# **RANDOX**

# INFECTIOUS DISEASE CONTROLS (SEROLOGY)

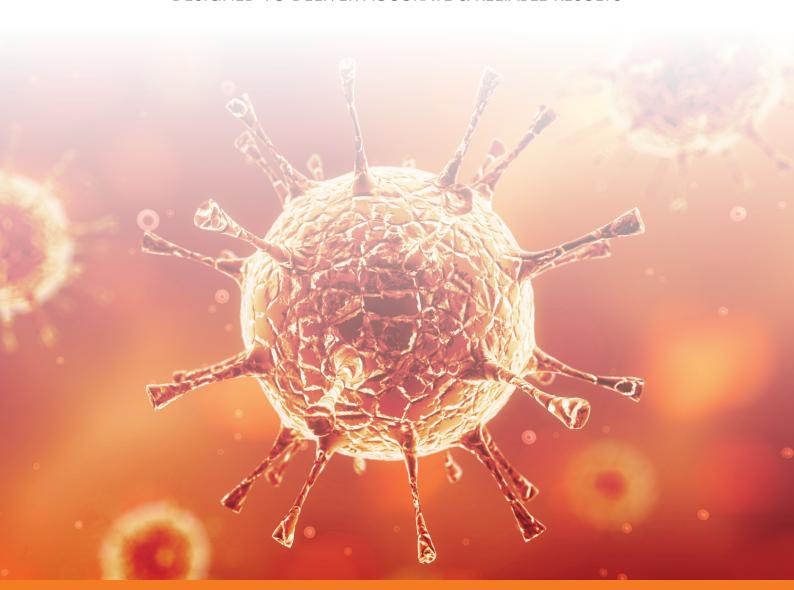




# **INFECTIOUS DISEASE CONTROLS**

THIRD PARTY, MULTI-MARKER CONTROLS

DESIGNED TO DELIVER ACCURATE & RELIABLE RESULTS



Our Acusera Infectious Disease (Serology) Controls are designed to deliver a cost effective, high quality solution for the analysis of infectious diseases whilst producing trustworthy results time and time again. Covering a wide range of infectious diseases, including HIV, Hepatitis, EBV, ToRCH, and Lyme Disease, our controls are compatible for use on some of the most popular immunoassay platforms including Roche, Abbott, Siemens and Beckman among others.



#### Liquid ready-to-use

• All samples are provided in a user-friendly, liquid ready-to-use format significantly reducing preparation time and the risk of pipetting errors.



#### Commutability

 Manufactured from human plasma each control is designed to react to the test system in the same manner as the patient sample, helping to meet ISO 15189:2012 requirements.



#### True third party controls

• Designed to deliver an independent, unbiased assessment of performance with any instrument or method the Acusera range will help to meet ISO 15189:2012 requirements and eliminate the need for multiple instrument specific controls.



#### Reduced waste

• With a working stability of 60 days at 2°C to 8°C waste and costs are kept to a minimum.



#### Consolidation

• The availability of multi-marker controls will reduce the number of individual controls required ultimately reducing costs, time and storage space.



#### Clinically relevant

• Designed to challenge clinically relevant ranges our low reactive samples will ensure accurate and reliable instrument performance.



#### Acusera 24•7

• Our Acusera Infectious Disease (Serology) Controls are compatible for use with our interlaboratory data management software Acusera 24•7.

## INFECTIOUS DISEASE CONTROLS

# Lyme Disease (Borrelia burgdorferi)



Lyme Disease is an infectious disease caused by the bacterium Borrelia burgdorferi and spread by ticks.

Our control delivers a true third-party solution for the detection of Lyme Disease on most immunoassay analysers. All samples are conveniently supplied in a user-friendly, liquid ready-to-use format.

#### **Analytes**

Borrelia burgdorferi IgG | Borrelia burgdorferi IgM

Description	Size	Cat. No.
Lyme Disease Negative Control	1 x 5 ml	SR10345
Lyme Disease Positive Control	$1 \times 5 \text{ ml}$	SR10346

#### Benefits

- Liquid ready-to-use
- 100% human serum
- Open vial stability of 60 days at 2°C to 8°C
- Suitable for use with most immunoassay analysers



ToRCH is most commonly associated with congenital anomalies caused by a variety of pathogens including Treponema pallidum (syphilis), Varicella Zoster Virus, Rubella, and Cytomegalovirus. Most ToRCH infections cause mild maternal morbidity but can have serious consequences on the foetus.

Our ToRCH portfolio includes positive controls for both IgG and IgM antibodies in addition to a negative control. Each control is manufactured using human plasma and is suitable for use with most immunoassay analysers. The availability of liquid ready-to-use samples helps to reduce preparation time and the potential for human error.

