

RANDOX

INFECTIOUS DISEASE  
CONTROLS (SEROLOGY)

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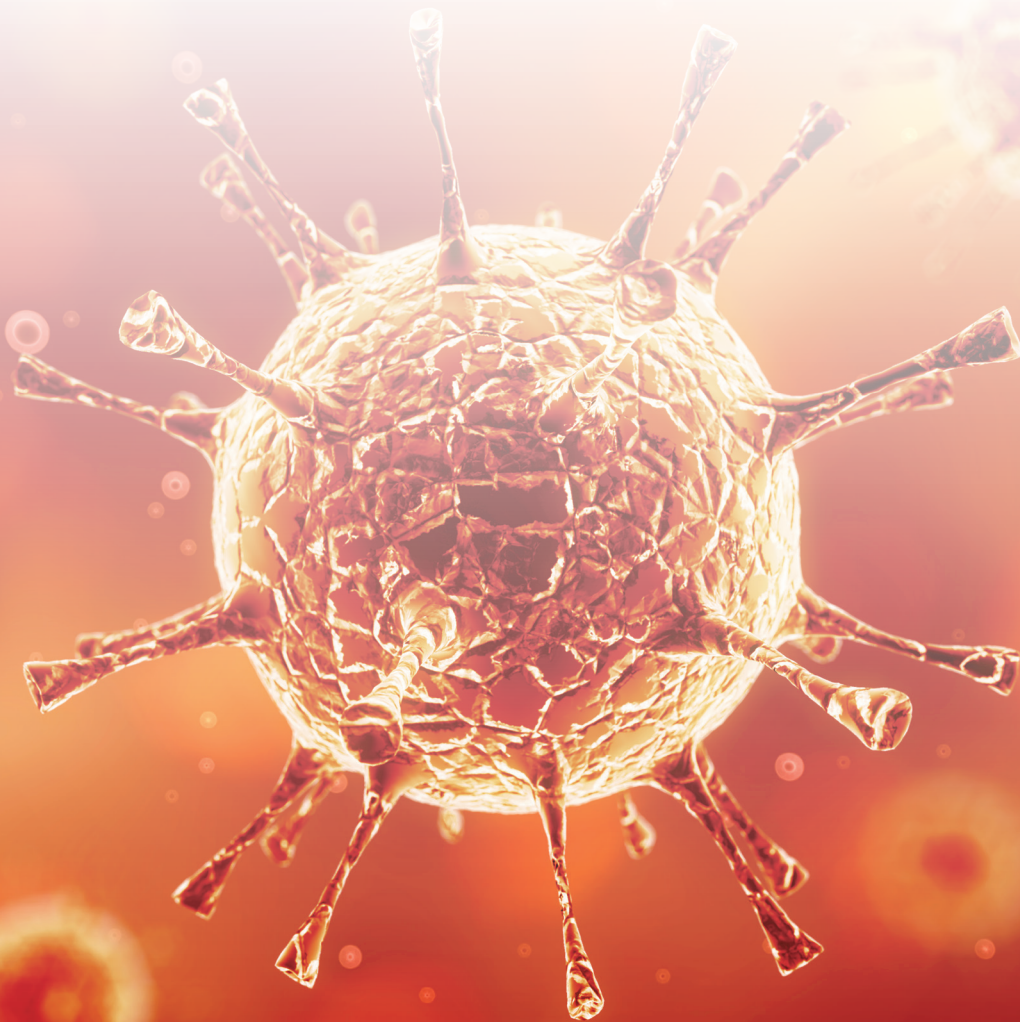
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**RAN**DOX  
QUALITY CONTROL

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## INFECTIOUS DISEASE CONTROLS

THIRD PARTY, MULTI-MARKER CONTROLS  
DESIGNED TO DELIVER ACCURATE & RELIABLE RESULTS



# BENEFITS

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.	Benefits
Lyme Disease Negative Control	1 x 5 ml	SR10345	<ul style="list-style-type: none"><li>• Liquid ready-to-use</li><li>• Human based plasma</li><li>• Open vial stability of 60 days at 2°C to 8°C</li><li>• Suitable for use with most immunoassay analysers</li></ul>
Lyme Disease Positive Control	1 x 5 ml	SR10346	

