Written / Revised By: _____ **Date:** _____
Dr. Mike Louw, Medical Director

Reviewed By: _____ **Date:** _____
Dr. Sinead Kelly, Infectious Serology Consultant

Authorised By: _____ **Date:** _____
Jean-Sébastien Charles, QA Manager

Effective Date: **28/03/18** **Supersedes:** **2.02**

File Type: **Master** **Assigned to:** **Quality Department**

Electronic copies are available to all staff on Q-Pulse and on the Eurofins Biomnis website.

The master copy is held in the Quality Department. Additional copies of this SOP must not be made without prior approval and documentation. Refer to SOP G02.

Issue No.	Revision Details	Effective Date
1.01	Original	07/05/15
1.02	Updated accreditation status	28/07/15
1.03	Corrected SOP numbers for CMV	15/10/15
1.04	Removal of anti-hepatitis A antibody testing. Addition of ASOT, and hepatitis C antigen accreditation.	04/01/17
1.05	Removal of obsolete E72 reference.	11/05/17
2.01	Eurofins Biomnis rebranding	24/05/17
2.02	Reporting as detected or not detected v positive or negative for qualitative and semi-quantitative tests	20/09/17
2.03	Marked ASOT as accredited. Added reference to SOP. Updated CMV ref range.	28/03/18

INTRODUCTION

This is a list of the infectious serology tests performed at Eurofins Biomnis' Dublin Laboratory. For a searchable list of tests performed by Eurofins Biomnis in France, in our laboratories in Lyon and Paris, click here.

Please note that these lists were comprehensive at the time of publishing. Eurofins Biomnis is continuously updating its menu of tests, and some tests may be available even though they are not listed in this document or at the above link. If you cannot find details of a test you require, please contact our Client Services department on Free Phone 1800-252-966, or e-mail client.services@eurofins-biomnis.ie.

For sample collection, please contact our Logistics department on Free Phone 1800-252-967, or e-mail logistics@eurofins-biomnis.ie.

LAYOUT OF TEST INFORMATION

TEST INFORMATION TEMPLATE	
Brief information on clinical background, indications for test and interpretation of test results.	
Preparation of Patient: any special preparation required, such as fasting. **Precautions:** any special circumstances, conditions etc. to be aware of.	
Accredited	Whether or not the test is accredited by INAB to ISO 15189
Method	Test method
Sample Requirements	Type of tube required, transport temperature and other information.
Turnaround Time	The maximum turnaround time from receipt of the sample in the laboratory's pre-analytics department.
Stability	Sample stability under various conditions. **RT = room temperature i.e.: 16 – 25 °C.** Please see **SAMPLE STABILITY** notes below. Stability data indicated by a superscript numeral 1 are taken from the publication referenced below[1].
Units - Reference Ranges and Source	Units and reference range(s) for the test. Source of the reference ranges: 1. Test manufacturer's instructions for use (IFU). 2. National and international guidelines. 3. Ranges established in-house.

NOTES ON SAMPLE STABILITY

The majority of incorrect laboratory test results are due to improper sample collection and transport. For details regarding correct phlebotomy technique and our patient identification requirements, please click here.

In order for you to arrange and properly time phlebotomy and sample collection, we have indicated, for each test, its stability after collection. Stability is indicated for whole blood at various temperatures, and for plasma or serum separated from cells, also at various temperatures.

Note: RT = room temperature, i.e. 16 – 25 °C.

Stability data are taken from the manufacturers' instructions for use (IFUs), and from the World Health Organisation publication indicated below[1].

Sample stability data is not available for all tests under all conditions, either in the manufacturers' IFUs or the published literature. If no information is available, in general, unless otherwise specified (such as when the required sample is whole blood), serum should be centrifuged and separated from cells after completion of clotting (20 – 30 minutes), and transported to the laboratory at 2 – 8 °C. Plasma may be centrifuged and separated from cells immediately after sampling and gently mixing the sample by inverting the tube 10 times. It should then be transported to the laboratory at 2 – 8 °C. Whole blood should be transported at 2 – 8 °C and reach the laboratory as soon as possible. **However, please check each test for specific stability information.**

If in doubt, please contact our Client Services department on Free Phone 1800-252-966, or e-mail client.services@eurofins-biomnis.ie.