#### **Analytes - ToRCH Negative**

Cytomegalovirus (CMV) IgG | Cytomegalovirus (CMV) IgM | Epstein Barr Virus (EBV) EBNA IgG Epstein Barr Virus (EBV) VCA IgG | Epstein Barr Virus (EBV) IgM | Helicobacter pylori IgG Herpes Simplex Virus 1 (HSV-1) IgG | Herpes Simplex Virus 2 (HSV-2) IgG | Herpes Simplex Virus 1 (HSV-1) IgM Herpes Simplex Virus 2 (HSV-2) IgM | Measles IgG | Mumps IgG | Rubella IgG | Rubella IgM | Toxoplasma *gondii* IgG Toxoplasma gondii IgM | Treponema pallidum (Syphilis) IgG | Varicella Zoster Virus (VZV) IgG

#### Analytes - ToRCH IgG Positive

Cytomegalovirus (CMV) IgG | Helicobacter pylori IgG | Herpes Simplex Virus 1 (HSV-1) IgG | Herpes Simplex Virus 2 (HSV-2) IgG Measles IgG | Mumps IgG | Rubella IgG | Toxoplasma gondii IgG | Treponema pallidum (Syphilis) IgG Varicella Zoster Virus (VZV) IgG

#### Analytes - ToRCH IgM Positive

Cytomegalovirus (CMV) IgM | Herpes Simplex Virus 1 (HSV-1) IgM | Herpes Simplex Virus 2 (HSV-2) IgM | Rubella IgM Toxoplasma gondii IgM

Description	Size	Cat. No.
ToRCH Negative Control	6 x 5 ml	SR10347
ToRCH IgG Positive Control	$3 \times 5 \text{ ml}$	SR10348
ToRCH IgM Positive Control	$3 \times 5 \text{ ml}$	SR10349

#### Benefits

- · Liquid ready-to-use
- 100% human serum
- Open vial stability of 60 days at 2°C to 8°C
- Suitable for use with most immunoassay analysers

## INFECTIOUS DISEASE CONTROLS

# Epstein Barr Virus (EBV)

EBV is an extremely common virus, spread primarily through saliva causing mononucleosis.

The Acusera EBV control is conveniently supplied liquid ready-to-use and is suitable for us with most immunoassay analysers.

#### **Analytes**

Epstein Barr Virus (EBV) EBNA IgG | Epstein Barr Virus (EBV) VCA IgG | Epstein Barr Virus (EBV) IgM

**Description**EBV Positive Control

Size 1 x 5 ml **Cat. No.** SR10350

#### Benefits

- · Liquid ready-to-use
- 100% human serum
- Open vial stability of 60 days at 2°C to 8°C
- Suitable for use with most immunoassay analysers

Serology 6

A range of positive and negative serology controls are available comprising various infectious diseases including HIV, Hepatitis, HTLV and Syphilis.

Acusera Serology controls are supplied liquid ready-to-use and are suitable for use on most immunoassay analysers.

#### Analytes - HBeAg Positive (RUO)

HBeAg

#### Analytes - HIV-1 P24Ag Positive (RUO)

HIV-1 p24Ag

#### Analytes - Serology Negative

Anti-HAV | Anti-HBc | Anti-HBs | Anti-HCV | Anti-HIV 1 / 2 | Anti-HTLV 1 / 2 | HAV IgM | HBc IgM | HbeAg HBsAg | HIV P24Ag | Treponema pallidum (Syphilis) IgG

#### Analytes - Serology I Positive

Anti-HCV | Anti-HIV 1 / 2 | Anti-HTLV 1 / 2 | HBsAg | Treponema pallidum (Syphilis) IgG

#### **Analytes** - Serology II Positive

Anti-HAV | Anti-HBc | Anti-Hbe | Anti-HBs

#### Analytes - Serology III Positive

HAV IgM | HBc IgM

Description	Size	Cat. No.			
HBeAg Positive Control	1 x 5 ml	SR10459			
HIV-1 P24Ag Positive Control	1 x 5 ml	SR10458			
Serology Negative Control	6 x 5 ml	SR10351			
Serology I Positive Control	$3 \times 5 \text{ ml}$	SR10352			
Serology II Positive Control	$3 \times 5 \text{ ml}$	SR10353			
Serology III Positive Control	$3 \times 5 \text{ ml}$	SR10354			

#### **Benefits**

- Liquid ready-to-use
- 100% human serum
- Open vial stability of 60 days at 2°C to 8°C
- Suitable for use with most immunoassay analysers

