Key Code TSMX7847B
www.oxoid.com/ifu

Europe +800 135 79 135 US 1 855 2360 190
CA 1 855 805 8539 ROW +31 20 794 7071

IMAGEN Chlamydia

REF K610111-2 ..... Σ 50 **EN**

1. INTENDED USE

The IMAGEN™ Chlamydia test is a qualitative direct immunofluorescence test for the detection of Chlamydia in human uro-genital and ophthalmic specimens and for the confirmation of Chlamydiae in cell culture.

IVD - For *in vitro* diagnostic use. For professional use only.

2. SUMMARY

Chlamydiae are obligate intracellular parasites closely related to Gram negative bacteria[1]. The genus Chlamydia contains three known species *Chlamydia trachomatis (C. trachomatis), Chlamydia psittaci (C. psittaci)* and *Chlamydia pneumoniae (TWAR)*.

The life cycle of Chlamydiae is complex but two main structures are recognised, the infectious elementary body and the reticulate body. Infection of a cell is initiated by the elementary body adhering to the host cell surface and gaining entry into the cell by endocytosis. The elementary body enlarges within the vacuole formed by the host cell membrane and differentiates to form a reticulate body. The reticulate body is concerned exclusively with the multiplication of Chlamydiae and divides by binary fission utilising the host cell energy supply. Approximately 24 hours post-infection the reticulate bodies differentiate within the expanding inclusion to form elementary bodies. The replicative cycle lasts 48-72 hours and terminates with inclusion rupture and release of elementary bodies. A mature inclusion may contain approximately 10^4 Chlamydial elementary bodies and occupy 75% of the host cell volume.

C. trachomatis has been recognised as a frequent cause of sexually transmitted diseases[1,2] and has been shown to cause a variety of human infections, some of which may be asymptomatic.

In adults *C. trachomatis* can also cause acute or subacute follicular conjunctivitis which may progress to a punctate keratitis. Occasionally scarring and endemic trachoma may develop. Most of these symptoms develop in patients who have unrecognised genital infections[1,3]. Ophthalmia neonatorum is also a complication found in children born to an infected mother.

Anatomical sites usually sampled for the diagnosis of Chlamydia include the conjunctiva, endocervix and urethra. In males, particularly adolescents and asymptomatic males investigated after follow-up contact tracing, invasive urethral swabbing may not be possible. In such cases collection of first catch urine specimens and examination of the centrifuged deposit has been suggested[4]. Respiratory specimens (eg. sputum) have also been examined directly for detection of *C. psittaci* and *C. pneumoniae* in the investigation of respiratory infections[5,6].

Currently there are 3 main diagnostic methods used for the detection of Chlamydia in clinical specimens. Firstly, by isolation of the organism and visualisation, in which viable elementary bodies present in clinical specimens infect tissue culture cells and the resultant inclusions are detected by staining techniques eg. iodine or immunofluorescence. Secondly, by direct demonstration of Chlamydia in clinical specimens using a fluorescein labelled monoclonal antibody. Thirdly, by enzyme immunoassay (eg. IDEIA Chlamydia) to determine the presence of Chlamydia antigen in clinical specimens[7].

Direct immunofluorescence techniques utilising fluorescein labelled monoclonal antibodies[8,9,10] have been shown to have good correlation when compared to cell culture techniques for the detection of *C. trachomatis*.

The IMAGEN Chlamydia test is a direct immunofluorescence test for the detection and identification of Chlamydiae in clinical specimens or cell cultures. The test utilises a genus specific monoclonal antibody to chlamydia lipopolysaccharide antigen present in all known strains of Chlamydiae.

3. PRINCIPLE OF THE TEST

The IMAGEN Chlamydia test Reagent contains fluorescein isothiocyanate (FITC) conjugated monoclonal antibody. The genus specific monoclonal antibody will detect elementary bodies from all known human serovars of *C. trachomatis* as well as strains of *C. psittaci* and *C. pneumoniae*.

The conjugated antibody is used in a one step direct immunofluorescence technique. Specimens are incubated with the FITC conjugated Reagent for 15 minutes. Excess Reagent is then removed by washing with phosphate buffered saline (PBS), the stained areas are mounted and viewed using epifluorescence illumination. If Chlamydia are present within the clinical specimen they will be seen as bright apple-green flourescent elementary bodies which contrast against the background of counterstained material. Infected cell culture monolayers stained with the FITC conjugated monoclonal antibody will contain bright apple-green intracytoplasmic chlamydial inclusions which contrast against the background of counterstained cellular material.