Reference:

1. World Health Organisation: Use of anticoagulants in diagnostic laboratory investigations. WHO/DIL/LAB99.1 Rev.2, 2002.

REASONS FOR REJECTION OF SAMPLES/NON-REPORTING OF TESTS

1. Samples received beyond the stability limits and/or not at the correct temperature indicated below for each test.

2. Samples received in the incorrect tube/with the incorrect anticoagulant or lack of the correct anticoagulant.

3. Samples received without the necessary patient identifiers. For more details, see here.

4. Samples which fail specific criteria for certain tests. See individual tests for details.

5. All samples have 3 tests run on them called "serum indices". These measure the extent of haemolysis, lipaemia and icterus in the sample. Each test has a specific level of each of these indices above which the test result is not valid. If any index is too high for a given test, that test is not reported. A comment such as "result invalid; sample haemolysed" is printed on the report instead.

Infectious Serology Consultant: Dr. Sinead Kelly
Telephone: 00-353-1-295-8545

CONTENTS

ANTI-HEPATITIS B CORE ANTIBODY

The ARCHITECT Anti-HBc assay utilizes microparticles coated with recombinant Hepatitis B Virus Core Antigen (rHBcAg) for the detection of anti-HBc. Anti-HBc determinations can be used to monitor the progress of hepatitis B viral infection. Anti-HBc is found in serum shortly after the appearance of Hepatitis B Surface Antigen (HBsAg) in acute hepatitis B infections. It will persist after the disappearance of HBsAg and before the appearance of detectable antibody to HBsAg (anti-HBs). In the absence of information about any other hepatitis B virus (HBV) markers, it must be considered that an individual with detectable levels of anti-HBc may be actively infected with HBV or that the infection may have resolved, leaving the person immune. Anti-HBc may be the only serological marker of hepatitis B viral infection and potentially infectious blood. The presence of anti-HBc does not differentiate between acute or chronic hepatitis B infections.

Preparation of Patient: There is no special physical preparation for the test.

Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) CC72
Sample Requirements	Tube Type: Serum (Gold and red cap); Plasma (lavender cap) Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	24h
Stability	Whole blood: RT 3 days. 14 days at + 4ºC Separated: RT 3 days. 14 days @ + 4ºC
Units - Reference Ranges and Source	Not detected (Negative) Abbott IFU G4-3061/R06 2013

ANTI-HEPATITIS B SURFACE ANTIBODY

Anti-HBs is a specific antibody directed against the hepatitis B surface antigen. Anti-HBs can be formed following an hepatitis B infection or after hepatitis B vaccination. This test is used within the scope of hepatitis B vaccination to check the necessity and success of vaccination. Moreover anti-HBs tests are used to monitor the course of disease following acute hepatitis B infection.

Preparation of Patient: There is no special physical preparation for the Anti Hepatitis B Antibody test.

Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC 48
Sample Requirements	Tube Type: Serum (Gold and red cap); Plasma (lavender cap) Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	24h
Stability	Whole blood: RT unknown. + 4ºC 14 days Separated: RT unknown; 14 days @ + 4ºC
Units - Reference Ranges and Source	IU/ml Greater than 10: reactive. Source: Abbott IFU G2-6352/R09 2012 For further guidance re. immunisation protocols and testing see http://www.immunisation.ie/en/Downloads/NIACGuidelines/PDFFile_17408_en.pdf

ANTI-STREPTOLYSIN O TITRE (ASOT)

The group A β-hemolytic streptococci produce various toxins that can act as antigens. One of these exotoxins is streptolysin-O. The affected organism produces specific antibodies against these exotoxins, among which concentration of antistreptolysin-O in the patient's serum will enable to establish the degree of infection due to the β-hemolytic streptococcus.
A positive test can indicate recent or current group A, C, and G streptococcal infection (eg, upper airway infections, scarlet fever, toxic shock syndrome) and may support the diagnosis of post-streptococcal infection complication (eg, glomerulonephritis and rheumatic fever).
The test is positive in only 80-85% of group A streptococcal infections, so a negative test does not necessarily exclude the diagnosis.

