



Clearview[®] Chlamydia MF

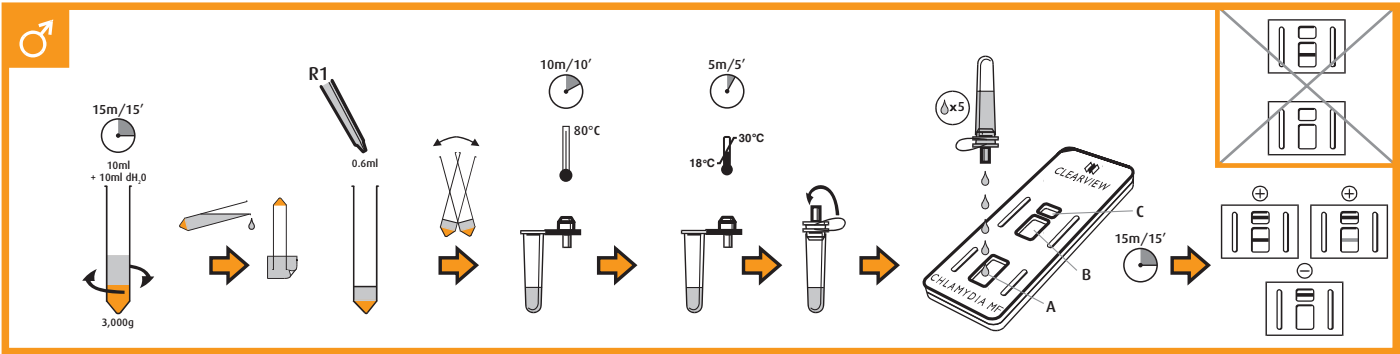
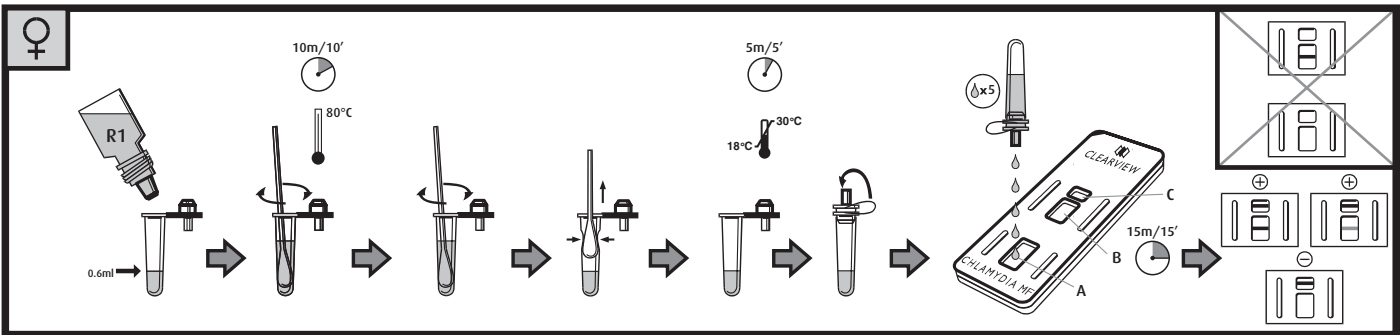
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Clearview® Chlamydia MF

Intended Use

Clearview Chlamydia MF is a rapid immunoassay for the direct qualitative detection of *Chlamydia trachomatis* antigen in either female endocervical swab specimens or male urine specimens. It is intended for in vitro diagnostic use only.

Introduction

Chlamydia trachomatis is the etiological agent in a number of sexually transmitted diseases. *Chlamydia trachomatis* infections are often asymptomatic, and if left untreated can cause pelvic inflammatory disease in women (a leading cause of infertility), permanent eye damage and pneumonia in neonates, and epididymitis in men (which may also lead to infertility)^{1,2}. Therefore a simple diagnostic test is an essential tool in the effective management of *Chlamydia*. **Clearview Chlamydia MF** provides a rapid and simple direct detection assay for chlamydial antigen in male and female specimens, without the need for expensive equipment or training.

