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| <b>Title:</b><br>Primary Sample Manual: Molecular Biology - Immunology                      |                                    |             |

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**Title:** Primary Sample Manual: Molecular Biology - Immunology

**Changes made since previous version:** *Updated reference for stability of samples to HLA-B27 PCR kit insert. Added extra piece about the assay used to the HLA-B27 introduction. Changed 'Reference Range' to 'Results' and added kit insert as source of results. Reworded 'stability' section for HLA-B27. Added section on Laboratory Sample Storage. Added section for HLA-B27 Extended.*

**Note:** *Please refer to the document record on QPulse / IQM 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](mailto: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](mailto:logistics@ctie.eurofinseu.com).

| TEST INFORMATION TEMPLATE                                                                                                                                           |                                                                                                                                                                                                                                                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Brief information on clinical background, indications for test and interpretation of test results.                                                                  |                                                                                                                                                                                                                                                                       |
| <b>Preparation of Patient:</b> any special preparation required, such as fasting.<br><b>Precautions:</b> any special circumstances, conditions etc. to be aware of. |                                                                                                                                                                                                                                                                       |
| <b>Accredited</b>                                                                                                                                                   | 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.                                                       |
| <b>Method</b>                                                                                                                                                       | Test method. Standard Operating Procedure reference for this test.                                                                                                                                                                                                    |
| <b>Sample Requirements</b>                                                                                                                                          | Type of tube required, transport temperature and other information.                                                                                                                                                                                                   |
| <b>Turnaround Time</b>                                                                                                                                              | 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. <b>Working days are Monday to Friday 08:00 to 18:00.</b>                                                      |
| <b>Stability</b>                                                                                                                                                    | Sample stability under various conditions.<br><b>RT = room temperature i.e.: 16 – 25 °C.</b><br>Please see <b>SAMPLE STABILITY</b> notes below.<br>Stability data indicated by a superscript numeral 1 are taken from the publication referenced below <sup>1</sup> . |
| <b>Laboratory Sample Storage</b>                                                                                                                                    | The length of time that the laboratory stores patient samples for and the conditions in which the samples are stored.                                                                                                                                                 |
| <b>Results and Source</b>                                                                                                                                           | The potential results that may be released for the test.<br><br>Source of the results.                                                                                                                                                                                |

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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 test manufacturer's instructions for use<sup>1</sup>.

### REFERENCES

1. ViennaLab HLA-B27 RealFast™ Assay Instructions For Use rev 1.0
2. geneMAP™ HLA-B\*27 Detection Kit For Real-Time PCR Instruction For Use F-08-05  
Rev.Date: 12.12.2024

### 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>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.</p> <p>HLA-B27 has a frequency of approximately 8% in the general Caucasian population.</p> <p>The qualitative assay used for the detection of HLA-B27 discriminates the presence or absence of HLA-B*27 alleles in a human genomic DNA extract from blood. This assay detects the following HLA-B*27 subtypes:</p> <p>B*27:05:09, B*27:05:23, B*27:12, B*27:16, B*27:18, B*27:23, B*27:85, B*27:91, B*27:92, B*27:101, B*27:109, B*27:119, B*27:129, B*27:140, B*27:153, B*27:157.</p> |                                                                                                                                                                                                                                                                                                                           |
| <b>Preparation of patient:</b> There is no physical preparation for the HLA-B27 test.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                           |
| <b>Precautions:</b> None.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                           |
| <b>Accredited</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Yes                                                                                                                                                                                                                                                                                                                       |
| <b>Method</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Molecular Biology – Real-time PCR<br>SOP: MB54                                                                                                                                                                                                                                                                            |
| <b>Sample Requirements</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Tube Type: Whole blood EDTA<br>Temperature: 2-8°C for up to 7 days. -20°C thereafter.<br>Miscellaneous: Non fasting                                                                                                                                                                                                       |
| <b>Turnaround Time</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 5 working days from sample receipt                                                                                                                                                                                                                                                                                        |
| <b>Stability</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Whole blood in EDTA at room temperature: 3 days<br>Whole blood in EDTA at 2-8°C: 7 days<br>Whole blood in EDTA at -20°C: 1 year (Unless the sample has gone through more than three freeze-thaw cycles)<br><br>DNA extracts at 2-8°C: 7 days<br>DNA extracts at -30°C to -15°C: Long-term. No specific time frame stated. |
| <b>Laboratory Sample Storage</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Primary sample tube (whole blood in EDTA): 1 month at -20°C<br><br>DNA extracts: 3 months at -20°C                                                                                                                                                                                                                        |
| <b>Results and Source</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | HLA-B27 Positive<br>HLA-B27 Negative<br>Invalid<br><br><b>Source:</b> ViennaLab HLA-B27 RealFast™ Assay Instructions For Use rev 1.0                                                                                                                                                                                      |