Acknowledgement

The monoclonal antibody originated in the Department of Pathology, University of Cambridge, Cambridge, United Kingdom and the Division of Communicable Diseases, Clinical Research Centre, Harrow, Middlesex, United Kingdom.

4. DEFINITIONS

The following symbols have been used throughout the product information.

REF	Catalogue Number
IVD	*In Vitro* Diagnostic Medical Device
	Consult Instructions for Use (IFU)
	Temperature Limitations (Storage temp.)
Σ N	Contains sufficient for <N> tests
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)
	Manufactured by

5. REAGENTS PROVIDED

2°C–8°C

Each kit contains sufficient materials for testing 50 cell culture preparations. The shelf-life of the kit is as indicated on the outer box label.

5.1. IMAGEN CHLAMYDIA REAGENTS

Instructions For Use

POSITIVE CONTROL SLIDE — 2 x 1 well Positive Control Slide containing acetone-fixed mouse connective tissue cells (L929) infected with L_1 strain of *C. trachomatis*.

One bottle of each of the following:

MOUNTING FLUID — 3mL of Mounting Fluid. The Mounting Fluid contains a photobleaching inhibitor in a glycerol solution (pH10.0).

REAGENT — 1.4mL of IMAGEN Chlamydia test Reagent. The Reagent contains purified murine monoclonal antibody specific to the genus Chlamydia conjugated to FITC.

5.2. PREPARATION, STORAGE AND RE-USE OF KIT COMPONENTS

In order to ensure optimal kit performance, it is important that all unused kit components are stored according to the following instructions:

5.3. POSITIVE CONTROL SLIDES - POSITIVE CONTROL SLIDE

Positive Control Slides are provided individually in sealed foil pouches with nitrogen. Store unused slides at 2-8°C. The slide should be left for 5 minutes at room temperature (15-30°C) before opening.

Stain the slide immediately after opening.

5.4. MOUNTING FLUID - MOUNTING FLUID

Ready to use. Store unused Mounting Fluid at 2-8°C. The Mounting Fluid should be left at room temperature (15-30°C) for 5 minutes before use.

5.5. REAGENT - REAGENT

Ready to use. Store unused Reagent in the dark at 2-8°C. The Reagent should be left at room temperature (15-30°C) for 5 minutes before use.

6. ADDITIONAL REAGENTS

6.1. REAGENTS

Fresh acetone (for fixation)

Phosphate buffered saline (PBS) pH 7.5 for washing stained specimens and monolayers.

6.2. ACCESSORIES

The following products are intended for use in conjunction with IMAGEN Chlamydia. Contact your local distributor for further information.

Teflon coated glass microscope slides with single 6mm diameter well (100 slides per box) available from your local distributor, (Code No. S611430-6).

IMAGEN Chlamydia Positive Control Slides (Code No. S610930-2).

7. EQUIPMENT

The following equipment is required:

Precision pipette and disposable tips to deliver 25µL Wash bath

Coverslips suitable to cover 6mm diameter well

Non-fluorescing immersion oil

Epifluorescence microscope with filter system for FITC (maximum excitation wavelength 490nm, mean emission wavelength 520nm) and lenses for x200-x400 and x600-x1000 magnification

Incubator at 37°C

Low speed centrifuge

Cell Culture

Sterile swabs and transport medium suitable for the collection, transportation and culture of Chlamydiae

Cell culture lines recommended for isolation of Chlamydia

8. PRECAUTIONS

8.1. SAFETY PRECAUTIONS

8.1.1 The IMAGEN Chlamydia test Reagent contains <0.1% sodium azide, which is a poison. Sodium azide may react with copper and lead plumbing systems to form explosive metal azides. Always dispose of materials containing azide by flushing with large quantities of water.

8.1.2 Chlamydiae on the Positive Control Slide have been shown to be non-infectious in cell culture, however the slide should be handled and disposed of as though potentially infectious.

8.1.3 Evans blue dye is present in the Reagent. Although present below the concentration for the product to be classified as carcinogenic, contact with the skin should be avoided.

8.1.4 Care should be taken when using the Mounting Fluid as it it contains a known skin irritant.Although present below the concentration for the product to be classified as an irritant, skin should be flushed with water if contact occurs.

8.1.5 The IMAGEN Chlamydia test Reagent contains human immunoglobulin. This material has been shown to be negative for the presence of antibody to HIV, Hepatitis C and Hepatitis B surface antigen, nevertheless it should be handled with care and treated as potentially infectious.