Test Principle

Chlamydial antigen is extracted from the swab or urine specimen by heating at 80°C with R1 (extraction reagent). Following extraction the only step required is to add the extract to the absorbent pad in the Sample Window (A). The absorbent pad contains coloured microspheres attached to genus-specific anti-*Chlamydia* monoclonal antibodies. The extract mobilises these microspheres, and moves up the attached test strip. The test strip contains a region of immobilised monoclonal anti-*Chlamydia* antibody in the Result Window (B). If the extract contains chlamydial antigen, it will complex with the antibodies attached to the coloured microspheres, and the immobilised antibodies in the Result Window. Therefore a line will form in the Result Window if chlamydial antigen is present in the extract. If no antigen is present, the Result Window will remain clear. **Clearview Chlamydia MF** also

provides an integral control feature; the appearance of a line in the Control Window shows the test has worked correctly.

Precautions

- Standard guidelines for handling and disposal of infectious agents and chemical reagents should be observed throughout all procedures. Dispose of all contaminated waste properly.
- Do not mix kit components from different lots.
- Do not mix reagent bottle caps.

Kit Contents and Storage

Each **Clearview Chlamydia MF** kits contains sufficient materials for 20 tests:

- 3 x 5ml R1 (extraction reagent)
- 1 x 1ml R2 (positive control containing non-infective chlamydial antigen)
- 20 individually foil-wrapped devices
- 20 extraction tubes

Clearview Chlamydia MF kits must be stored at 2-8°C.

Do not use after the stated expiry date.

Materials required but not provided:

- 80°C ($\pm 2^\circ\text{C}$) Heating source e.g. **Clearview Workstation** 220/240 volt (Cat. No. 500185), 240 volt (UK) (Cat. No. 500189), or 120 volt (Cat No 500200).
- **Clearview Chlamydia Female Specimen Collection Kit** (for female endocervical swab specimens) (Cat. No. 500168).
- 30ml v-based centrifugation tubes and centrifuge (for male urine specimens).

Specimen Collection & Storage

Female Endocervical Swabs

The correct specimen collection technique is very important. Use only the **Clearview Chlamydia Female Specimen Collection Kit** (Code 500168). The following technique is recommended to ensure an adequate specimen:

- Remove excess mucus from the exocervix with a separate swab or cotton ball and discard.
- Insert the swab into the endocervix and rotate against the surface of the cervical canal for 10 to 30 seconds. Avoid touching any vaginal surface when withdrawing the swab.
- Return the swab to the transportation tube and label with patient identification and date. Swabs may be transported to the test site under ambient conditions. Transport media should not be used.

If the specimen is not to be tested within 1 day, store at 2-8°C for up to 5 days. Do not freeze.

Male Urine Specimens

The patient should be instructed not to urinate for at least one hour prior to specimen collection. Approximately 20-30mls of first catch urine should be collected into a clean and dry container.

If the specimen is not to be tested within 6 hours, store at 2-8°C for up to 5 days. Do not freeze.

Assay Procedure

Ensure that the heating apparatus is at 80°C ± 2°C, and all reagents, devices and specimens are at 18-30°C before beginning the assay.

Extraction – Female Endocervical Swab Specimens

- Fill a clean extraction tube (provided) to the line (0.6ml) with R1. Immerse the swab in R1 and agitate for at least 5 seconds. Place the extraction tube containing

the swab into the heating apparatus and leave for 10-12 minutes.

- Remove the extraction tube from the heating apparatus. Rotate the swab in the extraction tube for at least 5 seconds. Remove liquid from the swab by pinching the rim of the extraction tube between thumb and finger and gently removing the swab from the tube. Discard the swab. Allow the swab extract to cool for at least 5 minutes at 18-30°C.
- The extract can be stored at 18-30°C for up to 3 hours without affecting the result of the **Clearview** test.

