5. DIRECT IMMUNOFLUORESCENCE

The IMAGEN Chlamydia test is a qualitative direct immunofluorescence test for the detection of Chlamydiaceae in clinical specimens and for the confirmation of Chlamydiae in cell culture.

2. SUMMARY

Chlamydiae are intracellular parasites closely related to Gram-negative bacteria. The genus Chlamydia contains three known species (Chlamydia trachomatis, C. pneumoniae and C. psittaci). The life cycle of Chlamydiae is complex and the structures that are recognized in infected human and animal cells are the intracellular reticulate bodies and the extracellular elementary bodies.

3. INTENDED USE

The following symbols have been used throughout the product instructions:

- **WARNING**: Use by date
- **CAUTION**: In vitro use
- **IMPORTANT INSTRUCTIONS**: Contains sufficient for <N> tests

The IMAGEN Chlamydia test is intended for use in the detection of Chlamydial bodies and to confirm the identity of Chlamydiae in clinical specimens. The test is designed to detect the following species of Chlamydia trachomatis, C. pneumoniae and C. psittaci.

1. INTENDED USE

- **Use by date**
- **In vitro use**
- **IMPORTANT INSTRUCTIONS**: Contains sufficient for <N> tests

Use by date: 20-22 April 2025

In vitro: All unused kit components are stored according to the following legislation.

3. PRINCIPLE OF THE TEST

The IMAGEN Chlamydia test Reagent contains a fluorescein isothiocyanate (FITC)-conjugated monoclonal antibody. The monoclonal antibody to Chlamydiae lipopolysaccharide antigen is specific for Chlamydiae and divides by binary fission approximately 104 Chlamydial elementary bodies and occupies 75% of the host cell volume. The reticulate body is concerned exclusively with the multiplication of Chlamydiae and divides by binary fission forming two reticulate bodies. Chlamydiae are non-motile and have no detectable extracellular forms of infectious material other than the elementary body. The reticulate body is the stage of Chlamydia within the host cell, infecting cells and growing to produce intracellular inclusions which contrast against the background of counterstained cell debris.

4. DEFINITIONS

- **Appearance of Chlamydial Bodies**
- **Antigen detection systems**
- **Clinical specimens**
- **Direct immunofluorescence techniques**
- **FITC**
- **Immunofluorescence**
- **IMAGEN Chlamydia problem kit**
- **IMAGEN Chlamydia test Reagent**
- **Immunofluorescence test**

5. REAGENTS PROVIDED

- **Control Slide**
- **Mounting Fluid**
- **Reagent**

The following symbols have been used throughout the product instructions:

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14.2.3 Cell Culture Confirmation

The IMAGEN Chlamydia test was evaluated as a culture confirmation test against 2 routinely used culture confirmation staining procedures (Giemsa and iodine). 132 uro-genital specimens were each inoculated on to 3 iododeoxyuridine treated McCoy cell cover slips (shell vial) monolayers. Monolayered monolayers were incubated at 37°C for 48 to 72 hours then fixed in methanol for 30 minutes. Fixed monolayers were stained with either Giemsa, iodine or the IMAGEN Chlamydia test Reagent. A specimen was scored positive when at least one stained intracytoplasmic inclusion was observed microscopically.

The results from this trial are shown in Table 14.2. Of 132 specimens tested, 56 (42%) developed inclusion bodies. Iodine staining detected Chlamydia in 46 of these specimens, Giemsa staining in 49 specimens and the IMAGEN Chlamydia in 56 specimens.

Table 14.2 Comparison of test results by cell culture and IMAGEN Chlamydia test on Ophthalmic Specimens

<table>
<thead>
<tr>
<th></th>
<th>IMAGEN Chlamydia</th>
<th>Cell Culture</th>
<th>Giemsa Staining</th>
<th>Iodine Staining</th>
<th>IMAGEN Chlamydia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Specimens</td>
<td>132</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>46</td>
<td>45</td>
<td>45</td>
<td>46</td>
<td>46</td>
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<tr>
<td>Negative</td>
<td>86</td>
<td>87</td>
<td>84</td>
<td>80</td>
<td>80</td>
</tr>
</tbody>
</table>

For all enquiries please contact your local distributor.