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Primary Sample Manual – Infectious Serology

Changes made since previous version: *Changed status to Accredited for Aspergillus. Removed HCV Ag.*

Note: *Please refer to document record on Q-Pulse for the revision history of this document.*

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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.

If you cannot find details of a test you require, please contact our Client Services department on Free Phone 1800-252-966 or 01 295 8545, or e-mail clientservices@ctie.eurofinseu.com.

For sample collection, please contact our Logistics department on Free Phone 1800-252-967, or e-mail logistics@ctie.eurofinseu.com.

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. If the test is accredited (Yes), this section is colour-coded in green; if the test is not accredited (No), this section is colour-coded in orange.
Method	Test method
Sample Requirements	Type of tube required, transport temperature and other information.
Turnaround Time	The maximum turnaround time in working days from receipt of the sample in the laboratory's pre-analytics department. **Working days are Monday to Friday 08:00 to 18:00.**
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

Most 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.

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 01 295 8545, or e-mail clientservices@ctie.eurofinseu.com.

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.

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ANTI-HEPATITIS B CORE ANTIBODY

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.

Location	**Eurofins Biomnis Blackthorn Road**
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) technology SOP: CC188
Sample Requirements	Tube Type: Serum (Gold and red cap); EDTA (Lavender cap) Plasma Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	1 working day.
Stability	≤3 days at 15-30 ºC ≤14 days at 2-8 ºC >14 days at -20 ºC or colder.
Units, Reference ranges and Source	Specimens with S/CO values < 1.00 are considered Non-reactive (NR). Specimens with S/CO values >= 1.00 are considered reactive (R). This is a screening test, and reactive samples will be referred to NVRL for confirmatory testing. Source: Abbott IFU

ANTI-HEPATITIS B SURFACE ANTIBODY

Anti-HBs is a specific antibody directed against the hepatitis B surface antigen. Anti-HBs can be formed following a Hepatitis B infection or after a 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 test.

Location	**Eurofins Biomnis Blackthorn Road**
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC188
Sample Requirements	Tube Type: Serum (Gold and red cap); EDTA (Lavender cap) Plasma Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	1 working day
Stability	Whole blood ≤ 14 days at 2-8°C. Separated: >14 days frozen (-20°C or colder)
Units, Reference ranges and Source	mIU/ml <10 : Non reactive /Non-Immune If post-vaccination, patient is a non-responder. Test for Anti-HBc. If anti-HBc negative, give booster dose of the same hepatitis B vaccine. Recheck anti-HBs 2 months later and if anti-HBs remains <10 mIU/ml, give two further doses of the same hepatitis B vaccine (i.e. complete a second course of the same hepatitis B vaccine). Recheck anti-HBs 2 months later and if anti-HBs remains <10 mIU/ml, person is susceptible to HBV. ≥ 10: Reactive/Immune Based on the World Health Organisation and NIAC recommendations, an Anti-HBs concentration ≥ 10 mIU/mL is regarded as being protective against Hepatitis B viral infection. Source: Abbott IFU For further guidance re. immunisation protocols and testing see https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter9.pdf

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.	
Location	**Eurofins Biomnis Blackthorn Road**
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC188
Sample Requirements	Tube Type: Serum (Gold and red cap); Heparin (Green cap) or EDTA (Lavender cap) Plasma Temperature: + 4ºC. Miscellaneous: Non fasting
Turnaround Time	1 working day
Stability	Whole blood: Up to 24 hours at RT or ≤ 6 days at 2-8ºC Separated: ≥ 6 days at -20ºC or colder. Avoid more than 3 freeze/thaw cycles
Units - Reference Ranges and Source	Specimens with S/CO values < 1.00 are considered nonreactive (NR). Specimens with S/CO values >=1.00 are considered reactive (R). This is a screening test and reactive samples will be referred to NVRL for confirmatory testing. Hep B surface antigen alone is not useful during the "window period" of acute hepatitis B infection (i.e. after the disappearance of Hep B surface antigen and before the appearance of Hep B surface antibody). Testing for acute hepatitis B infection should also include Hepatitis B core IgM antibody. Source: Abbott IFU

ANTI-STREPTOLYSIN O TITRE (ASOT)

The group A β-haemolytic 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 Anti-Streptolysin-O in the patient's serum will enable to establish the degree of infection due to the β-haemolytic streptococcus.
A positive test can indicate recent or current group A, C, and G streptococcal infection (e.g., upper airway infections, scarlet fever, toxic shock syndrome) and may support the diagnosis of post-streptococcal infection complication (e.g., 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 this test.

