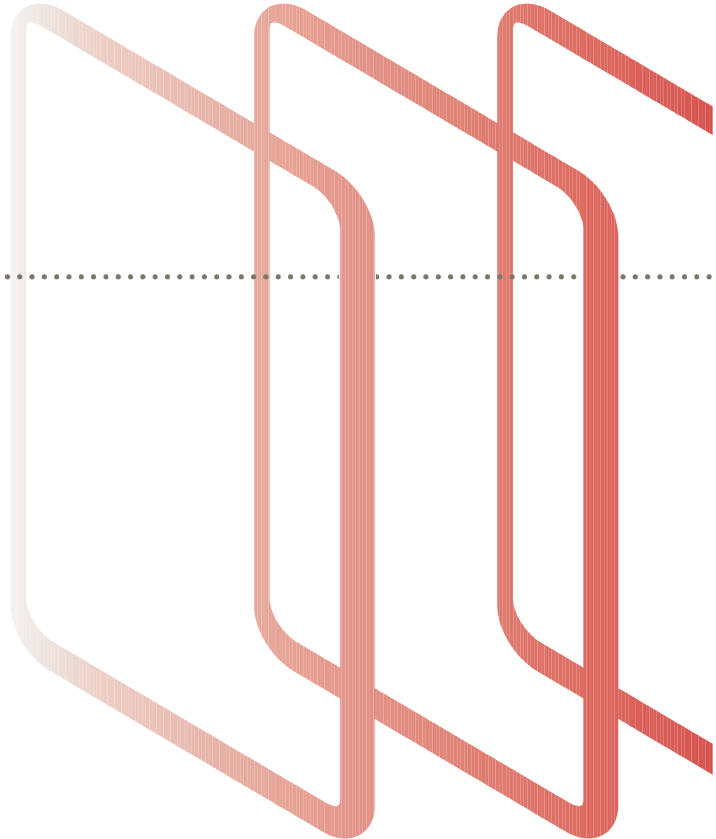




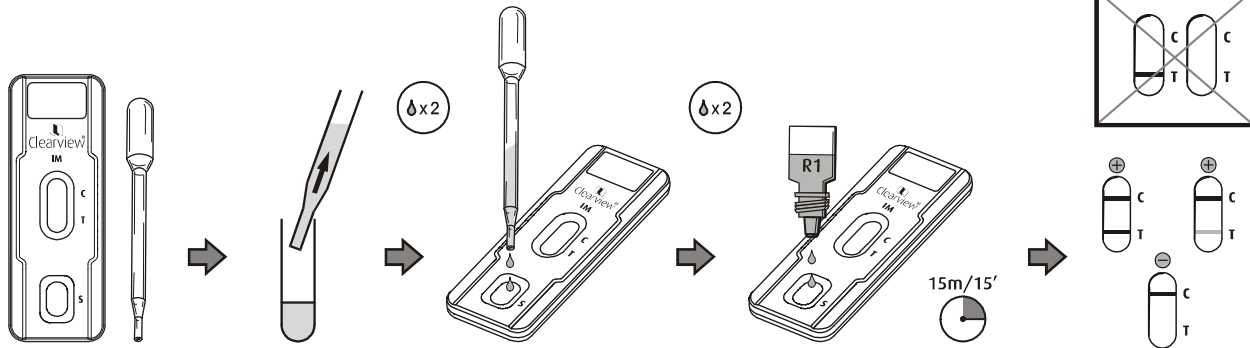
Clearview<sup>®</sup> **IM**



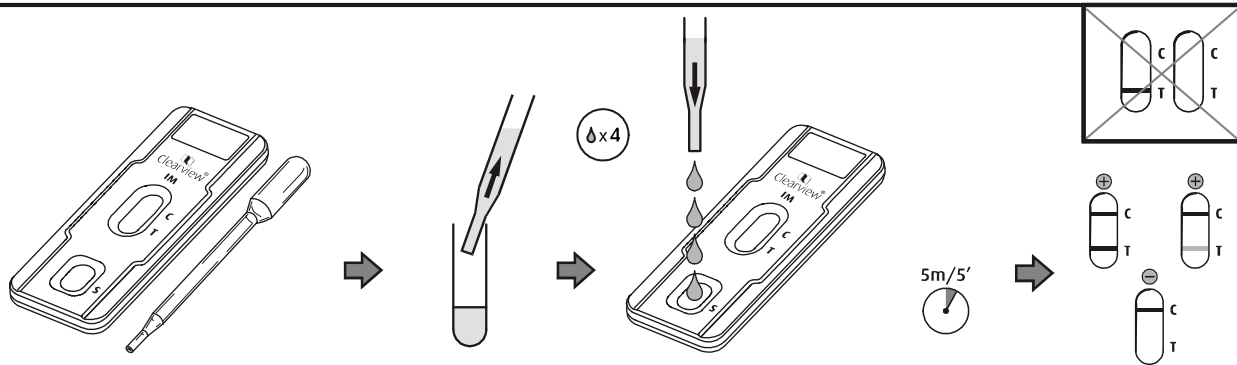


**A**

Whole blood/Vollblut/  
 Fulblod/Sangre total/  
 Kokoveri/Sang total/  
 Ολικό αίμα/Sangue  
 intero/Volbloed/Fullbold/  
 Sangue total/Helblod

**B**

Serum plasma/  
 Serum oder plasma/  
 Serum eller plasma/  
 Suero o plasma/  
 Seerumi tai plasma/  
 Sérum plasma/  
 φυσιολογικός ορός πλάσμα/  
 Siero plasma/Serum plasma/  
 Serum eller plasma/  
 Soro ou plasma/  
 Serum plasma





## Intended Use

**Clearview IM** is a simple, rapid immunoassay for the qualitative detection of infectious mononucleosis IgM heterophile antibodies in human whole blood, serum or plasma specimens. It is intended for professional *in vitro* diagnostic use only.

## Introduction

Infectious mononucleosis (IM) is an acute herpes virus infection caused by the Epstein-Barr Virus (EBV). It is a disease of variable severity, being characterised by a range of symptoms that can include lethargy, sore throat, lymphadenopathy, splenomegaly, hepatitis and jaundice. Unusual consequences of the disease include autoimmune haemolytic anaemia, spontaneous splenic rupture and progression to acute lymphoblastic leukaemia. Treatment of the disease is primarily symptomatic, with enforced bed rest to prevent serious complications of the liver or spleen, and analgesics to control the pain<sup>1</sup>.

During the acute phase of illness, IM heterophile antibodies (primarily of the IgM class) appear in 80-90% of IM cases<sup>1,2,3</sup>. IM heterophile antibodies are usually demonstrable 1-12 weeks after the onset of the illness, but have been shown to persist for a year<sup>3,4</sup>.