8.1.6 Do not eat, drink, smoke, store or prepare foods, or apply cosmetics within the designated work area.

8.1.7 Do not pipette materials by mouth.

8.1.8 Wear disposable gloves while handling clinical specimens and infected cells, always wash hands after working with infectious materials.

8.1.9 Dispose of all clinical specimens in accordance with local legislation.

8.1.10 Safety data sheet available for professional user on request.

8.2. TECHNICAL PRECAUTIONS

8.2.1 Components must not be used after the expiry date printed on the labels. Do not mix or interchange different batches/lots of Reagents.

8.2.2 The Reagents are provided at fixed working concentrations. Assay performance will be adversely affected if the Reagents are stored under conditions other than those detailed in Section 5.

8.2.3 Prepare fresh Phosphate Buffered Saline (PBS) as required on the day of use.

8.2.4 Washing in PBS is necessary. Use of other wash solutions such as tap water or distilled water will compromise test results.

8.2.5 Avoid microbial contamination of Reagents.

8.2.6 The Reagents must not be frozen.

9. COLLECTION AND PREPARATION OF SPECLMENS[7,8]

Specimens collected from the male urethra, female cervix and from conjunctiva must contain as many epithelial cells as possible as Chlamydiae are intracellular organisms that infect epithelial surfaces[1].

9.1. CLINICAL SPECIMENS

9.1.1 Urethral specimens (male)

Swab urethra by inserting an alginate or cotton wool-tipped thin swab, 2-4cm into the urethra. Rotate the swab several times and withdraw from the urethra.

9.1.2 Cervical specimens (female)

Before sampling the endocervix clean the cervical os with sterile gauze to remove excess mucus, blood/pus etc. Swab endocervix by using alginate or cotton wool-tipped swab or a cytology brush approximately 1cm into the cervical canal. Rotate several times at the squamo-columnar epithelial junction and withdraw the swab without touching vaginal surfaces.

9.1.3 Ophthalmic specimens

Apply local anaesthetic to the eye, then expose upper and lower conjunctiva. Using a cotton or Dacron® tipped swab vigorously wipe both upper and lower conjunctival surfaces, rotating the swab during the sampling process to ensure that the entire conjunctival surface is sampled.

NOTE: The Chlamydia Specimen Collection Kit (see Section 6.2) is suitable for the collection of the above specimens.

9.1.4 Preparation of slides

Roll the specimen swab, using slight pressure, within the 6mm well area on the microscope slide. Ensure that the whole swab tip is used to prepare the slide. Allow the specimen to air dry thoroughly at room temperature (15-30°C) and then fix in fresh acetone for 10 minutes. Allow the slide to air dry. If the specimen is not stained immediately store at 4°C overnight or freeze at –20°C for up to 2 months.

9.2. CELL CULTURE MONOLAYERS

Remove medium from surface of the monolayer. Do not allow the cells to dry as inclusion bodies may burst. Immediately fix monolayer in fresh methanol for 10 minutes then carefully blot dry using blotting paper.

Fixed monolayers should be stained immediately, however they may be stored at 4°C overnight prior to staining.

10. TEST PROCEDURE

PLEASE REFER TO SECTION 8.2 TECHNICAL PRECAUTIONS BEFORE PERFORMING TEST PROCEDURE.

10.1. ADDITION OF REAGENT

Add 25µL of Reagent to the fixed specimen smear (see Section 9.1), fixed cell culture monolayer (see Section 9.2) or the Positive Control Slide. Ensure that the Reagent covers the entire well area.

10.2. FIRST INCUBATION

Incubate the slides with Reagent in a **moist chamber** for **15 minutes** at **37°C**. **Do not** allow the Reagent to dry on the specimen, as this will cause the appearance of non-specific staining.

10.3. WASHING THE SLIDE

Wash off excess Reagent with Phosphate Buffered Saline (PBS) then gently wash the slide in an agitating bath containing PBS for 5 minutes. Drain off PBS and allow the slide to air dry at room temperature (15-30°C).

10.4. ADDITION OF MOUNTING FLUID

Add one drop of Mounting Fluid to the centre of each well and place a coverslip over the Mounting Fluid and specimen ensuring that no air bubbles are trapped.

