molecular designs

DOC-COV096-INSERT-C

COVID-19 *Simplicity Panel*™ 96-Well - EUA

Product Specification Sheet

Product Description:

The COVID-19 panel is an *in-vitro* multiplex real-time reverse transcription polymerase chain reaction (rRT-PCR) assay for the qualitative identification of SARS-CoV-2 virus that is frequently found in the upper respiratory tract. This method is highly accurate, analytically sensitive, and is used for the identification of pathogen causing COVID-19 by amplifying and detecting genetic material (ribonucleic acid or RNA) of SARS-CoV-2.

This panel detects the following targets:

- SARS-CoV-2 N1 variants including Omicron sub-variants BA.4 and BA.5
- Ribonuclease P (RP)

Product Information	
COVID-19 Panel (96-Well Plate)	
Part Number	P-COV096-001-A P-COV096-002-A P-COV096-003-A P-COV096-004-A P-COV096-005-A
Number of Panels	94
Positive Control	SARS-CoV-2 N1
Storage Temperature	-25°C to -15°C

Product Specifications	
QC Test	qPCR Cycle Threshold Percent CV
Specification	≤ 2.5

QC Results	
Positive	meets specification
Negative	meets specification
Targets	meets specification

Disclaimer - Use of PCR and Patent

This product is for basic PCR and is outside of any valid US patents assigned to Hoffman La-Roche.

ISO Certification

This product was manufactured in a facility whose Quality Management System is certified as being in conformity with ISO 13485:2016 by Intertek.

* Limitations of Use

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories; This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, 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. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner. This product is built in accordance with the SARS-CoV-2 Panel Emergency Use Authorization granted to Assurance Scientific Laboratories by the U.S. Food and Drug Administration

Product Guarantee

This kit has been shown to generate reliable, repeatable and high-performance results.

Please contact Molecular Designs for technical assistance. If not completely satisfied, our team will help you identify and address the issue and replace the assays as needed.

Usage Information

Reagent Storage and Use Guidelines

1. Store all reagents at -25°C to -15°C.
2. Do not freeze-thaw plates more than 3 times.

The Following is Included in the Kit:

1. 96-well PCR plate pre-loaded with the multiplex assays and positive control. Negative control assay is plated but negative control is user supplied.

The Following is Supplied by the User: Materials

1. Extracted Sample(s)
2. qPCR optical film
3. Sealer for optical film
4. Negative control

Equipment

1. Manual defrost -20°C freezer
2. Laminar Flow or PCR Dead Air Box for general plate setup. Do not use Laminar Flow for infectious samples
3. Pipettes and appropriate filtered pipette tips
4. Plate Vortex [recommend Vortex Genie 2 (Model G560) with the 3-inch platform and rubber cover]
5. Plate centrifuge
6. Lab utility knife

Instrumentation

1. CFX96 Touch Real-Time PCR Detection System (or equivalent)

General Guidelines and Safety Precautions

1. As with any test procedure, good laboratory practice is essential to the proper performance of this assay. Due to the high sensitivity of this test, care should be taken to keep reagents and amplification mixtures free of contamination.
   a) Do not pipette by mouth.
   b) Do not eat, drink, or smoke in designated work areas.
   c) Wear laboratory gloves, laboratory coats, and eye protection when handling samples and reagents. Gloves must be changed between handling samples to prevent contamination. Avoid contaminating gloves when handling samples and controls.
   d) Wash hands thoroughly after handling. samples and kit reagents, and after removing the gloves.
   e) Thoroughly clean and disinfect all laboratory work surfaces.
   NOTE: Do not use sodium hypochlorite solution (bleach) to clean up a spill or to disinfect a plate before disposal as it can react with the common extraction reagents and generate toxic byproducts.
   If spills occur, follow internal procedures to immediately clean and decontaminate the surface of instrument.
2. A laminar flow or PCR Dead Air Box is recommended to reduce contamination probability.
3. The use of filtered, sterile and nuclease-free pipette tips is recommended.
4. False positive results may occur if carryover of samples is not adequately controlled during sample handling and processing.