IM heterophile antibodies can be detected by the agglutination of mammalian red blood cells. Differential absorption of sera to remove other non-specific heterophile antibodies increases specificity. Antigens obtained from the membranes of bovine erythrocytes are more specific to the IM heterophile antibodies than those antigens obtained from either sheep or horse erythrocytes<sup>5,4</sup>.

**Clearview IM** uses a glycoprotein from bovine erythrocytes and is therefore highly specific, requiring no pre-treatment of the specimen and producing clear, unambiguous results.


## Test Principle

Patient specimen (whole blood, serum or plasma) is added to the absorbent pad in the Sample Window (S) of the device. For whole blood specimens, a diluent (R1) is also added. The absorbent pad contains blue microspheres attached to bovine erythrocyte glycoprotein. When the specimen is applied these microspheres are mobilised and

the specimen migrates up the test strip. If the specimen contains IM heterophile antibodies these will bind to the bovine erythrocyte glycoprotein attached to the blue microspheres forming a complex. These complexes are then bound by the region of immobilised bovine erythrocyte glycoprotein in the Test Line Region (T) forming a blue test line. If IM heterophile antibodies are not present, a line will not form in the Test Line Region (T).

**Clearview IM** also provides an integral control feature. The appearance of a blue line in the Control Line Region (C) shows the test has worked correctly.