10.5. READING THE SLIDE

Examine the entire well area containing the stained specimen using an epifluorescence microscope. Fluorescence, as described in Section 11, should be visible at x600–x1000 magnification. (For best results slides should be examined immediately after staining, but may be stored at 2-8°C, in the dark, for up to 24 hours).

11. INTERPRETATION OF TEST RESULTS

11.1. CONTROLS

11.1.1 Positive Control Slides

When viewed as described in Section 10, the Positive Control Slide should show extracellular elementary bodies (EBs) which appear as very small bright apple-green fluorescent smooth edged disc shapes approximately 300nm in diameter. EBs can be observed against a background of red counterstained cells and cellular debris. Other chlamydial forms 2-3 times larger than EBs may be seen, some of which fluoresce evenly or possess dark centres surrounded by a halo of apple-green fluorescence. These may be intermediate forms of chlamydia or reticulate bodies. Occasionally, large brightly fluorescent intact intracytoplasmic chlamydial inclusions may be observed.

11.1.2 Negative Control

If a negative control is required, uninfected intact or ruptured cells of a type used for the culture and isolation of Chlamydia are recommended. The cells should be prepared and fixed as described in Section 9.2 and stained as described in Section 10.

11.2. CLINICAL SPECIMENS

11.2.1 Appearance of Chlamydial Bodies

Extracellular elementary bodies are the most common form of chlamydia in clinical specimens and appear as bright apple- green smooth edged bodies approximately 300nm in diameter as described in Section 11.1.1.

11.2.2 Interpretation of Results

A positive diagnosis is made when fixed, stained specimens show at least 10 chlamydial bodies. This level is recommended in order to reduce false positive results due to misinterpretation of non-specific fluorescence. Counterstained cells must be visible in a well before negative results are reported. These cells may be intact or ruptured columnar and squamous epithelial cells or occasionally polymorphonuclear leucocytes. The absence of cellular material may indicate poor quality of specimen collection and repeat sampling is recommended.

11.2.3 Non-specific Fluorescence

Irregularly shaped material that differs in morphology from the chlamydia bodies described in Section 11.1.1. which fluoresces white, red or yellow rather than apple-green should be considered as non-specific staining.

11.3. CELL CULTURE CONFIRMATION

11.3.1 Appearance of Chlamydial Inclusions

Intracellular chlamydia inclusions appear as bright apple-green sacs within the cytoplasm of infected cells. An inclusion may occupy up to 75% of the host cell cytoplasm.

11.3.2 Interpretation

A positive diagnosis is made when one or more stained intracellular chlamydia inclusion is seen in the monolayer.

12. PERFORMANCE LIMITATIONS

12.1. The visual appearance of the fluorescence image obtained may vary due to the type of microscope and light source used.

12.2. Use only the Mounting Fluid provided.

12.3. It is recommended that 25µL of Reagent is used to cover a 6mm diameter well area. A reduction in this volume may lead to difficulties in covering the specimen area and may reduce sensitivity.

12.4. All Reagents are provided at fixed working concentrations. Test performance may be affected if the Reagents are modified in any way or not stored under the recommended conditions as outlined in Section 5.

12.5. Failure to detect chlamydia in cell culture may be a result of factors such as collection of specimen at an inappropriate time of disease, improper sampling and/or handling of specimen, failure of cell culture etc. A negative result does not exclude the possibility of chlamydial infection.

12.6. Antigen detection systems such as IMAGEN Chlamydia should not be used to provide information for medico-legal cases. Only standard chlamydia cultures should be used in the evaluation of suspected abuse or other situations in which the possibility of a false positive result with antigen detection systems is unacceptable[11].

12.7. The presence of chlamydia in clinical specimens does not necessarily exclude the possibility of concomitant infection with other pathogens. Test results should be interpreted in conjunction with information available from epidemiological studies, clinical assessment of the patient and other diagnostic procedures.

13. EXPECTED VALUES

The prevalence of Chlamydia infections in a study population will vary according to the type of population studied[1,2]. The prevalence of uro-genital Chlamydia infection for unselected patients attending a genito-urinary medicine clinic will vary between 10% to 25%. For patients attending with non-specific urethritis and post-gonococcal urethritis the prevalence may be as high as 30% to 60%.

A lower prevalence of uro-genital Chlamydia infection (less than

10%) may be found in populations of patients attending obstetric and gynaecology clinics[1,12].

The prevalence of ophthalmic Chlamydia infections may vary between 5% to 20% in studies of paratrachoma (inclusion conjunctivitis)[1,9].

