if Yes and a user comprehension study was **NOT** performed:

Please describe risk mitigation.

1. **Analytical Equivalency Studies**

*Section V.B(12) of Guidance*

Are there any components or workflows included in the instructions for use that were not evaluated during the clinical study (e.g., different collection medias, specimen matrices, extraction and/or PCR instruments, etc.)? [ ]  Yes [ ]  No

 If Yes:

[ ]  Provide detailed study protocol

[ ]  Provide complete study line data in Excel-compatible format

1. For more information about software documentation level, see Section V of the FDA Guidance document entitled “Content of Premarket Submissions for Device Software Functions,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions> [↑](#footnote-ref-2)
2. E.g., Wired: USB, ethernet, SD, CD, and RGA; Wireless: Wi-Fi, Bluetooth, Radio Frequency, inductive communication, Near Field Communication (NFC), and Cloud. [↑](#footnote-ref-3)
3. These samples are intended to supplement, not replace, the clinical specimens in your study. [↑](#footnote-ref-4)