

Cellabs Product Profile

PNEUMO CEL

INTENDED USE AND PRINCIPLE OF THE TEST

The Pneumo Cel IF Test is a rapid *in vitro* direct immunofluorescence test for the detection of *Pneumocystis carinii* (*P.jiroveci*) in human specimens. The fluorescein-labelled mouse monoclonal antibody reagent binds specifically to *P. carinii* (*P.jiroveci*) in the specimen. *P. carinii* (*P.jiroveci*) display bright green fluorescence with typical morphology.

CONTENTS OF THE KIT

The Pneumo Cel range is available in the 50 Test (KP1) kit format, 200 Test Reagent, Positive Control Slide and Mounting Fluid. Note that the Pneumo Cel Reagent has been optimised for use with Cellabs *Pneumocystis carinii* Positive Control Slide and Mounting Fluid.

			KP1	Bulk
RP1	Pneumo Cel Reagent		1.25mL	5mL
CONTROL +	Positive Control Slide (Single Use o	nly)	1	-
RMF	Mounting Fluid		2.5mL	-
		Tests	50	200

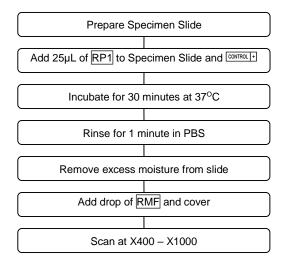
All components should be stored at 2-8°C, and are supplied ready for use. Expiry dates are clearly marked on each kit component and on the box and do not change once opened.

MATERIALS REQUIRED BUT NOT PROVIDED

- Microscope slides with 6-8mm diameter wells
- Acetone 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 x400-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.





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READING AND INTERPRETATION OF RESULTS AND DIAGNOSIS

Pneumocystis carinii (P.jiroveci) should exhibit bright, apple-green fluorescence of the round, thick-walled cysts and pleomorphic trophozoites in contrast to the reddish-brown colour of counterstained material. The organisms occur either singularly or more commonly in clusters in an extracellular matrix, which is also stained. The control slide should be used for comparison with the appearance and size of the organisms found in the specimens.

PERFORMANCE DATA FOR PNEUMO CEL

Sensitivity/Specificity

А	n = 60 clinical specimens. Pneumo Cel versus another commercial Pneumocystis IFA.	Sensitivity: 100% Specificity: 100%
В	n = 855 clinical specimens. Pneumo Cel versus another commercial Pneumocystis IFA.	Sensitivity: 100% Specificity: 100%
С	n = 148 sputum specimens. Pneumo Cel versus another commercial Pneumocystis IFA.	Sensitivity: 100% Specificity: 100%
D	n = 193 bronchoalveolar lavage samples. Pneumo Cel versus another commercial Pneumocystis IFA.	Sensitivity: 100% Specificity: 95.1%

Repeatability & Reproducibility

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

Cross reactivity

The Pneumo Cel does not cross react with:

Cryptococcus neoformans Candida tropicalis Saccharomyces cerevesiae Aspergillus niger Candida krusei Candida albicans

For Ordering Assistance:

See Your Local Distributor:

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



EC REP Authorised Representative in the European Community:

WMDE Bergerweg 18 6085 AT Horn The Netherlands