Extraction – Male Urine Specimens

- Mix the urine specimen by inversion. Transfer 10ml of the urine specimen into a v-based centrifugation tube and add 10ml distilled or deionised water. Centrifuge the specimen at 3000g for 15 minutes. Carefully pour off the supernatant and discard. Keep the tube inverted and remove any supernatant from the rim of the tube by blotting onto clean absorbent paper.
- Pipette 0.6ml R1 into the centrifugation tube. Vortex mix for at least 30 seconds. Transfer the resuspended pellet to a clean extraction tube (provided). Place into the heating apparatus and heat for 10-12 minutes.
- Remove the extraction tube from the heating apparatus. Allow the sample extract to cool for at least 5 minutes at 18-30°C.
- The extract can be stored at 18-30°C for up to 3 hours without affecting the result of the **Clearview** test.

Test Procedure – male and female extracted specimens

When ready to test remove a **Clearview Chlamydia MF** device from the foil wrapper and place on a level surface. Cap the extraction tube with the attached dropper, and apply 5 drops of extract to the Sample Window (A).

The test must be read 15 minutes after applying the extract.

Interpretation of Results

- A line appearing in the Control Window (C) within 15 minutes shows that the test has worked correctly. If no line appears in the Control Window within 15 minutes the test must be repeated with a new **Clearview Chlamydia MF** device. The remaining extract can be used for this purpose provided it has been prepared for less than 3 hours. Alternatively, a fresh specimen may be collected following the procedures described earlier.
- A **positive result** is indicated by a line in the Result Window (B) at 15 minutes. A difference of intensity may occur between the lines in the Result and the Control Windows, but this does not affect the interpretation of the results.
- A **negative result** is indicated if no line has formed in the result window at the 15 minute read time.

Quality Control

Good laboratory practice recommends the use of control materials to ensure proper kit performance. A positive antigen control (R2) is provided for this purpose. Add 5 drops of R2 to a clean extraction tube and fill to the line with R1. Swirl for at least 5 seconds to mix, and place in the heating apparatus (pre-heated to 80°C ± 2°C) for 10-12 minutes. Allow to cool for 5 minutes at 18-30°C. Cap the tube with the attached dropper and complete the test procedure as for an extracted specimen. Lines in the Result and Control Windows show that the test has worked correctly.

Note: A negative control can be performed by following the female specimen extraction and test procedure but without the addition of a swab.

Limitations of the Test

1. **Clearview Chlamydia MF** is for use only with female endocervical swab specimens or male urine specimens. The performance of the test with specimens taken from other sites has not been established.
2. The test cannot differentiate between viable and non-viable organisms.

3. Do not use devices that have become wet or the packaging has become damaged.
4. False negative results may occur if specimens are collected or stored improperly (see Specimen Collection and Storage).
5. Negative results may be obtained when the amount of extracted antigen is below the sensitivity of the test.
6. If the **Clearview Chlamydia MF** result is negative and clinical symptoms persist additional follow-up testing is recommended e.g. using polymerase or ligase chain reaction.
7. Female test results should remain stable for up to 20 minutes after applying the extract to the Sample Window.

Expected Results

For women in high-risk populations, such as GUM (Genito-Urinary Medicine) clinic attendees, the prevalence of *Chlamydia* infection has been reported to be 16.4%. In low risk populations such as those attending Family Planning Clinics, Obstetrics and Gynaecology clinics and GP attendees, the mean prevalence is 4.5-8.0%³. Estimated prevalence of *Chlamydia* infection amongst men attending a STD (Sexually Transmitted Disease) clinic is 15.4%⁴, with highest prevalence amongst 20-24 age group³.