Location	**Eurofins Biomnis Blackthorn Road**
Accredited	Yes
Method	Turbidimetric/Immunoturbidimetric SOP: CC188
Sample Requirements	Tube Type: Serum (Gold and red cap). Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	1 working day
Stability	Serum ≤2 days at 2-8 ºC > 2 days -20 ºC
Units - Reference Ranges and Source	IU/mL Up to 7 years: less than 100 Greater than 7 years: less than 200 Source: Abbott IFU

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 these tests.

Location	**Eurofins Biomnis Blackthorn Road**
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC188
Sample Requirements	Tube Type: Serum (Gold and red cap); Heparin (Green cap) or EDTA (Lavender cap) Plasma Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	3 working days
Stability	Whole blood: RT unknown; ≤14 days. 2-8ºC Separated: RT unknown; ≥14 days -10°C or colder
Units - Reference Ranges and Source	CMV IgG: ≥6.0 AU/mL are considered reactive (POSITIVE) Less than 6.0 AU/mL are nonreactive (NEGATIVE) CMV IgM: Index <0.85 are considered nonreactive (NEGATIVE) Index 0.85 to 0.99: GRAYZONE, Repeat in 7 to 14 days Index greater than or equal to 1.00: reactive (POSITIVE) Source: Abbott IFU

HEPATITIS C VIRUS ANTIBODIES	
HCV is a bloodborne virus. Serological studies employing EIAs for detection of antibodies to recombinant antigens of HCV have established HCV as the cause of most bloodborne as well as community-acquired non-A, non-B hepatitis. The presence of anti-HCV indicates that an individual may have been infected with HCV, may harbor infectious HCV, and/or may be capable of transmitting HCV infection. Although the majority of infected individuals may be asymptomatic, HCV infection may develop into chronic hepatitis, cirrhosis, and/or increased risk of hepatocellular carcinoma. The implementation of blood donation screening for anti-HCV by EIAs has led to a marked decline in the risk of transfusion-transmitted hepatitis,	
Preparation of Patient: There is no special physical preparation for the Hepatitis C Ab test.	
Location	**Eurofins Biomnis Blackthorn Road**
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC188
Sample Requirements	Tube Type: Serum (Gold and red cap); Heparin (Green cap) or EDTA (Lavender cap) Plasma Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	1 working day
Stability	≤ 7 days at 2-8ºC ≤ 3 months at -20ºC or colder.
Units - Reference Ranges and Source	Specimens with S/CO values < 1.00 are considered Non-reactive (NR). Specimens with S/CO values >= 1.00 are considered Reactive (R). This is a screening test and reactive samples will be referred to NVRL for confirmatory testing Source: Source: Abbott IFU

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 the HTLV-I/II test.	
Location	**Eurofins Biomnis Blackthorn Road**
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC188
Sample Requirements	Tube Type: Serum (Gold and red cap); Heparin (Green cap) or EDTA (Lavender cap) Plasma) Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	5 working days
Stability	≤ 3 days at 15-30 ºC ≤ 14 days at 2-8ºC Separated: ≥ 14 days at -20ºC or colder.
Units - Reference Ranges and Source	Specimens with S/CO values < 1.00 are considered nonreactive (NR). Specimens with S/CO values >= 1.00 are considered reactive (R). This is a screening test and reactive samples will be referred to NVRL for confirmatory testing. A negative (non-reactive) test result does not exclude the possibility of exposure to human T-cell lymphotropic virus types I and II. Levels of total antibodies to these viruses may be undetectable in early infection. Source: Abbott IFU

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.	
Location	**Eurofins Biomnis Blackthorn Road**
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC188
Sample Requirements	Tube Type: Serum (Gold and red cap); Heparin (Green cap) or EDTA (Lavender cap) Plasma Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	1 working day
Stability	Whole blood: ≥ 3 days at RT or 14 days at 2-8ºC Separated: at -20ºC or colder.
Units - Reference Ranges and Source	Negative Non-Reactive Please send a further sample taken at least 7 days after the current sample if HIV infection is still suspected. Specimens with S/CO values < 1.00 are considered nonreactive (NR). Specimens with S/CO values >= 1.00 are considered reactive (R). This is a screening test, and reactive samples will be referred to NVRL for confirmatory testing. Source: Abbott IFU

