OPTI SARS-CoV-2/Influenza A/B RT-PCR Test Version 2

REF

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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.

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:

1 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/Influenza A/B 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, Flu A, Flu B 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 the OPTI SARS-CoV-2/Influenza A/B RT-PCR Test

IVD CE ℞

For *in vitro* diagnostic use
For use under Emergency Use Authorization (EUA) 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/Influenza A/B RT-PCR Test:
IDEXX USA Tel: +1 800 548 9997 or +1 207 556 4895
IDEXX Europe Tel: +800 727 43399
Contact your IDEXX area manager or distributor or visit our website.

Symbol Descriptions

LOT	Batch Code (Lot)
SN	Serial Number
REF	Catalog Number
EC REP	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
IVD	*In vitro* diagnostic

Manufactured in France for
OPTI Medical Systems, Inc., 235 Hembree Park Drive, Roswell, Georgia 30076 USA

EC REP

MT Promedt Consulting GmbH, Altenhofstrasse 80, 66386 St. Ingbert Germany
Tel: +49 6894 581020 info@mt-procons.com

IDEXX Laboratories, Inc., One IDEXX Drive, Westbrook, Maine 04092 USA