Direct PCR Buffer

Product Specification Sheet

RUO Product*

Product Description:

The Molecular Designs Direct PCR Buffer is the fastest and easiest way of getting high quality samples prepared for molecular testing. The Direct PCR sample preparation process minimizes the cost, time, and equipment required compared to traditional sample purification.

The Direct PCR Buffer and the following procedure has been designed and developed to work with the following panel offered by Molecular Designs:

COVID/Flu/RSV *Simplicity Panel*™ (Product #P-SABR096-001-A)

Product Information	
Direct PCR Buffer	
Part Number	S-DPCR008-001-A
Number of Reactions	384
Storage Temperature	-25°C to -15°C

Product Specifications	
QC Test	Functional QC with qPCR Cycle Threshold and percent CV Requirements
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

For Research Use Only. Not for use in diagnostic procedures.

Product Guarantee

This product 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 Direct PCR Buffer more than 3 times

The Following is Included:

1. Tubed Direct PCR Buffer
2. Strip tubes for Direct PCR Reaction

The Following is Supplied by the User: Materials

1. Sample to be tested
2. Negative control sample, if necessary

Equipment

1. Manual defrost -20°C freezer
2. Biosafety Cabinet
3. Laminar Flow or PCR Dead Air Box for general setup. Do not use Laminar Flow for infectious samples
4. Pipettes and appropriate filtered pipette tips
5. Plate Vortex [recommend Vortex Genie 2 (Model G560) with the 3-inch platform and rubber cover]
6. Mini centrifuge with strip tube rotor (3000-6000 RPM) Recommended
7. Plate centrifuge
8. Lab utility knife
9. Strip tube rack

Instrumentation

1. Thermocycler (non-RT-PCR with 0.2 mL block), 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 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 biosafety cabinet is recommended for handling infectious agents.
3. A laminar flow or PCR Dead Air Box is recommended to reduce contamination probability.
4. The use of filtered, sterile and nuclease-free pipette tips is recommended.
5. False positive results may occur if carryover of samples is not adequately controlled during sample handling and processing.

Please contact Molecular Designs for more information
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Usage Information

Sample Information

1. Sample being tested should be a fresh sample collected into Liquid Amies Viral Transport Medium

Recommended: Puritan Opti-Swab Liquid Amies Media Transport System (Puritan Part # LA106 or LA116), or equivalent.

2. Use of other transport media for sample collection (e.g., VTM, Saline) has not been verified and is not recommended.
3. Fresh sample should be stored at 4°C for up to 5 days before testing.
4. It is not recommended to test frozen/thawed samples using this procedure.

Direct PCR Reaction Setup

1. Determine the number of Direct PCR reactions that will be needed.
2. Each tube of Direct PCR Buffer contains enough volume for six samples. Remove the appropriate number of Direct PCR Buffer tubes. Snap off no more than the number of tubes needed to prevent unnecessary freeze-thaw of the Direct PCR Buffer.
3. Thaw at room temperature. Return any remaining Direct PCR Buffer to -20°C for later use.
4. Thaw the Direct PCR Buffer at room temperature until clear.
5. Dispense 75.0 µL of the Direct PCR Buffer into the determined number of strip tubes (or equivalent). 1 tube per sample.
6. Gently vortex the sample at room temperature. Add 25.0 µL of the sample to the Direct PCR Buffer into the strip tubes.
7. Pulse vortex the strip tubes on the plate vortex.
8. Briefly spin down the tubes in the Mini centrifuge with strip tube rotor (approximately 3000-6000 RPM).
9. Proceed to the Direct PCR Reaction Heating Procedure

Direct PCR Reaction Heating Procedure

1. This procedure can be run on a thermocycler or an equivalent instrument capable of the following temperature protocol:

1. Initial Reaction Hold:
   5 minutes at 65°C
2. Reaction Inactivation:
   2 minutes at 98°C
3. Room Temperature Normalization:
   Permanent Hold at 20°C

Direct PCR Reaction Notes

1. The Direct PCR Reaction will be ready for addition into the PCR reaction plates after it progresses to the Room Temperature Normalization step in the Heating Procedure (Permanent Hold at 20°C). Recommended for use with COVID/Flu/RSV *Simplicity Panel*™ (Product #P-SABR096-001-A).
2. The Direct PCR Reaction should be used within 4 hours if stored at room temperature.
3. The Direct PCR Reaction can also be stored at 4°C for up to 4 hours after completion of the Heating Procedure if preferred.
4. The Direct PCR Reaction can be stored at -20°C for up to 5 days for additional testing that may be required.

NOTE: It is not recommended to store the Direct PCR Reaction at room temperature or 4°C for longer than 4 hours. Reaction should be moved to -20°C for storage beyond 4 hours.

4. The Direct PCR Reaction stored at -20°C can be freeze-thawed up to 4 times for repeat testing.

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