## Precautions

- Standard guidelines for handling infectious agents and chemical reagents should be observed throughout all procedures.
- It is recommended that disposable gloves should be worn while handling specimens.
- Properly dispose of all contaminated waste such as IM devices and pipettes.
- Hazard information for the components under applicable European Community (EC) Directives is as follows:  
R1 - Harmful: Contains sodium azide.  
**Xn** R22 Harmful if swallowed.  
 S60 This material and its container must be deposited as hazardous waste.

## Kit Contents and Storage

Each **Clearview IM** kit contains sufficient materials for 20 tests:

- 20 individually foil wrapped devices: containing separate regions of bovine erythrocyte glycoprotein and latex-labelled bovine erythrocyte glycoprotein.
- 20 disposable pipettes.
- 1 x 2ml R1: phosphate buffered saline.
- 1 package insert.

**Clearview IM** should be stored at 2-30°C.

**Do not use after the stated expiry date.**

## Materials required but not provided

- Timer
- Blood collection tubes:

**For whole blood:** 50µl capillary tubes coated with anti-coagulant for finger-prick or blood tubes containing anticoagulant. EDTA, citrate or

heparin are suitable anti-coagulants. Follow the manufacturer's instructions.

**For serum:** Use a standard blood tube followed by a separation step using centrifugation and, if desired, use a physical separator to isolate the serum. Follow the manufacturer's instructions.

**For plasma:** Use a standard blood tube containing any of the following anti-coagulants: EDTA, citrate or heparin, followed by a centrifugation step.

## Specimen Storage

Whole blood specimens must be used immediately. Do not freeze. Serum or plasma specimens can be stored for up to three days at 2-8°C, or frozen at ≤ -20°C for up to one month.

## Assay Procedure

Ensure all devices and specimens are at 18-30°C. When ready to test, tear open the foil wrapper and remove the **Clearview IM** device and place it on a level surface. Follow **one** of the following procedures:

1. **Whole Blood:** Using the pipette provided, add 2 drops of whole blood to the Sample Window. Then immediately add 2 drops of R1 straight from the bottle. The test **must** be read 15 minutes after the addition of the specimen. **OR**
2. **Whole Blood (Finger prick):** Obtain blood from the finger using a 50 µl capillary tube coated with anti-coagulant. Directly add the whole blood to the Sample Window. Then immediately add 2 drops of R1. The test **must** be read 15 minutes after the addition of the specimen. **OR**
3. **For Serum or Plasma:** Using the pipette provided add 4 drops of the specimen to the Sample Window. The test **must** be read 5 minutes after the addition of the specimen.

## Interpretation of Results

- A **positive result** is indicated by a blue line in both the Test Line Region (T) and Control Line Region (C), within the specified time. A difference in intensity may occur between the two lines but this does not affect the interpretation of the results.
- A **negative result** is indicated by the formation of a blue line in only the Control Line Region (C) within the specified read time.
- A blue line appearing in the Control Line Region (C) within the specified read time indicates the test has worked correctly. If no line appears in the Control Line Region (C) within the specified time, then the test must be repeated with a new **Clearview IM** device.

## Limitations of the Test

1. **Clearview IM** is for use only with blood specimens (whole blood, serum or plasma). The performance of the test taken from other sources has not been established.
2. Specimens which are contaminated or grossly haemolysed should not be used. Serum or plasma specimens must be clear and particle free.
3. Negative results may be obtained if insufficient antibody is present in the specimen. Where negative results are obtained and symptoms still persist, it is recommended that a further test be carried out at a later date, allowing time for the antibody to develop.
4. It has been reported that up to 10-20% of infected adults and 50% of children under 4 years of age may fail to produce IM heterophile antibodies<sup>1,2,3</sup>.
5. The presence of heterophile antibodies has been demonstrated in other disease states such as leukaemia, Burkitts lymphoma, rheumatoid arthritis, viral hepatitis and cytomegalovirus infections<sup>2</sup>.
6. As heterophile antibody may persist for several months after recovery<sup>3</sup>, a positive result should not be regarded as indicative of acute infectious mononucleosis in isolation from the clinical and haematological information. Therefore the result obtained from **Clearview IM** must be considered with both haematological findings and the clinical symptoms of the patient before a diagnosis of infectious mononucleosis is made.
7. Do not use devices that have become wet or if the packaging has become damaged.

