

Chlamydia Training Panel

Chlamydia Panel, 24 samples (0.6-mL fill volume)

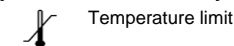
REF: 02-431024

For Training Use

Please contact Quidel Corporation Technical Support for technical assistance regarding this procedure.

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Symbols Lexicon/Glossary



Temperature limit



Consult e-labeling instructions for use



Manufacturer



Authorized representative in the European Community



Batch code/lot number



Catalog number



Use by YYYY-MON-DD



CE mark of conformity (Conformité Européenne)

Intended Use:

For Training use.

The *Chlamydia* panel is comprised of 24 frozen 0.6-mL liquid aliquots. Nine of these aliquots have been tested and confirmed to contain viable *Chlamydia trachomatis* strains that are used at varying infectious titers. The remaining fifteen aliquots have been tested and confirmed as negative. The panel has been designed for use with cell culture. The validation of this panel with non-cell culture systems is the responsibility of the end-user.

Principle:

Three *Chlamydia trachomatis* strains have been propagated in cell culture, diluted and frozen at -70° C. The actual titer in each aliquot is unknown, and has not been quantitatively assayed. Inoculation of this panel should be performed as described in the Product Insert or Instructions for Use of the system in which it will be used.

Storage and handling instructions:

It is recommended that the panel be stored at -70°C or lower. Once the panel has been thawed it should not be re-frozen.

Warnings and Precautions:

1. Personnel working with this panel must be properly trained in virus culture and safe handling techniques.¹
2. Manipulations which present potential personnel hazards should be conducted in a Class II hood with gloves worn at all times and in accordance with the guidelines presented in the CDC-NIH Manual.

¹ Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition, 2007, CDC-NIH manual.
<http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>

Virus Handling and Usage Instructions:

1. The Chlamydia panel should be transferred from the shipping container to a -70°C or lower freezer immediately upon receipt.
2. At the time of use, rapidly thaw the panel aliquots in a 35° to 37°C water bath.
3. Vortex the aliquots for 10-seconds prior to use.
4. Inoculate the panel aliquots without further dilutions. (200-µL is the recommended volume for inoculation)

Chlamydia Training Panel Key

Panel Member	Expected Result	Panel Member	Expected Result
1	Negative	13	Negative
2	<i>Chlamydia</i>	14	<i>Chlamydia</i>
3	<i>Chlamydia</i>	15	Negative
4	Negative	16	Negative
5	Negative	17	<i>Chlamydia</i>
6	<i>Chlamydia</i>	18	Negative
7	Negative	19	<i>Chlamydia</i>
8	<i>Chlamydia</i>	20	Negative
9	Negative	21	Negative
10	<i>Chlamydia</i>	22	Negative
11	Negative	23	<i>Chlamydia</i>
12	Negative	24	Negative

Warranty Statement

These products are warranted to perform as described in their labeling and the Diagnostic HYBRIDS literature when used in accordance with their instructions. THERE ARE NO WARRANTIES WHICH EXTEND BEYOND THIS EXPRESS WARRANTY AND DIAGNOSTIC HYBRIDS DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR WARRANTY OF FITNESS FOR PARTICULAR PURPOSE. Diagnostic HYBRIDS sole obligation and purchaser's exclusive remedy for breach of this warranty shall be, at the option of Diagnostic HYBRIDS to repair or replace the products.