Preparation of Patient: There is no special physical preparation for the test.

Accredited	Yes
Method	Quantia ASO latex particle agglutination. SOP CC153
Sample Requirements	Tube Type: Serum (Gold and red cap). Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	24h
Stability	Serum 2 days @ + 4ºC
Units - Reference Ranges and Source	IU/mL Up to 7 years: less than 100 Greater than 7 years: less than 200 Abbott IFU 6K38-01 April 2013.

CYTOMEGALOVIRUS IGG AND IGM ANTIBODIES

Infections with CMV (a member of the herpes virus family) are very common and usually mild and asymptomatic. In immunocompromised patients, however, infections can be severe and sometimes fatal. Also, *in utero* infection of the foetus can lead to birth defects. If the CMV IgG is positive, CMV IgM is measured to determine if the infection is current or recent.

Preparation of Patient: There is no special physical preparation for the CMV Ab test.

Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC75/CC83
Sample Requirements	Tube Type: Serum (Gold and red cap); Plasma (green and lavender cap) Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	3 days
Stability	Whole blood: RT unknown; + 4ºC 14 days. Separated: RT unknown; 14 days @ + 4ºC
Units - Reference Ranges and Source	IgG: Greater than or equal to 6.0 AU/mL are regarded as POSITIVE Less than 6.0 AU/mL are NEGATIVE. IgM: Index less than or equal to 0.85: NEGATIVE Index 0.86 to 1.00: GRAYZONE, Repeat in 7 to 14 days Index greater than 1.00: POSITIVE Source: Abbott IFU G3-0217/R06 and G2-6298/R02 2012

HEPATITIS B SURFACE ANTIGEN	
This is a polypeptide component of the Hepatitis B virus particle external envelope. Its presence in the blood indicates infection by the virus; it is the first hepatitis B immunological marker and is present in blood days or weeks before symptoms appear. It may persist in persons who are chronic carriers of hepatitis B.	
Preparation of Patient: There is no special physical preparation for this test.	
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC 28
Sample Requirements	Tube Type: Serum (Gold and red cap); Plasma (green and lavender cap) Temperature: + 4ºC. Miscellaneous: Non fasting
Turnaround Time	24h
Stability	Whole blood: RT unknown. + 4ºC: 14 days. Separated: 14 days @ + 4ºC
Units - Reference Ranges and Source	Not detected (Negative) Source: Abbott IFU G2-3418/R01 2012

HEPATITIS C VIRUS ANTIBODIES	
This test detects the presence of antibodies to the Hepatitis C virus.	
Preparation of Patient: There is no special physical preparation for the Hepatitis C Ab test.	
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC74.
Sample Requirements	Tube Type: Serum (Gold and red cap); Plasma (green and lavender cap) Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	24h
Stability	Whole blood: RT unknown. + 4ºC: 7 days. Separated: RT 5 days[1], 7 days @ + 4ºC
Units - Reference Ranges and Source	Not detected (Negative) Source: Abbott IFU G2-6275/R08 2012.

HEPATITIS C VIRUS ANTIGEN

ARCHITECT HCV Ag is a Chemiluminescent Microparticle Immunoassay (CMIA) using microparticles coated with monoclonal anti-HCV for the detection of HCV Ag. HCV Ag assays are used as an aid in the diagnosis of suspected Hepatitis C viral (HCV) infection and to monitor the status of infected individuals, i.e., whether the patient's infection has resolved or the patient has become a chronic carrier of the virus. For the diagnosis of acute or chronic hepatitis, HCV Ag reactivity should be correlated with patient history and the presence of other Hepatitis C serological markers.

