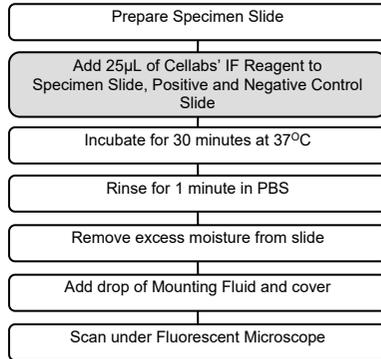
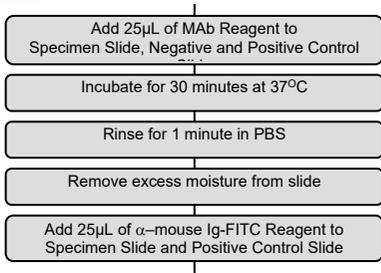


**FIGURE 1: NEGATIVE CONTROL SLIDE DIAGRAM FOR USE**  
Please refer to individual Cellabs IFA Kit Insert when performing test



**For Chlamydia Cel Pn IFA insert the following steps**



**EXPLANATION OF SYMBOLS**

- Consult Instructions for Use
- In Vitro Diagnostic Medical Device
- Temperature Limitation
- Batch
- Control Positive
- Use By/Expiration Date
- Do Not Re-use

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22 Nov 2023  
 0843



**NEGATIVE CONTROL SLIDE**

The following Instructions for Use provides information on Cellabs' Negative Control Slides.

**INTENDED USE AND PRINCIPLE OF THE DEVICES**

The Negative Control Slide is to be used as a control when performing an *in vitro* direct immunofluorescence test (using Cellabs Chlamydia and Crypto/Giardia IFA Reagent) for the detection and diagnosis of tropical and infectious organisms in patient specimens and environmental samples. Negative Control Slide (NCS) for a particular IFA reagent and test kit is manufactured to simulate a background or matrix that does not contain the specific organism of interest. The slides contain background material free from any organisms or non-viable basal cells. The control slide is used to compare negative test results visually. It also functions to demonstrate the specificity of the Cellabs IFA reagent where the background matrix shall not exhibit bright green fluorescence that resembles a particular organism.

**PACKAGING**

Negative Control Slide is individually packaged in a foil bag with one desiccant sachet, and is ready for use. There are 10 individual slides in one box. Store slides at 2-8°C. Expiry dates are clearly marked on each slide and do not change once opened.

**MATERIALS THAT MAY BE REQUIRED BUT ARE NOT PROVIDED**

Microscope slides with 6-8mm diameter wells for test samples; acetone or methanol for specimen fixation (refer to Kit insert or Reagent insert for which fixative to use); Cellabs' IF Reagent; precision pipette for delivering 25µL; humid chamber; wash bath; (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 x10-x1000 magnification.

**PRECAUTIONS**

For *in vitro* diagnostic use only. Do not use after the expiry date shown on the label. If protective packaging is damaged, contact your local distributor and ask for a replacement. Patient specimens should be handled as though potentially infectious. The negative control slide has been fixed and does not contain viable cells, however should always be handled as though potentially infectious. Use as a reference negative slide. Refer to Safety Data Sheet (SDS) for further information.

**SPECIMEN COLLECTION AND PREPARATION OF SPECIMEN SLIDES**

Refer to Kit Package Insert for detailed instructions on using this Negative Control Slide along with the Cellabs test kit or reagent and respective Positive Control Slide (PCS).

**INSTRUCTIONS FOR USE**

Refer to Kit Package Insert for detailed instructions on using Positive Control Slide with Cellabs IF Reagent. This negative control slide can be used for Chlamydia CEL IFA reagent and Crypto/Giardia IFA reagent.

**READING AND INTERPRETATION OF RESULTS AND DIAGNOSIS**

Refer to Kit Package Insert for reading and interpreting results of using Positive Control Slide and Mounting Fluid with Cellabs IF Reagent.

**WASTE DISPOSAL**

Dispose of any unused components as biohazardous waste. For more information, please refer to the MSDS.

**SENSITIVITY, SPECIFICITY, & OTHER DATA ON POSITIVE CONTROL SLIDE AND MOUNTING FLUID**

Not applicable.

**INDEMNITY NOTICE**

Modifications or changes made in the recommended procedure may affect the stated or implied claims. A positive or negative result does not preclude the presence of other underlying causative agents. Cellabs and its agents and distributors shall not be liable for damages under these circumstances.