# **ANALYTE INDEX**

			ToRCH				Serology						
		Lyme Disease (Borrelia burgdorferi)	ToRCH Negative	ToRCH IgG Positive	ToRCH IgM Positive	Epstein Barr Virus (EBV)	HBeAg Positive	HIV-1 P24Ag Positive	Serology Negative	Serology I Positive	Serology II Positive	Serology III Positive	
Α	Anti-HAV								Χ		Χ		
	Anti-HBc								X		Χ		
	Anti-Hbe								X		Χ		
	Anti-HBs								Χ		Χ		
	Anti-HCV								Χ	Χ			
	Anti-HIV 1 / 2								X	Χ			
	Anti-HTLV 1 / 2								Χ	Χ			
В	Borrelia burgdorferi IgG	Χ											
	Borrelia burgdorferi IgM	X											
С	Cytomegalovirus (CMV) IgG		Χ	Χ	Χ								
	Cytomegalovirus (CMV) IgM		Χ										
Е	Epstein Barr Virus (EBV) EBNA IgG		Χ			Χ							
	Epstein Barr Virus (EBV) VCA IgG		Χ			X							
	Epstein Barr Virus (EBV) IgM		Χ			Χ							
Н	HAV IgM								Χ			Χ	
	HBc IgM								Χ			Χ	
	HbeAg						Χ		Χ				
	HBsAg								Χ	Χ			
	Helicobacter pylori IgG		Χ	X									
	Herpes Simplex Virus 1 (HSV-1) IgG		Χ	X									
	Herpes Simplex Virus 2 (HSV-2) IgG		Χ	X									
	Herpes Simplex Virus 1 (HSV-1) IgM		Χ		Χ								
	Herpes Simplex Virus 2 (HSV-2) IgM		Χ		Χ								
	HIV P24Ag							Χ	Χ				
М	Measles IgG		Χ	Χ									
	Mumps IgG		Χ	Χ									
R	Rubella IgG		Χ	Χ									
	Rubella IgM		Χ		Χ								
Т	Toxoplasma gondii IgG		Χ	Χ									
	Toxoplasma gondii IgM		Χ		Χ								
	Treponema pallidum (Syphilis) IgG		Χ	Χ					Χ	Χ			
V	Varicella Zoster Virus (VZV) IgG		Χ	Χ									

### Contact us for more information on any of our products and services:

#### **HEADQUARTERS**

Randox Laboratories Ltd, 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom

#### **INTERNATIONAL OFFICES**



#### AUSTRALIA

Randox (Australia) Pty Ltd. Tel: +61 (0) 2 9615 4640



#### CZECH REPUBLIC

Randox Laboratories S.R.O. Tel: +420 2 1115 1661



#### HONG KONG

Randox Laboratories Hong Kong Limited Tel: +852 3595 0515



#### POLAND

Randox Laboratories Polska Sp z oo. Tel: +48 22 862 1080



#### REPUBLIC OF IRELAND

Randox Teoranta Tel: +353 7495 22600



#### SOUTH KOREA

Randox Korea Tel: +82 (0) 31 478 3121



#### UAE

Randox Medical Equipments Trading LLC Tel: +971 55 474 9075



Randox Brasil Ltda. Tel: +55 11 5181 2024



#### FRANCE

Laboratoires Randox Tel: +33 (0) 130 18 96 80



Randox Laboratories Ltd. Tel: +39 34 0080 9323



#### PORTUGAL

Irlandox Laboratorios Quimica Analitica Ltda Tel: +351 22 589 8320



#### SLOVAKIA

Randox S.R.O. Tel: +421 2 6381 3324



#### SPAIN

Laboratorios Randox S.L. Tel: +34 93 475 09 64



#### USA

Randox Laboratories-US, Ltd. Tel: +1 304 728 2890



Randox Laboratories Ltd. Tel: +86 021 6288 6240



#### **GERMANY**

Randox Laboratories GmbH Tel: +49 (0) 215 1937 0611



Randox Laboratories India Pvt Ltd. Tel: +91 80 6751 5000



#### PUFRTO RICO

Clinical Diagnostics of Puerto Rico, LLC Tel: +1 787 701 7000



#### SOUTH AFRICA

Randox Laboratories SA (Pty) Ltd. Tel: +27 (0) 11 312 3590



#### SWITZERLAND

Randox Laboratories Ltd (Switzerland) Tel: +41 41 810 48 89



#### VIETNAM

Randox Laboratories Ltd Vietnam Tel: +84 (0) 8 3911 0904

## For technical support contact:

technicalservices@randox.com















