

PNEUMO CEL Indirect

INTENDED USE AND PRINCIPLE OF THE TEST

The Pneumo Cel Indirect IF Test is a rapid *in vitro* direct immunofluorescence test for the detection of *Pneumocystis carinii* (*P.jiroveci*) in human specimens. The monoclonal antibody reagent binds specifically to *P. carinii* (*P.jiroveci*) in the specimen. The second antibody, FITC-conjugated goat anti-mouse Ig, stains the *P. carinii* (*P.jiroveci*) displaying bright green fluorescence with typical morphology.

CONTENTS OF THE KIT

The Pneumo Cel Indirect range is available in the 50 Test (KP1) kit format, and separately in the 200 Test Reagents and Mounting Fluid. Note that the Pneumo Cel Indirect Reagents has been optimised for use with the Cellabs Mounting Fluid.

		KP1	Bulk
RP2	Pneumo Cel Reagent	1.25mL	5mL
RM	Anti-mouse Ig-FITC Reagent	1.25mL	5mL
RMF	Mounting Fluid	2.5mL	10mL
	Tests	50	200

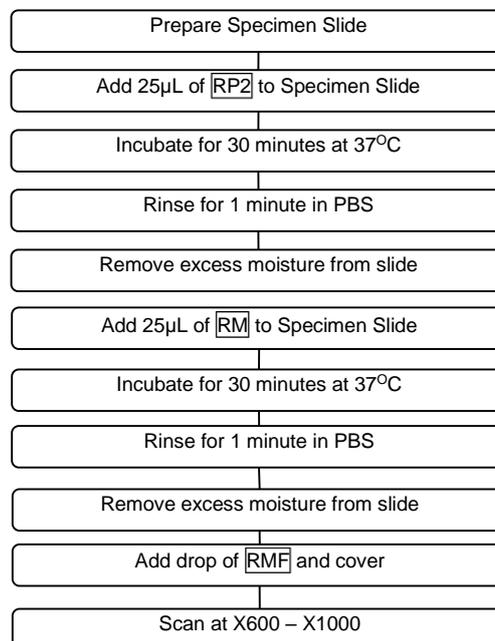
All components should be stored at 2-8°C, and are supplied ready for use. Expiry dates are clearly marked on each kit component and on the box and do not change once opened.

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. Note: The Pneumo Cel Indirect is not supplied with a positive control due to ethical considerations on the use of human derived material. End-users need to procure a suitable positive control for use in the test. The Pneumo Cel Indirect test has been released using a validated internal reference positive control.





Cellabs Product Profile

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

A	n = 60 clinical specimens. Pneumo Cel versus another commercial Pneumocystis IFA.	Sensitivity: 100% Specificity: 100%
B	n = 855 clinical specimens. Pneumo Cel versus another commercial Pneumocystis IFA.	Sensitivity: 100% Specificity: 100%
C	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:

OR

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