## ToRCH

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.	Benefits
ToRCH Negative Control	6 x 5 ml	SR10347	<ul style="list-style-type: none"><li>• Liquid ready-to-use</li><li>• Human based serum</li><li>• Open vial stability of 60 days at 2°C to 8°C</li><li>• Suitable for use with most immunoassay analysers</li></ul>
ToRCH IgG Positive Control	3 x 5 ml	SR10348	
ToRCH IgM Positive Control	3 x 5 ml	SR10349	

# 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 use 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
- Human based serum
- Open vial stability of 60 days at 2°C to 8°C
- Suitable for use with most immunoassay analysers

## Serology

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-Hbe | 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-HBc | 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

HBeAg Positive Control

### Size

1 x 5 ml

### Cat. No.

SR10459

HIV-1 P24Ag Positive Control

1 x 5 ml

SR10458

Serology Negative Control

6 x 5 ml

SR10351

Serology I Positive Control

3 x 5 ml

SR10352

Serology II Positive Control

3 x 5 ml

SR10353

Serology III Positive Control

3 x 5 ml

SR10354

### Benefits

- Liquid ready-to-use
- Human based plasma
- 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 ( <i>Borrelia burgdorferi</i> )	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
A	Anti-HAV								X		X	
	Anti-HBc								X	X	X	
	Anti-Hbe								X		X	
	Anti-HBs								X		X	
	Anti-HCV								X	X		
	Anti-HIV 1 / 2								X	X		
	Anti-HTLV 1 / 2								X	X		
B	<i>Borrelia burgdorferi</i> IgG	X										
	<i>Borrelia burgdorferi</i> IgM	X										
C	Cytomegalovirus (CMV) IgG		X	X	X							
	Cytomegalovirus (CMV) IgM		X									
E	Epstein Barr Virus (EBV) EBNA IgG		X			X						
	Epstein Barr Virus (EBV) VCA IgG		X			X						
	Epstein Barr Virus (EBV) IgM		X			X						
H	HAV IgM								X			X
	HBc IgM								X			X
	HbeAg						X		X			
	HBsAg								X	X		
	<i>Helicobacter pylori</i> IgG		X	X								
	Herpes Simplex Virus 1 (HSV-1) IgG		X	X								
	Herpes Simplex Virus 2 (HSV-2) IgG		X	X								
	Herpes Simplex Virus 1 (HSV-1) IgM		X		X							
	Herpes Simplex Virus 2 (HSV-2) IgM		X		X							
	HIV P24Ag							X	X			
M	Measles IgG		X	X								
	Mumps IgG		X	X								
R	Rubella IgG		X	X								
	Rubella IgM		X		X							
T	<i>Toxoplasma gondii</i> IgG		X	X								
	<i>Toxoplasma gondii</i> IgM		X		X							
	<i>Treponema pallidum</i> (Syphilis) IgG		X	X				X	X			
V	Varicella Zoster Virus (VZV) IgG		X	X								

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

☎ +44 (0) 28 9442 2413   ✉ marketing@randox.com   🌐 randox.com

## INTERNATIONAL OFFICES



### AUSTRALIA

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



### BRAZIL

Randox Brasil Ltda.  
Tel: +55 11 5181 2024



### CHINA

Randox Laboratories Ltd.  
Tel: +86 021 6288 6240



### CZECH REPUBLIC

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



### FRANCE

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



### GERMANY

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



### HONG KONG

Randox Laboratories Hong Kong Limited  
Tel: +852 3595 0515



### ITALY

Randox Laboratories Ltd.  
Tel: +39 34 0080 9323



### INDIA

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



### POLAND

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



### PORTUGAL

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



### PUERTO RICO

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



### REPUBLIC OF IRELAND

Randox Teoranta  
Tel: +353 7495 22600



### SLOVAKIA

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



### SOUTH AFRICA

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



### SOUTH KOREA

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



### SPAIN

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



### SWITZERLAND

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



### UAE

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



### USA

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



### VIETNAM

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

For technical support contact:

technicalservices@randox.com

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