## Expected Results

The peak incidence of infectious mononucleosis occurs between 15 and 19 years of age with 345-671 cases per 100,000 per year<sup>2</sup>. Infection during childhood is usually sub-clinical, whereas infection of adolescents or young adults results in IM in 30-70% of cases<sup>5</sup>. After 35 years of age the incidence of the disease declines rapidly and is uncommon in persons over 40 years of age<sup>2</sup>.

## Calibration

**Clearview IM** is calibrated using in-house standards produced from dilutions of a stock preparation derived from a serum pool of high titre IM positive patients.

## Performance Characteristics

The performance of **Clearview IM** has been determined in a multi-centre clinical evaluation. Specimens from patients with suspected Infectious Mononucleosis were tested using the **Clearview IM** kit and a commercially available differential red cell test (Test A). Any discordant specimens were tested further in a specific Epstein-Barr Virus immunoassay for the presence of antibodies (IgG or IgM) against either capsid or nuclear antigen.

The resolved data are as follows:

Specimen tested	Test A	Clearview IM Result		Sensitivity	Specificity
		+	-		
Whole Blood	+	64	0	95.5%	100%
	-	3	187		
Serum/Plasma	+	66	0	98.5%	100%
	-	1	187		

These findings are supported in independent studies<sup>4,6</sup>.

## Advice Line

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

UK: **08705 134952**

International: +44 (0) 1234 835959

[www.clearview.com](http://www.clearview.com)

© 2008 Inverness Medical. All rights reserved. Clearview is a trademark of the Inverness Medical group of companies.

© 2008 Inverness Medical. Alle Rechte vorbehalten. Clearview ist eine Marke der Unternehmensgruppe Inverness Medical.

© 2008 Inverness Medical. All Rights Reserved. Clearview er et varemærke tilhørende Inverness Medical Group of Companies.

© 2008 Inverness Medical. Todos los derechos reservados. Clearview es una marca comercial del grupo empresarial Inverness Medical.

© 2008 Inverness Medical. Kaikki oikeudet pidätetään. Clearview on Inverness Medical -konsernin tavaramerkki.

© 2008 Inverness Medical. Tous droits réservés. Clearview est une marque commerciale du groupe de compagnies Inverness Medical.

© 2008 Inverness Medical. **Με επιφύλαξη κάθε δικαιώματος. Το Clearview είναι εμπορικό σήμα του Inverness Medical Group of Companies.**

© 2008 Inverness Medical. Tutti i diritti riservati. Clearview è un marchio di fabbrica del gruppo Inverness Medical.

© 2008 Inverness Medical. Alle rechten voorbehouden. Clearview is een handelsmerk van de Inverness Medical Group of Companies.

© 2008 Inverness Medical. Med enerett. Clearview er et varemærke for Inverness Medical-gruppen.

© 2008 Inverness Medical. Todos os direitos reservados. Clearview é uma marca comercial do grupo de empresas Inverness Medical.

© 2008 Inverness Medical. Med ensamrätt. Clearview är ett varumärke som tillhör Inverness Medical Group of Companies.



Recycle Symbol/Grüner Punkt/Genvindingsymbol/Símbolo de reciclaje/Kierrätysmerkki/Symbole de recyclage/**Σύμβολο ανακύκλωσης/Símbolo del riciclaggio/Recyclage/Resirkuleringsring/Ponto verde/Återvinning**

For *in vitro* diagnostic use only/Für die *In-vitro*-Diagnose/Kun til *in vitro*-diagnostisk brug/Para uso en diagnósticos *in vitro*/Vain *in vitro*-diagnostiikkaan/Pour usage diagnostic *in vitro*/**Για *in vitro* διαγνωστική χρήση/Unicamente per uso diagnostico *in vitro*/For *in vitro* diagnostic use/Til bruk ved *in vitro*-diagnostikk/Para utilização em diagnóstico *in vitro*/Für *in vitro*-diagnostiskt bruk**

IVD



Store at 2-30°C/Bei 2-30°C lagern/Opbevar ved 2-30°C/Almacenar a una temperatura de entre 2 y 30°C/Säilytä 2-30 °C:ssa/Conserver entre 2 et 30°C/**Φυλάσσετε στους 2-30 °C/Conservare a 2-30°C/Bewaren bij 2 à 30°C/Opbevares ved 2-30 °C/Armazenar a 2-30°C/Förvaras vid 2-30°C**