14. REACTIVITY PERFORMANCE CHARACTERISTICS

14.1. SPECIFICITY OF THE MONOCLONAL ANTIBODY

The monoclonal antibody utilised in the IMAGEN Chlamydia Reagent has been shown to react with an epitope of chlamydial lipopolysaccharide antigen common to all strains of Chlamydiae.

Non specific staining is sometimes observed in immunochemical staining due to binding between antibody Fc regions and protein A produced by some strains of *Staphylococcus aureus*. The IMAGEN Chlamydia Reagent has been designed to reduce such binding.

14.2. CLINICAL PERFORMANCE[13]

14.2.1 Uro-Genital Specimens

The IMAGEN Chlamydia test was evaluated in 2 routine diagnostic laboratories against established cell culture systems (Giemsa staining of pre-treated McCoy cell monolayers after primary culture with specimens). Urethral and cervical specimens were collected from unselected patients attending sexually transmitted disease clinics. The incidence of Chlamydia infection in the population groups sampled ranged from 10 to 20%. Smears were made from specimen swabs at the clinic and the swabs were then placed in transport medium for cell culture evaluation. A specimen was scored positive in the IMAGEN Chlamydia test when 10 or more fluorescing bodies were observed (see Section 11.2.2).

A specimen was scored positive in the cell culture test when at least one stained intracytoplasmic chlamydial inclusion was observed.

The results from 2 trials are shown in Table 14.1. Of the 935 specimens tested, the same result was obtained by both methods in 898 cases, a correlation of 96%. The overall sensitivity and specificity of the IMAGEN Chlamydia test was 92% and 97% respectively, assuming that the cell culture methods were 100% sensitive and specific. The predictive values for positive and negative tests were 84% and 98% respectively.

Table 14.1 Comparison of test results by cell culture and IMAGEN Chlamydia test on Uro-Genital Specimens

TEST	RESULT			
Cell Culture	Negative	Positive	Positive	Negative
IMAGEN Chlamydia	Negative	Positive	Negative	Positive
Centre 1	337	74	4	17
Centre 2	427	60	8	8
Total	764	134	12	25

14.2.2 Ophthalmic Specimens

The IMAGEN Chlamydia test was evaluated in a routine diagnostic laboratory against an established cell culture system (Giemsa staining of pre-treated McCoy cell monolayers after primary culture with specimens).

Conjunctival swabs were collected from 178 patients with acute follicular conjunctivitis attending an eye hospital; 163 were aged 13-55 years, 3 were babies (10 weeks-12 months) and 12 were neonates (12 days-4 weeks). The incidence of Chlamydia infection in the population group sampled was 8%. Smears were made from specimen swabs at the clinic and the swabs then placed in transport medium for cell culture evaluation.

A specimen was scored positive in the IMAGEN Chlamydia test when 10 or more fluorescing bodies were observed (see Section 11.2.2). A specimen was scored positive in the cell culture test when at least one stained intracytoplasmic inclusion was observed.

The results from this trial are shown in Table 14.2. Of 178 specimens tested, the same result was obtained by both methods in 174 cases, a correlation of 98%. The sensitivity and specificity of the IMAGEN Chlamydia test was 100% and 97.5% respectively, assuming that the cell culture method was 100% sensitive and specific. The predictive values for positive and negative tests were 79% and 100% respectively.

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

TEST	RESULT			
Cell Culture	Negative	Positive	Positive	Negative
IMAGEN Chlamydia	Negative	Positive	Negative	Positive
Number of Specimens	159	15	0	4*

* These specimens were taken from patients undergoing antibiotic therapy. This may have compromised the cell culture result[9].

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 coverslip (shell vial) monolayers. Inoculated monolayers were incubated at 37°C for 48 to 72 hours then fixed in methanol for 10 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 14.3. 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 14.3 Comparison of staining methods for the detection of Chlamydial inclusions in shell vial culture

TEST	RESULT				
IMAGEN Chlamydia	Positive	Negative	Positive	Positive	Positive
Giemsa Staining	Positive	Negative	Negative	Positive	Negative
Iodine Staining	Positive	Negative	Negative	Negative	Positive
Number of Specimens	42	76	3	7	4

14.3. CROSS REACTIVITY

The monoclonal antibody used in the IMAGEN Chlamydia has been shown to be non-reactive to the following micro-organisms.

