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Title: Primary Sample Manual: Molecular Biology - Immunology		

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Changes made since previous version: *Storage temperatures updated.*

Note: *Please refer to the document record on QPulse for the revision history of this document*

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INTRODUCTION

This is a list of the Molecular immunology 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 contact our Client Services department on Free Phone 1800-252-966 or 01 295 8545, or e-mail clientservices@ctie.eurofinseu.com with any questions.

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. Standard Operating Procedure reference for this test.
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 to the authorisation of the result. 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).

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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 data are taken from the reference literature indicated below¹.

REFERENCE

1. Permenter, J., Ishwar, A., Rounsavall, A., Smith, M., Faske, J., Sailey, C.J., Alfaro, M.P. (2015). Quantitative analysis of genomic DNA degradation in whole blood under various storage conditions for molecular diagnostic testing. *Molecular and Cellular Probes*, 29(6):449-453.

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.

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HLA-B27	
HLA-B27 is a class I surface antigen strongly associated with seronegative spondyloarthropathies, such as ankylosing spondylitis. Ankylosing spondylitis is a type of arthritis characterised by long-term inflammation of the joints of the spine. 90% of patients diagnosed with Ankylosing spondylitis (AS) test positive for HLA-B27, thus genotyping is suitable for the differential diagnosis of AS. However, only 1-2% of those who test positive for HLA-B27 develop AS. Therefore, the test is not indicated as a screening test. HLA-B27 has a frequency of approximately 8% in the general Caucasian population.	
Preparation of patient: There is no physical preparation for the HLA-B27 test.	
Precautions: None.	
Accredited	Yes
Method	Molecular Biology – Real-time PCR SOP: MB54
Sample Requirements	Tube Type: Whole blood EDTA Temperature: 2-8°C Miscellaneous: Non fasting
Turnaround Time	5 working days from sample receipt
Stability	Whole blood at room temperature: 3 days Whole blood at 2-8°C: 7 days DNA extracts: 3 Months at -20°C Primary EDTA tube: 3 Months at -20°C
Units - Reference Ranges	HLA-B27 Positive HLA-B27 Negative Invalid

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