Preparation of Patient: There is no special physical preparation for the Hepatitis C Ag test.

Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC134
Sample Requirements	Tube Type: Serum (Gold and red cap); plasma (green and lavender cap) Temperature: + 4ºC Misc.: Non fasting
Turnaround Time	3 days
Stability	Whole blood: RT unknown. + 4ºC: 5 days. Separated: RT unknown. 5 days @ + 4ºC
Units - Reference Ranges and Source	Not detected (Negative) Source: Abbott IFU F5-Y206-2/R03 2012

HTLV-I/II	
HTLV-I and HTLV-II are closely related human type C retroviruses. HTLV-I has been etiologically associated with neoplastic conditions and a variety of demyelinating neurologic disorders including: adult T-cell leukaemia, tropical spastic paraparesis and/or HTLV-I associated myelopathy and more recently HTLV-I associated polymyositis, arthritis, and infective dermatitis. Detection of antibodies against HTLV-I and HTLV-II serves to aid in the diagnosis of HTLV infection and to protect the safety of blood supply.	
Preparation of Patient: There is no special physical preparation for this test.	
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC93
Sample Requirements	Tube Type: Serum (Gold and red cap); Plasma (green and lavender cap) Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	5 days
Stability	Whole blood: RT 3 days. 14 days at + 4ºC Separated: RT 3 days, 14 days @ + 4ºC
Units - Reference Ranges and Source	Not detected (Negative). Source: Abbott IFU G3-0216/R04 2012

HUMAN IMMUNODEFICIENCY VIRUS (HIV) ANTIBODY/ANTIGEN COMBO	
This Combo test measures antibodies to HIV-1 and HIV-2, and the HIV p24 antigen. The test is positive if either or both of these are present, and does not distinguish between them.	
Preparation of Patient: There is no special physical preparation for the HIV test.	
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC73
Sample Requirements	Tube Type: Serum (Gold and red cap); Plasma (green and lavender cap) Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	24h
Stability	Whole blood: RT unknown. 14 days + 4ºC Separated: RT 7 days[1], 14 days @ + 4ºC
Units - Reference Ranges and Source	Not detected (Negative) Source: Abbott IFU G3-0570/R03 2012

RUBELLA IGG AND IGM ANTIBODIES	
Primary *in utero* rubella infection can lead to severe birth defects. A positive IgG with a negative IgM result indicates previous rubella infection/vaccination and implies immunity to further infection. A positive IgM result indicates current/recent infection and risk to the foetus in case of pregnancy.	
Preparation of Patient: There is no special physical preparation for the rubella Ab test.	
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC76/CC81
Sample Requirements	Tube Type: Serum (Gold and red cap); Plasma (green and lavender cap) Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	3 days
Stability	Whole blood: RT unknown. 14 days at + 4ºC Separated: RT unknown. 14 days @ + 4ºC
Units - Reference Ranges and Source	IgG: < 5.0 IU/mL = Not detected (Negative) 5.0 – 9.9 = equivocal >/= 10 = Detected (Positive) IgM: Index less than 1.20 = negative Index 1.20 – 1.60 = equivocal; repeat in 7 to 14 days Index >/= 1.60 = positive Source: Abbott IFU 840627/R3 2009

SYPHILIS TREPONEMA PALLIDUM AB

Syphilis is caused by infection with the bacterium TP which can be transmitted congenitally or by sexual contact. The disease can evolve into a latent phase in which syphilis is clinically inapparent. Serological tests (nontreponemal and treponemal specific), in addition to patients' clinical history, are currently the primary methods for the diagnosis and management of syphilis.

Preparation of Patient: There is no special physical preparation for the Syphilis Ab test.

Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC41
Sample Requirements	Tube Type: Serum (Gold and red cap); Plasma (green and lavender cap) Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	3 days
Stability	Whole blood: unknown. Separated: RT: 24 hours, 7 days @ + 4ºC
Units - Reference Ranges and Source	Not detected (Negative) Source: Abbott IFU F5-Y203-2/R02 2013