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DOC-CTNG-INSERT-D

CT/ NG Microbiota *Simplicity Panel™* 96-Well

Product Specification Sheet

RUO Product*

Product Description:

The CT / NG Microbiota *Simplicity Panel™* (*Chlamydia trachomatis and Neisseria gonorrhoeae* Panel) is an *in-vitro* real-time polymerase chain reaction (RT-PCR) assay for the identification of nucleic acids from *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. This method is highly accurate, extremely sensitive, and is used
to identify these organisms by amplifying and detecting genetic material of pathogens in samples. The panel will aid the research of causative agents of infections due to sexually transmitted organisms and their prevalence.

The target organisms included in the panel are as follows:
Chlamydia trachomatis, and *Neisseria gonorrhoeae*.

Product Information	
CT/ NG Microbiota *Simplicity Panel™* (96-Well Plate)	
Part Number	P-CTNG096-001-A
Number of Panels	24
Positive Control	*Chlamydia trachomatis*
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

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

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.
3. Minimize light exposure to the plate to prevent photobleaching of the probe.

The Following is Included in the Kit:

1. 96-well PCR plate pre-loaded with the CT/NG *Simplicity Panel*™ 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. Pipette 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.

Please contact Molecular Designs for more information
2 Perimeter Park, Birmingham, AL 35243
www.moleculardesigns.com

Usage Information

Reaction Plate Setup

1. Remove a reaction plate from the -20°C manual defrost freezer.
2. 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 labeled and sealed and promptly place the remainder back in the -20°C freezer.
3. Each column is sufficient to test 2 samples. However, one column would be needed if testing single sample due to configuration of positive and negative controls.
4. Use the plate within 1 hour of thawing, keep sealed and store refrigerated at 4°C if not using immediately.
5. Spin down the plate for 30 seconds in a plate centrifuge.
6. Carefully remove the foil seal from the plate.
7. Add 4.0 µL of the sample being tested to each of the target wells.
8. Do not add any additional liquid to the Positive Control All components have been added to these wells.
9. Add 4.0 µL of negative control (user provided) to the Negative Control well
10. 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. Important: plate must be completely sealed to prevent evaporation and subsequently invalid results.
11. Optional: vortex the plate, at least 5 seconds per plate quadrant.
12. 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, 24 panels per plate). See Page 5 for the complete layout of a 96-well plate.

C. trachomatis	Panel 1
N. gonorrhoeae	
Endogenous Control	
C. trachomatis	Panel 2
N. gonorrhoeae	
Endogenous Control	
Positive Control	
Negative Control	

The fluorophore is FAM which will be detected on the qPCR instrument.

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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.

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CT/ NG Microbiota *Simplicity Panel*™ 96-Well 24 panels

	1	2	3	4	5	6	7	8	9	10	11	12
	Panels 1-2	**Panels 3-4**	**Panels 5-6**	**Panels 7-8**	**Panels 9-10**	**Panels 11-12**	**Panels 13-14**	**Panels 15-16**	**Panels 17-18**	**Panels 19-20**	**Panels 21-22**	**Panels 23-24**
A	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis
B	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae
C	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**
D	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis	C. trachomatis
E	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae	N. gonorrhoeae
F	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**	**Endogenous Control**
G	**Positive Control**	**Positive Control**	**Positive Control**	**Positive Control**	**Positive Control**	**Positive Control**	**Positive Control**	**Positive Control**	**Positive Control**	**Positive Control**	**Positive Control**	**Positive Control**
H	**Negative Control**	**Negative Control**	**Negative Control**	**Negative Control**	**Negative Control**	**Negative Control**	**Negative Control**	**Negative Control**	**Negative Control**	**Negative Control**	**Negative Control**	**Negative Control**

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