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| HLA-B27 EXTENDED                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>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.</p> <p>HLA-B27 has a frequency of approximately 8% in the general Caucasian population.</p> <p>The qualitative assay used for the detection of HLA-B27 discriminates the presence or absence of HLA-B*27 alleles in a human genomic DNA extract from blood. This assay detects the following HLA-B*27 subtypes:</p> <p>B*27:01, B*27:02:01:01-05, B*27:02:02-05, B*27:03, B*27:04:01-06, B*27:05:02:01-3, B*27:05:02:04Q, B*27:05:02:05-21, B*27:05:03-17, B*27:05:18:01-02, B*27:05:19-47, B*27:06:01:01-02, B*27:08-10, B*27:12:01:01-03, B*27:13:01-02, B*27:15-18, B*27:23, B*27:25-29, B*27:31, B*27:35, B*27:37-42, B*27:44-49, B*27:50:01-02, B*27:51-58, B*27:59N, B*27:60-62, B*27:64N-66N, B*27:67-69, B*27:71-72, B*27:74-79, B*27:82-89, B*27:91-93, B*27:94N, B*27:96:01-02, B*27:97-98, B*27:100-101, B*27:103-123, B*27:126, B*27:128-129, B*27:131-137, B*27:139-149, B*27:151-152, B*27:154, B*27:156-163, B*27:165-175, B*27:176N, B*27:177-179, B*27:181-184, B*27:185Q, B*27:186, B*27:189-204, B*27:206-211, B*27:212N, B*27:213-214, B*27:215N, B*27:220-222, B*27:223N, B*27:225N, B*27:226.</p> |                                                                                                                                                       |
| <b>Preparation of patient:</b> There is no physical preparation for the HLA-B27 Extended test.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                       |
| <b>Precautions:</b> None.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                       |
| <b>Accredited</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Yes                                                                                                                                                   |
| <b>Method</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Molecular Biology – Real-time PCR<br>SOP: MB69                                                                                                        |
| <b>Sample Requirements</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Tube Type: Whole blood EDTA<br>Temperature: 2-8°C for up to 30 days. -20°C thereafter.<br>Miscellaneous: Non fasting                                  |
| <b>Turnaround Time</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 5 working days from sample receipt                                                                                                                    |
| <b>Stability</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Whole blood in EDTA at 2-8°C: 30 days<br>Whole blood in EDTA at -20°C: 1 year (Unless the sample has gone through more than three freeze-thaw cycles) |
| <b>Laboratory Sample Storage</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Primary sample tube (whole blood in EDTA): 1 month at 2-8°C<br>DNA extracts: 3 months at -20°C                                                        |

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|                           |                                                                                                                                                                         |
|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Results and Source</b> | HLA-B*27 Present<br>HLA-B*27 Absent<br>Invalid<br><br><b>Source:</b> geneMAP™ HLA-B*27 Detection Kit For Real-Time PCR Instruction For Use F-08-05 Rev.Date: 12.12.2024 |
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