Manufacturer of Record: Molecular Designs, LLC
2 Perimeter Park, Birmingham, AL 35243
www.moleculardesigns.com

molecular designs

Usage Information

Reaction Plate Setup

1. Remove a reaction plate from the -20°C manual defrost freezer.
2. For the Breakaway plates (P-COV096-001-A and P-COV096-002-A), determine the number of panels that will be used from the reaction plate, score the foil seal on the PCR break-away plates using the lab utility knife and tear the plate along the perforated edge between samples wells to obtain the number of panels needed. Ensure the excess panels on the plate are properly labelled and sealed and promptly place the remainder back in the -20°C freezer.
3. Use the plate within 1 hour of thawing, keep sealed and store refrigerated at 4°C if not using immediately.
4. Spin down the plate for 30 seconds in a plate centrifuge.
5. Carefully remove the foil seal from the plate.
6. Add 4.0 µL of the sample being tested to each of the target wells.
7. Do not add any additional liquid to the Positive Control. All components have been added to this well.
8. Add 4.0 µL of negative control (user provided) to the Negative Control B1 well.
9. If using a partial plate add 4.0 µL positive control to the positive control well. This is not needed for the initial run because positive control comes preloaded in A1.
10. If using a partial plate, add 4.0 µL nuclease-free water to the negative control well.
11. Seal the PCR plate using optical qPCR film. Note: If using a partial plate, remove the excess optical seal using the utility knife and ensure the plate is sealed.
12. Optional: vortex the plate, at least 5 seconds per plate quadrant.
13. Optional: spin down the plate in a plate centrifuge.

Procedural Notes

1. Do not reuse consumables. They are for one-time use only.
2. Always use caution when transferring specimens from a primary collection tube to a secondary tube.
3. Use pipettes with aerosol-barrier or positive-displacement tips to handle specimens.
4. Always use a new pipette tip for each specimen.
5. For testing of previously frozen sample, ensure samples are equilibrated to room temperature and well mixed prior to use.

Target Layout per panel (96-well plate, 94 panels per plate). See Page 5 for the complete layout of a 96-well plate)

1. Each well on the plate contains the COVID-19 panel master mix.
2. If using full plate:
   a) The Positive Control is plated in A1.
   b) The Negative Control is plated in B1.

   Note: No additional liquid needs to be added to the pre-plated PC. However, negative control needs to be added to B1.

3. If using partial plates, positive and negative controls can be prepared by plating 4 µL of the positive control and 4 µL of the negative control in the wells chosen.

4. We recommend that positive is setup on the left top and next to it negative is setup.

Following fluorophores are used: FAM for SARS-CoV-2; and CAL-Fluor Red 610 for Ribonuclease P

Manufacturer of Record: Molecular Designs, LLC
2 Perimeter Park, Birmingham, AL 35243
www.moleculardesigns.com

Usage Information

Real-Time PCR Detection System qPCR Run Setup

1. Open the specified run template and fill in the sample name fields with unique sample IDs corresponding to the samples being processed.
2. **NOTE:** This step can also be done prior to reaction plate setup if sample IDs have already been specified.
3. Place the reaction plate into the instrument in the appropriate orientation (A1 in the upper left corner), close the instrument lid and initiate the run.
4. **NOTE:** When running a partial plate, a balance is required at the other side of the instrument to ensure that the lid is sealed properly and doesn't break the instrument.

Thermocycling Protocol

1. Reverse Transcription
   a) 5 minutes at 50°C
2. Denaturation
   a) 3 minutes at 95°C
3. Annealing and Extension
   40 cycles consisting of:
   a) 5 seconds at 95°C
   b) 30 seconds at 60°C, with fluorescence acquisition during this step

Amplification Interpretation and Troubleshooting

1. The laboratory should establish cycle threshold (CT) cutoffs as appropriate for their sample workflow and procedures. It is recommended that CT cutoffs are determined during the validation of the test.
2. The laboratory should evaluate the curve shape when considering whether a sample with a given CT should be considered positive:
   a) Plate sealing issues can lead to jagged curve shapes or rising/decreasing baselines that lead to inaccurate data (erroneous CT value).
   b) Inappropriate mixing or centrifuging can lead to inaccurate data.
3. If user suspects contamination, it is recommended to clean and disinfect the laboratory area and re-test to ensure proper results.
4. Any failure of the positive or negative control should require a repeat run. If the control failure continues, it is recommended to have the qPCR instrument and the sample extraction workflow evaluated to ensure they are functioning properly.

Manufacturer of Record: Molecular Designs, LLC
2 Perimeter Park, Birmingham, AL 35243
www.moleculardesigns.com

COVID-19 *Simplicity Panel*™ 96-Well - EUA
94 panels

	1	2	3	4	5	6	7	8	9	10	11	12
A	**Positive Control**	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)
B	**Negative Control**	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)
C	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)
D	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)
E	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)
F	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)
G	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)
H	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)	SARS-CoV-2/ **RP** (CFR)

Manufacturer of Record: Molecular Designs, LLC
2 Perimeter Park, Birmingham, AL 35243
www.moleculardesigns.com

molecular designs