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.	
Location	**Eurofins Biomnis Blackthorn Road**
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC188
Sample Requirements	Tube Type: Serum (Gold and red cap); Heparin (Green cap) or EDTA (Lavender cap) Plasma Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	3 working days
Stability	Whole blood: ≤ 14 days at 2-8ºC Separated: ≥ 14 days -20ºC or colder.
Units - Reference Ranges and Source	Rubella IgG Antibody: kIU/L 0.0 to 4.9: Non-reactive 5.0 to 9.9: Equivocal >/= 10 : Reactive Rubella IgM Antibody: - Index Index less than 1.20: nonreactive (Negative) Index 1.20 - 1.59: equivocal; repeat in 7 to 14 days. Index >/= 1.60: reactive (Positive). Source: Abbott IFU

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 unapparent. Serological tests (non-treponemal 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.	
Location	**Eurofins Biomnis Blackthorn Road**
Accredited	Yes
Method	Chemiluminescent microparticle immunoassay (CMIA) SOP: CC188
Sample Requirements	Tube Type: Serum (Gold and red cap); Heparin (Green cap) or EDTA (Lavender cap) Plasma Temperature: + 4ºC Miscellaneous: Non fasting
Turnaround Time	3 working days
Stability	Serum: RT ≤ 72 hours; 2-8°C ≤ 7 days Plasma: RT ≤ 72 hours; 2-8°C ≤ 30 days
Units - Reference Ranges and Source	Specimens with S/CO values < 1.00 are considered nonreactive (negative). Specimens with S/CO values >=1.00 are considered reactive (positive). This is a screening test and reactive samples will be referred to NVRL for confirmatory testing Source: Abbott IFU

ASPERGILLUS FUMIGATUS (M3) AND FLAVUS (M228) IGG	
The ImmunoCAP Specific lgG is an immunoassay for the quantitative measurement of antigen specific lgG antibodies *to A. fumigatus* and *A. flavus* in serum. It is intended for in vitro diagnostic use to assess lgG associated immune response using Phadia 250 instrument. Allergic bronchopulmonary aspergillosis (ABPA) and allergic bronchopulmonary mycosis (ABPM) involve the colonisation by *Aspergillus fumigatus* and other fungal species which elicit a characteristic humoral immune response to antigens or allergens of these fungi. *A. fumigatus* and *A. flavus* are opportunistic pathogens in humans. They can cause mild infections but also life-threatening diseases in those who are immunocompromised.	
Preparation of Patient: No special preparation.	
Location	**Eurofins Biomnis Blackthorn Road**
Accredited	**Yes**
Method	Fluoroenzyme immunoassay (Phadia 250) SOP BCC82
Sample Requirements	Tube Type: Serum (Gold and red cap); Heparin (Green cap) or EDTA (Lavender cap) Plasma Temperature: + 4ºC
Turnaround Time	4 working days
Stability	Whole blood: unknown. Separated: RT 7 days 7 days @ + 4ºC or longer @ -20 ºC Source: Phadia IFU

Units - Reference Ranges and Source	mgA/L <14 Negative 14-27 Equivocal >27 Positive All equivocal or positive screening result is to be confirmed by confirmatory technique. According to a review of the literature, cut-offs in diseased population (ABPA or aspergillosis) vary between 27 and 50 mgA/L. A grey zone was defined for values between 14 and 27 mgA/L with 14 mgA/L representing the threshold triggering confirmation of aspergillosis serology using the ASPERGILLOSIS IgG Western Blot (LDBIO). Reminder: Aspergillus serology (screening and confirmation by Western blot) cannot and should not be used as a tool for monitoring aspergillosis. According to a review of the literature, the kinetics of anti-Aspergillus antibodies are subject to numerous variables: the usefulness of this serology is debated and depends on the pathology concerned: -CPA (chronic pulmonary aspergillosis): inconsistent levels. -ABPA (allergic bronchopulmonary aspergillosis): useful as a supplement to clinical and imaging tests + no benefit if nodules are present. -IA (invasive aspergillosis): useful as a supplement to soluble antigen testing (in serum or BAL) and beta-D-glucan assay. In all cases, results must be compared with the patient's medical history, clinical findings, and any therapeutic infromation available, and must be verified with a new sample if the context warrants it. Source: Eurofins Biomnis France