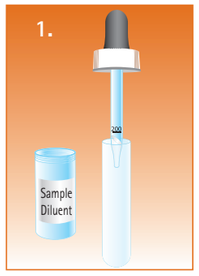
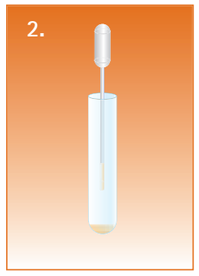
TRU EBV-G™ PROCEDURAL CARD

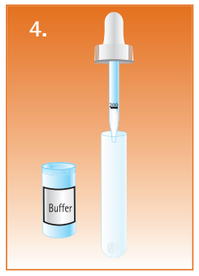


Add 200 µL of Sample Diluent to a clean test tube.



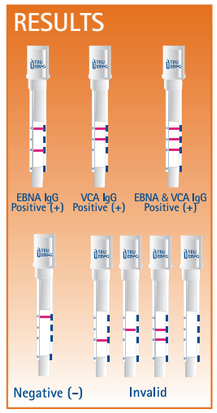
Using a transfer pipette provided, add 50 µL (second mark on pipette) of patient specimen to the tube with Sample Diluent. Vortex or swirl for 10 seconds.

Using the same transfer pipette, add 25 µL (first mark on pipette) of diluted specimen to the area on the Test Strip indicated by the "S". Incubate for 2 minutes at 20 - 25 C.



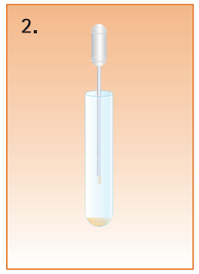
Remove the Conjugate Tube from the foil pouch and uncap. Within 1 minute, add 200 µL of Buffer to the Conjugate Tube. Vortex or swirl for 10 seconds.

Insert the Test Strip into the Conjugate Tube and firmly press down to close. Incubate for 15 minutes at 20 - 25 C. Read results within 1 minute



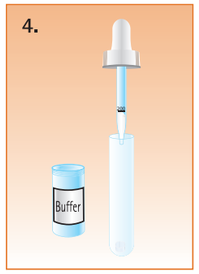
TRU EBV-M™ PROCEDURAL CARD

Add 350 µL of Sample Diluent to a clean test tube.

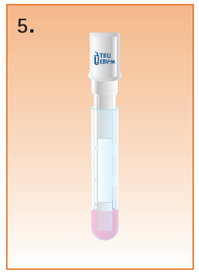


Using the transfer pipette provided, add 25 µL (first mark on pipette) of patient specimen to the tube with Sample Diluent. Vortex or swirl for 10 seconds.

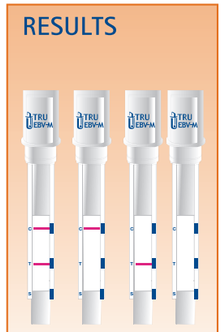
Using the same transfer pipette, add 25 µL (first mark on pipette) of diluted specimen to the area on the Test Strip indicated by the "S". Incubate for 2 minutes at 20 - 25 C.



Remove the Conjugate Tube from the foil pouch and uncap. Within 1 minute, add 200 µL of Buffer to the Conjugate Tube. Vortex or swirl for 10 seconds.



Insert the Test Strip into the Conjugate Tube and firmly press down to close. Incubate for 15 minutes at 20 - 25 C. Read results within 1 minute.



ORDERING INFORMATION

PRODUCT	TEST SIZE	CATALOG NO.
TRU EBV-M™	30 tests	751730
TRU EBV-G™	30 tests	751830
OTHER TRU™ PRODUCTS		
TRU RSV®	32 tests	751330
TRU FLU®	32 tests	751230
OTHER PRODUCTS		
FLU/RSV Positive Control	24 tests	751110

Meridian Bioscience Europe Srl
Via dell' Industria, 7
I-20020 Villa Cortese, Milano
Italy
Telephone +39 (0331) 43 36 36
Fax +39 (0331) 43 36 16
e-mail: info@mdeur.com

Meridian Bioscience Europe sa/nv
Rue de l'Industrie, 7
B-1400 Nivelles
Belgium
Telephone +32 (67) 89 59 59
Fax +32 (67) 89 59 58
e-mail: info@mdeur.be

Meridian Bioscience Europe France
Le Quadra
455, Promenade des Anglais
F-06299 Nice Cedex 3
France
Telephone +33 (4) 93 18 72 10
Fax +33 (4) 93 18 72 11
e-mail: info@meridianbioscience.fr

Meridian Bioscience Europe bv
Halderheiweg, 6
NL-5282 SN Boxtel
The Netherlands
Telephone +31 (411) 62 11 66
Fax +31 (411) 62 48 41
e-mail: meridian.info@planet.nl

Meridian Bioscience, Inc.
Corporate Office
3471 River Hills Drive
Cincinnati, Ohio 45244, USA
Telephone +1 (513) 271 37 00
Fax +1 (513) 271 37 62
e-mail: mbi@meridianbioscience.com

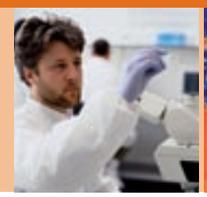
www.meridianbioscience.com
www.mdeur.com

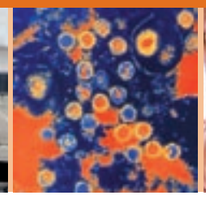
MBE EN0308

DISTRIBUTED BY

TRU EBV™

Rapid test for EBV Specific Antibodies Detection





Accurate EBV diagnosis has never been so fast and easy

Meridian Bioscience Europe

INFECTIOUS MONONUCLEOSIS

KEY CONCERNS IN EBV DIAGNOSTICS

DIFFERENTIAL DIAGNOSIS

Clinical diagnosis of infectious mononucleosis is suggested on the basis of the symptoms of fever, sore throat, swollen lymph glands, and the age of the patient. As the symptoms may be overlapping with those of infections like CMV, HIV, Rubella, Parvovirus and Toxoplasma gondii, serological tests are needed to confirm a diagnosis.

