

Appendix B: Laboratory Procedure for Qualification of RUO Instruments

Testing laboratories that use Bio Molecular Systems MIC qPCR or Roche® LightCycler 480 PCR systems should use this protocol to qualify their RUO instrument(s) for SARS-CoV-2/ Influenza A/B testing using the OPTI SARS-CoV-2/ Influenza A/B RT-PCR Test Kit.

Materials required:

| Description | Included in the kit |
|--|------------------------|
| OPTI PCR Grade Water | Yes |
| Genomic RNA from OPTI Medical | Available upon request |
| A negative upper respiratory (UR) specimen (pool if necessary) | Not provided |

Preparation of contrived positive specimens for RUO instrument qualification:

Prepare contrived positive specimens for RUO instrument qualification as detailed below. Each contrived positive specimen will be extracted and tested in triplicate.

| Description | Negative UR Specimen (µL) | Genomic RNA (µL) |
|-------------------------------|---------------------------|------------------|
| Negative UR Specimen | 1000 | 0 |
| Contrived Positive Specimen 1 | 982 | 18 |
| Contrived Positive Specimen 2 | 955 | 45 |

Set up extraction and assay:

1. For each extraction instrument, assign ten wells on an extraction plate. Load three wells each of the Negative UR Specimen, Contrived Positive Specimen 1, and Contrived Positive Specimen 2. Assign a separate well for a negative extraction control using molecular grade water only.
2. Use 200 µL of the prepared materials and extract nucleic acids according to the extraction kit instructions provided by the manufacturer. Refer to the “Extraction” section of the IFU.
3. Test each extract on the PCR instruments as described in the OPTI SARS-CoV-2 RT-PCR Test Instructions for Use. Include a positive and a negative control in the PCR run.

Analyze data

1. The following control results must be obtained for the PCR run to be deemed valid.

| Control | Target | Ct value | Qualitative Result |
|-----------------------------|-----------------------------|-----------------------------------|--------------------|
| PCR Positive Control | Flu A Positive Control | <40 (FAM) | Positive |
| | Flu B Positive Control | <40 (CAL Fluor red 610) | Positive |
| | SARS-CoV-2 Positive Control | <40 (Cy5) | Positive |
| | Internal Control | <36 (CAL Fluor Orange 560) | Positive |
| PCR Negative Control | Flu A Positive Control | No signal | Negative |
| | Flu B Positive Control | No signal | Negative |
| | SARS-CoV-2 Positive Control | No signal | Negative |
| | Internal Control | No signal* (CAL Fluor Orange 560) | Negative |
| Extraction Negative Control | Flu A Positive Control | No signal | Negative |
| | Flu B Positive Control | No signal | Negative |
| | SARS-CoV-2 Positive Control | No signal | Negative |
| | Internal Control | No signal* (CAL Fluor Orange 560) | Negative |

*The negative controls are expected to test negative for both the SARS-CoV-2 and Internal Control targets. If the laboratory observes nucleic acid contamination (e.g. CAL Fluor Orange 560 Ct values >36), please review and evaluate your established laboratory procedures intended to prevent environmental sources of human nucleic acid contamination. The internal control target is human RNase P nucleic acid and trace amounts may be present in the laboratory environment.

2. The following results for the three replicates of Negative Specimen, Contrived Positive Specimen 1, and Contrived Specimen 2 must be obtained in order to qualify the extraction and PCR instruments for clinical testing.

| Control | Target | Ct value | Qualitative Result |
|-------------------------------|-----------------------------|-------------------------------|--------------------|
| Negative Specimen | Flu A Positive Control | No signal (FAM) | Negative |
| | Flu B Positive Control | No signal (CAL Fluor red 610) | Negative |
| | SARS-CoV-2 Positive Control | No signal (Cy5) | Negative |
| | Internal Control | <36 (CAL Fluor Orange 560) | Positive |
| Contrived Positive Specimen 1 | Flu A Positive Control | <40 (FAM) | Positive |
| | Flu B Positive Control | <40 (CAL Fluor red 610) | Positive |
| | SARS-CoV-2 Positive Control | <40 (Cy5) | Positive |
| | Internal Control | <36 (CAL Fluor Orange 560) | Positive |
| Contrived Positive Specimen 2 | Flu A Positive Control | <40 (FAM) | Positive |
| | Flu B Positive Control | <40 (CAL Fluor red 610) | Positive |
| | SARS-CoV-2 Positive Control | <40 (Cy5) | Positive |
| | Internal Control | <36 (CAL Fluor Orange 560) | Positive |

3. Any unexpected or invalid results would indicate that the instruments do not meet the established performance requirement. Review laboratory procedure to resolve and optimize performance if applicable.

Appendix C: Additional Label

Please print and place this label on the front panel of the instrument. If the instruments include labeling indicating “For Research Use Only”, please cover with the below “Emergency Use Only” labeling. The instrument should retain this labeling throughout the EUA use of the OPTI SARS-CoV-2/ Influenza A/B RT-PCR Test.

Emergency Use Only
This instrument is authorized for use
with OPTI Medical Systems assays
that have received Emergency Use
Authorization (EUA)

For in vitro diagnostic use

For Emergency Use Authorization Only

For Prescription Use only

This product has not been FDA cleared or approved, but been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

This product has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A and/or influenza B not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b) (1), unless the declaration is terminated or authorization is revoked sooner

For technical assistance on the OPTI SARS-CoV-2 RT-PCR Test:

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Contact your IDEXX area manager or distributor or visit our website.

Dye compounds in this product are sold under license from Biosearch Technologies, Inc. and protected by U.S. and world-wide patents either issued or in application.

Patent information: idexx.com/patents

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Symbol Descriptions

| | |
|---|---|
|  | Batch Code (Lot) |
|  | Serial Number |
|  | Catalog Number |
|  | Authorized Representative in the European Community |
|  | Use by date |
|  | Date of manufacture |
|  | Manufacturer |
|  | Temperature limitation |
|  | Consult instructions for use |
|  | Major change in the user instructions |
|  | In vitro diagnostics |

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