Consult instructions for use/Siehe Gebrauchsanweisung/Se brugervejledningen/Consulte las instrucciones para la utilización del dispositivo/Ks. Käyttöohjeet/Lire les instructions d'utilisation/**Συμβουλευτείτε τις οδηγίες χρήσης/Consultare le istruzioni per l'uso/Raadpleeg instructies voor gebruik/Se bruksanvisningen/Consultar as instruções de utilização/Las instruktionerna för användning**



Use By/Expiry Date/Haltbarkeits-/Ablaufdatum /Anvendes før/Udløbsdato/Utilizar antes de/fecha de caducidad/Käytettävä ennen/Date d'expiration/**Χρήση έως/Ημερομηνία λήξης/Utilizzare entro/Data di scadenza/Uiterste houdbaarheidsdatum/Brukes før/Utløpsdato/Utilizar até/Data de validade/Utgångsdatum**

LOT

Lot Number/Chargennummer/Lotnummer/Número de lote/Sarjanumero/Numéro de lot/**Αριθμός παρτίδας/Numero di lotto/Lotnummer/Partinummer/Número de lote/Partinr**



CE Mark/CE-Zeichen/CE-mærke/Marca de la CE/CE-merkintä/Marque CE/**Σήμηση CE/Marchio CE/CE-markering/CE-merke/Marcação CE/CE-märkning**



Contains sufficient for 20 tests/usreichend für 20 Tests/Indeholder materiale til 20 test/ontiene material suficiente para realizar 20 pruebas/Sisältää tarvittavat välineet 20 testiin/Quantité suffisante pour 20 tests/**Το περιεχόμενο επαρκεί για 20 δοκιμασίες/Contiene materiale sufficiente per 20 test/Contains sufficient for 20 tests/Innholdet er tilstrekkelig for 20 tester/Quantidade suficiente para 20 testes/Innehållet räcker till 20 test**



Do not reuse/Nicht wiederverwenden/Må ikke genbruges/No reutilizar/Älä käyttää uudelleen/Ne pas réutiliser/**Να μην χρησιμοποιηθεί ξανά/Non riutilizzare/Niet opnieuw gebruiken/Bare for engangsbruk/Não reutilizar/Får ej återanvändas**

REF

Catalogue Number/Bestellnummer/Katalognummer/Número de referencia/Luettelonumero/Numéro de catalogue/**Αριθμός καταλόγου/Numero di catalogo/Catalogusnummer/Katalognummer/Número de catálogo/Katalognummer**



Manufactured by/Hergestellt von/Fremstillet af/**Fabricado por/Valmistaja/Fabriqué par/Κατασκευάζεται από την/Prodotto da/Gefabriceerd door/Produisert av/Fabricado por/Tilverkare**



Harmful/Gesundheitsschädlich/Sundhedsskadeligt/Peligroso/**Haitallinen Nocif/Επιβλαβές/Nocivo/Schadelijk/Helseskadeligt/Nocivo/Skadigt**

## References/Quellen/Referencer/Referencias/Viitteet/Références/Βιβλιογραφία/Bibliografia/Literatuur/Referanser/Bibliografia/Källhänvisningar

1. Moffat LE (2001). Primary Care Update Ob Gyns 8 (2), 73-77.
2. Bailey RE (1994) Am Fam Physician. 49 (4), 879-888.
3. Gray JJ, Caldwell J & Sills M (1992) J. Infect. 25, 39-46.
4. Elgh F & Linderholm M (1996). Clin. Diag. Virol. 7, 17-21.
5. Morris MC & Edmunds WJ (2002). J. Infect. 45, 107-132.
6. Bruu AL, Hjetland R, Holter E, Mortensen L, Natas Q, Petterson W, Slar AG, Skarpaas T, Tjåde T & Asjo B (2000). Clin. Diag. Lab Immun. 7 (3), 451-456.



Unipath Ltd.  
Bedford MK44 3UP, UK  
Tel: +44(0) 1234 835000  
Fax: +44(0) 1234 835009