Performance Characteristics

The performance of **Clearview Chlamydia MF** has been compared with conventional cell culture in a multi-centre clinical evaluation of 1493 male and female patients. The prevalence of Chlamydial infections at these sites ranged from 11-12% in women, and 5.4-29.9% in men. Discordant results (negative by cell culture, positive by **Clearview Chlamydia MF**) were resolved with an immunofluorescence test (IF). In these studies **Clearview Chlamydia MF** was shown to have a Positive Predictive Value (PPV) of 98.3% in women and 86.6% in men, and a Negative Predictive Value (NPV) of 99.2% in women, and 95.4% in men⁵.

The results are summarised below:

Samples (number tested)	Cell culture result	Clearview Chlamydia MF Result		Sensitivity	Specificity	PPV	NPV
		+	-				
Female (582)	+	60	4	93.8% (60/64)	99.8% (517/518)	98.3%	99.2%
	-	1	517				
Male (911)	+	123	35	77.8% (123/158)	97.5% (734/753)	86.6%	95.4%
	-	19	734				

Cross Reactivity

Cross reactivity with other organisms has been studied using suspensions of 10^5 - 10^8 CFU/ml. The following organisms were not detected using **Clearview Chlamydia MF**:

Clearview Chlamydia MF:

Acinetobacter spp, *Branhamella catarrhalis*, *Candida albicans*, *Candida glabrata*, *Escherichia coli*, *Gardnerella vaginalis*, *Haemophilus influenzae*, *Herpes simplex 1 and 2*, *Klebsiella pneumoniae*, *Moraxella lacunata*, *Mycoplasma hominis*, *Neisseria gonorrhoeae*, *Neisseria lactamica*, *Neisseria meningitidis*, *Peptostreptococcus spp.*, *Proteus mirabilis*, *Proteus vulgaris*, *Pseudomonas aeruginosa*, *Salmonella minnesota*, *Salmonella typhimurium*, *Staphylococcus aureus*, *Group A/B/C Streptococcus*, *Streptococcus faecalis*, *Streptococcus faecium*, *Trichomonas vaginalis*, *Ureaplasma urealyticum*.

Advice Line

For further information, please contact your distributor, or call Inverness Medical Technical Specialists on:

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International: +44 (0) 1234 835959.

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IVD



Store at 2-8°C/Lagerung bei 2° bis 8°C/Opbevares ved 2-8°C/Almacenar a 2-8°C/Säilytettävä 2-8°C/Conserver entre 2 et 8 °C/Φυλάσσεται στους 2-8°C/Conservare a 2-8°C/Opstaan bij 2-8°C/Opbevares ved 2-8°C/Conservar a 2°C-8°C/Förvaras vid 2-8°C



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References/Literatur/Henvisninger/Referencias/Viiteluettelo/Références/Παραπομπές/Bibliografia/Referenties/Referanser/Referências/Referenser

- Oriel JD and Ridgway GL (1982). Genital Infection by *Chlamydia trachomatis*. Edward Arnold, London.
- Sweet RL (1982). Chlamydial salpingitis and infertility. *Fertil. Steril.* 38: 530-533.
- Department of Health (1988). Main Report of the Chief Medical Officers Expert Advisory Group on *Chlamydia trachomatis*. Department of Health, London.
- Higgins SP, Klapper PE, Struthers JK, Bailey AS, Gough AP, Moore R, Corbitt G, Bhattacharyya MN (1998). Detection of male genital infection with *Chlamydia trachomatis* and *Neisseria gonorrhoeae* using automated multiplex PCR system. *Int. J. STD AIDS*; 9(1): 21-4.
- Matthews R, Ridgeway G, Carder C, Hook III E, Pate M, Radcliffe K, Robinson A, Gleason B, Davidson I and Sheard P (1996). Evaluation of a New Rapid Immunoassay (Clearview Chlamydia MF) for the Detection of *Chlamydia trachomatis* in Female Endocervical Swabs and in Male Urine Samples. *ASM*