Acholeplasma laidlawii
Acinetobacter calcoaceticus var anitratus
Aeromonas hydrophila
Bacteroides fragilis
Bacillus cereus
Campylobacter coli
Candida albicans
Citrobacter freundii
Clostridium perfringens
Clostridium difficile
Enterobacter cloacae
Enterococcus faecalis
Escherichia coli
Gardnerella vaginalis
Haemophilus influenzae
Klebsiella aerogenes
Mycoplasma arginini
Mycoplasma hyorhinis
Mycoplasma pneumoniae
Mycoplasma genitalium
Neisseria gonorrhoeae
Peptococcus sp
Peptostreptococcus anaerobius
Proteus mirabilis
Pseudomonas aeruginosa
Salmonella minnesota
Serratia marcescens
Shigella sonnei
Staphylococcus epidermidis
Staphylococcus aureus
Streptococcus agalactiae
Streptococcus dysgalactiae
Streptococcus pyogenes
Streptococcus dysgalactiae subsp. equisimilis
Lactobacillus lactis
Streptococcus pneumoniae
Listeria monocytogenes
Ureaplasma sp
Mycoplasma orale
Veillonella spp
Mycoplasma hominis

Viruses

Herpes simplex virus

15. REFERENCES

1. **Chlamydial Disease (1983)**
   Ed. Darougar S
   British Medical Bulletin **39**: 107-203.
2. **Schachter, J. and Dawson, C.R. (1979)**
   Psittacosis - lymphogranuloma venereum agents/TRIC agents.
   In: Diagnostic procedures for viral, rickettsial and chlamydial infections. Eds: Lennene, E.H., and Schmidt, N.J.
   5th edition. American Public Health Association. 1021-1059.
3. **Goh, B. (1988)**
   Chlamydia trachomatis genital infection.
   The Practitioner **232**: 813-818.
4. **Caul, E.O., Paul, I.D., Milne, J.D. and Crowley, T. (1988)**
   Non-invasive sampling method for detecting *Chlamydia trachomatis*. *Lancet* **11**: 1246-1247.
5. **Sillis, M. and White, P. (1990)**
   Rapid identification of *Chlamydia psittaci* and TWAR (*C. pneumoniae*) in sputum samples using an amplified enzyme immunoassay.
   Journal Clinical Pathology **43**: 260-262.
6. **Hammerschlag, M.R. (1992)**
   Chlamydia pneumoniae: A New Respiratory Pathogen. Infectious Diseases Newsletter, **Vol 11**: No 1, January 1992.
7. **Pugh, S.F., Slack, R.C.B., Caul, E.O., Paul, I.D., Appleton, P.N. and Gatley, S. (1985)**
   Enzyme amplified immunoassay: A novel technique applied to direct detection of Chlamydia trachomatis in clinical specimens.
   Journal of Clinical Pathology **38**: 1139-1141.
8. **Alexander, I., Paul, I. D. and Caul, E.O. (1985)**
   Evaluation of a genus reactive monoclonal antibody in rapid identification of Chlamydia trachomatis by direct immunoflourescence.
   Genitourinary Medicine **61**: 252-254.
9. **Potts, M.J., Paul, I.D., Roome, A.P.C.H. and Caul, E.O. (1986)**
   Rapid diagnosis of Chlamydia trachomatis infection in patients attending an ophthalmic casualty department.
   British Journal of Ophthalmology **70**: 677-681
10. **Thornley, M.J., Zamze, S.E., Byrne, M.D., Lusher, M. and Evans, R.T. (1985)**
    Properties of monoclonal antibodies to the genus specific antigen of Chlamydia and their use for antigen detection by reverse passive haemagglutination.
    Journal of General Microbiology **131**: 7-15.
11. **CDC Report (1991)**
    False-Positive Results with the Use of Chlamydia Test in the Evaluation of Suspected Sexual Abuse - Ohio, 1990.
    Morbidity and Mortality **39**: 932-935.
12. **Chlamydial Infections (1986)**
    Eds Oriel, D., Ridgway, G., Schachter, J., Taylor-Robinson, D., and Ward, M.
    From Proceedings of the Sixth International Symposium on Human Chlamydial infections. Cambridge University Press.
13. **Galen, R.S. (1982)**
    Application of the Predictive Value Model in the analysis of test effectiveness. In: Clinics in Laboratory Medicine. Symposium on Test Selection Strategies. Volume 2. W B Saunders Company 685-699.

CE
2797

IFU X7847B updated July 2020 Printed in the UK

Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, UK

For all enquiries please contact your local Oxoid subsidiary or distributor.