STAGING OF THE INFECTION

Heterophile testing

Heterophile antibody detection is frequently used for confirmation of a diagnosis of acute primary EBV infection but may lead to false positive (5%) and false negative (10 to 20%) results in adults[1]. Under the age of 14, the test is less sensitive and false-negative results may be obtained in 10% to 50% of children.

EBV Specific serology

A crucial concern in EBV diagnosis is to distinguish acute from past infection and susceptibility to EBV. Nearly 90% of adults in the world are seropositive having contracted EBV infection in the past. Effective laboratory diagnosis can be made on a single acute-phase serum sample by testing for antibodies directed against EBV antigens.
In immunocompetent patients three antibodies VCA IgG, VCA IgM and EBNA-1 IgG enable EBV infection stage-specific diagnosis.

VCA

EBNA

Viral Capsid Antigens are present in every cell infected with EBV. During primary EBV infection VCA-IgM appears first and VCA-IgG antibodies develop shortly after and persist lifelong.

IgG antibodies to EBNA-1 (Nuclear Antigen) appear weeks or months after the acute phase of infection and their presence together with VCA-IgG is indicative of past infection.

KEY FEATURES IN EBV SEROLOGY

OPTIMAL SELECTION OF REACTIVE AND SPECIFIC ANTIGENS

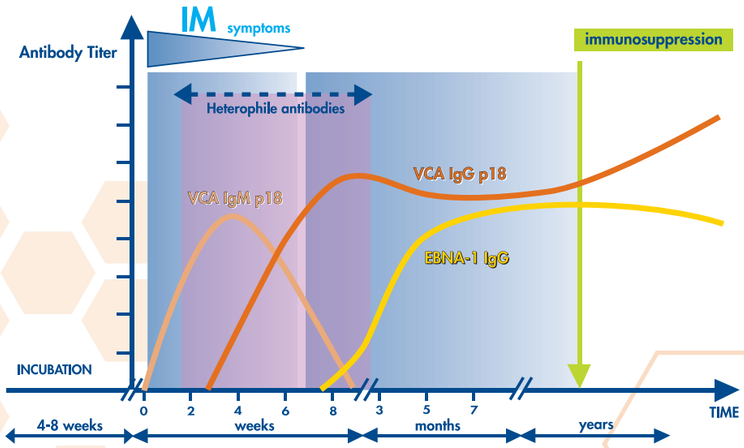
Performance of serological assays strongly depends on the nature of selected antigens. EBV–specific serological assays (IFA and EIA) differ in the substrates or antigens that they use. Antigen selection is critical for accurate EBV detection.

ADVANTAGES OF ASSAYS BASED ON p18 ANTIGEN

The small VCA-p18 protein is a component of viral capsid antigen complex of Epstein Barr Virus. p18 is highly immunogenic in humans and shows several advantages over other proteins for the detection of VCA IgM and IgG antibodies in serological assays.

- Sensitive VCA IgM and IgG detection due to highly immunogenic p18 peptide[2]
- No cross reactions with other Herpesviruses: p18 doesn't contain homologous sequences to HHV
- Better marker for past infections/long term immunity: VCA IgG antibodies against p18 appear only in late/past infections and not in the early acute phase[2]
- IgG against p18 do not disappear in case of immunosuppression[3] and are always present in patients non-respondent to EBNA-IgG

EBV specific antibodies profile



REFERENCES: *1. K. H. Chan, JCM 1998 - 2. W. Hinderer, JCM 1999 - 3. G. Bauer, Clin. Lab. 2001*

TRU EBV-M™

VCA IgM detection

TRU EBV-G™

VCA IgG and EBNA-1 IgG detection

- Rapid immunochromatographic assay for EBV VCA and EBNA-1 antibodies detection in human serum
- Based on highly specific EBV proteins
  - Recombinant p18 peptide for VCA IgM and VCA IgG detection
  - Recombinant EBNA-1 p72 for EBNA IgG detection
- Closed test design
- Time to results: less than 20 minutes
- Storage: 2-8 C
- High accuracy
- Clear differentiation of acute and past stages of EBV infection

INTERPRETATION OF COMMON EBV SEROLOGICAL PROFILES

VCA IgM p18	VCA IgG p18	EBNA-1 IgG	INTERPRETATION
−	−	−	No serological evidence of infection
+	−	−	Acute infection
+	+	−	Acute infection
+	+	+	Convalescence phase with persisting VCA IgM or reactivation with VCA IgM (very rare)
−	+	+	Past infection

TRU EBV™ PERFORMANCE CHARACTERISTICS

REFERENCE EIA EBV ASSAYS*	TRU EBV-M (VCA IgM)	TRU EBV-G (VCA IgG)	TRU EBV-G (EBNA-1 IgG)
Sensitivity	91.6%	96.5%	98.8%
Specificity	96.4%	95.8%	98.8%

*Two commercial EIA's have been used as reference tests to determine the TRU EBV performance for each parameter