

## Cellabs Product Profile




# CHLAMYDIA CEL

### INTENDED USE AND PRINCIPLE OF THE TEST

The Chlamydia Cel IF Test is a rapid *in vitro* direct immunofluorescence test for the detection and diagnosis of *Chlamydia trachomatis* organisms in patient specimens. The fluorescein-labelled mouse monoclonal antibody reagent binds specifically to *C. trachomatis* in the specimen.

### CONTENTS OF THE KIT

The Chlamydia Cel range is available in the 50 Test (KC1) kit format and separately as 200 Test Reagent, Positive Control Slide and Mounting Fluid. Note that the Chlamydia Cel Reagent has been optimised for use with Cellabs *C. trachomatis* Positive Control Slide and Mounting Fluid.

		KC1	Bulk
	Chlamydia Cel Reagent	1.25mL	5mL
	Positive Control Slide (Single Use only)	1	-
	Mounting Fluid	2.5mL	-
	<i>Tests</i>	<i>50</i>	<i>200</i>

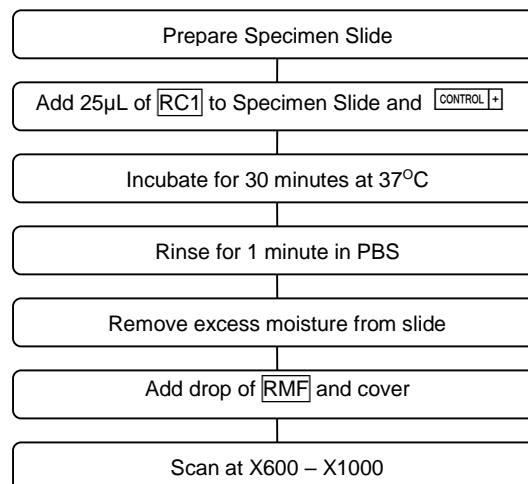
All components should be stored at 2-8°C, and are supplied ready for use. Expiry dates are clearly marked on each kit component and on the box and do not change once opened.

### MATERIALS REQUIRED BUT NOT PROVIDED

- Microscope slides with 6-8mm diameter wells
- Methanol for specimen fixation
- Precision pipette for delivering 25µL
- Humid chamber
- Wash bath
- Phosphate buffered saline (PBS) for washing step
- Cover slips
- Non-fluorescing immersion oil
- Fluorescence microscope with filter system for FITC (maximum excitation wavelength 490nm, mean emission wavelength 530nm) and x600-x1000 magnification

### DIAGRAM FOR USE

Use Cellabs Instructions for Use Insert contained in kit when performing test, and refer to Material Safety Data Sheet (MSDS) for further information.



### READING AND INTERPRETATION OF RESULTS AND DIAGNOSIS

*C. trachomatis* elementary bodies and reticulate bodies fluoresce bright apple green (with typical morphology) against a background of reddish/brown counterstained material. Results should be compared with the Positive Control Slide.



# Cellabs Product Profile

## PERFORMANCE DATA FOR CHLAMYDIA CEL

### Sensitivity/Specificity

A	n = 184 clinical specimens (180 female cervical, 4 male urethral). Chlamydia Cel versus another commercial Chlamydia IFA.	Sensitivity: 100% Specificity: 99.4%
B	n = 29 clinical specimens (6 female cervical, 23 male urethral). Chlamydia Cel versus another commercial Chlamydia IFA.	Sensitivity: 95.8% Specificity: 100%
C	n = 200 clinical specimens (62 female cervical, 138 male urethral).. Chlamydia Cel versus a commercial ELISA.	Sensitivity: 100% Specificity: 100%
D	n = 200 clinical specimens (62 female cervical, 138 male urethral). Chlamydia Cel versus another commercial Chlamydia IFA.	Sensitivity: 100% Specificity: 100%
E	n = 400 clinical specimens (332 female cervical, 68 male urethral). Chlamydia Cel versus coverslip culture.	Sensitivity: 100% Specificity: 99.5%
F	n = 270 clinical specimens (121 female cervical, 149 male urethral). Chlamydia Cel versus another commercial Chlamydia IFA.	Sensitivity: 100% Specificity: 100%
G	n = 315 clinical specimens. Chlamydia Cel versus primary culture.	Sensitivity: 100% Specificity: 100%

### Repeatability & Reproducibility

5 identical antigen samples were tested by 3 different operators and there was 100% correlation in the results.

### Cross reactivity

The Chlamydia Cel does not cross react with:

*Beta haemolytic Streptococcus group B*  
*Beta haemolytic Streptococcus group A*  
*Lactobacillus acidophilus*  
*Peptostreptococcus anaerobius*  
*Proteus mirabilis*  
*Escherichia coli*  
*Streptococcus faecalis*  
*Staphylococcus aureus*

*Pseudomonas aeruginosa*  
*Staphylococcus epidermidis*  
*Bacteriodes melaninogenicus*  
*Actinomyces israelii*  
*Gardnerella vaginalis*  
*Neisseria gonorrhoeae*  
*Candida albicans*  
*Trichomonas vaginalis*

### For Ordering Assistance:

See Your Local Distributor:

OR

Cellabs Pty Ltd  
 Unit 7, 27 Dale Street  
 Brookvale, NSW 2100 Australia  
 Tel: +61 2 9905 0133 Fax: +61 2 9905 6426  
 Web: <http://www.cellabs.com.au>  
 Email: [sales@cellabs.com.au](mailto:sales@cellabs.com.au)



0843  
Authorised Representative in the European Community:

WMDE  
 Bergerweg 18  
 6085 AT Horn  
 The Netherlands