

# Specification List

## Molecular Genetics and Special Immunodiagnostics

### General Information

The specifications list contains the range of analysis provided by the clinical immunological laboratory and informs you about the methods, sample types and volumes used, the frequency of analysis, reference values and, if necessary, preanalytical aspects. The specifications list is available on the internet at [www.labor-stoecker.de](http://www.labor-stoecker.de).

#### Duration:

The samples are registered upon receipt in the laboratory. Preferably, analysis is performed or started on the same day to ensure that the report can be sent to the customer generally one day after receipt of the sample at the latest. The time period may be longer in individual cases if the analysis is not carried out daily or retesting of the sample or performing of a dilution series is required.

#### Reference range:

The reference values given in the specifications list are in accordance with the manufacturer's recommendations for the test system used and with current scientific and technological knowledge. However, reference ranges may change due to new scientific findings and technical developments in analytical techniques. Interpretation of results is always based on the reference ranges and additional remarks which are given on the report.

#### Measurement deviations:

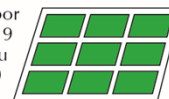
The clinical immunological laboratory performs regular checks and maintenance to minimise variations and method-related deviations in the measurement results. Due to existing measurement deviations, borderline and weak-positive results or results that lie near to the reference value or other medical decision limits should be interpreted with care. Information about measurement deviations in individual quantitative analyses can be provided upon request. However, most analyses that are performed by the clinical immunological laboratory (antibody diagnostics) are considered qualitative.

#### Comparability of test results:

Results from different methods (e.g. immunofluorescence, ELISA, blot techniques) for detecting the same antibodies in a sample may differ. This can be due to the use of different antigens or to varying immobilisation of the same antigen to different carrier materials, which can influence the binding of the antibody to the antigen through conformational changes in the antigen or through steric inhibition.

#### Laboratory developed test (LDT):

The laboratory tests are usually CE marked. Tests that are not CE marked but validated by the laboratory are identified in the specification list as laboratory developed tests (LDT) and are not covered by the accreditation of the clinical immunological laboratory.

**25-OH-vitamin D ELISA**

sample types: serum, EDTA, heparin, citrat plasma  
sample volume: 1,5ml  
method: ELISA  
frequency: biweekly  
reference value: see result report  
remarks: The analysis is not covered by the accreditation of our laboratory.  
as at: 12/21

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**APOE**

sample types: EDTA blood  
alternative sample types: isolated genomic DNA  
sample volume: 1,5 ml  
method: EUROARRAY  
frequency: biweekly  
reference value: see result report  
remarks: Declaration of consent for human genetic diagnostics required.  
The analysis is not covered by the accreditation of our laboratory.  
as at: 12/21

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**dermatomycosis**

sample types: skin material  
alternative sample types: hair material, nail material, culture material, purified DNA  
sample volume: culture material 1 cm<sup>2</sup>  
method: EUROARRAY  
frequency: biweekly  
reference value: see result report  
remarks: The analysis is not covered by the accreditation of our laboratory.  
as at: 12/21

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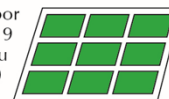
**FII+**

sample types: EDTA blood  
alternative sample types: isolated genomic DNA  
sample volume: 1,5 ml  
method: EUROARRAY  
frequency: biweekly  
reference value: see result report  
remarks: Declaration of consent for human genetic diagnostics required.  
The analysis is not covered by the accreditation of our laboratory.  
as at: 12/21

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**FV**

sample types: EDTA blood  
alternative sample types: isolated genomic DNA  
sample volume: 1,5 ml  
method: EUROARRAY  
frequency: biweekly  
reference value: see result report  
remarks: Declaration of consent for human genetic diagnostics required.  
The analysis is not covered by the accreditation of our laboratory.  
as at: 12/21

**HLA-B27**

sample types: EDTA blood  
sample volume: 1,5 ml  
method: EUROARRAY  
frequency: biweekly  
reference value: see result report  
remarks: Declaration of consent for human genetic diagnostics required.  
as at: 12/21

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**HLA-B57**

sample types: EDTA blood  
sample volume: 1,5 ml  
method: EUROARRAY  
frequency: biweekly  
reference value: see result report  
remarks: Declaration of consent for human genetic diagnostics required.  
as at: 12/21

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**HLA-Cw6**

sample types: EDTA blood  
sample volume: 1,5 ml  
method: EUROARRAY  
frequency: biweekly  
reference value: see result report  
remarks: Declaration of consent for human genetic diagnostics required.  
as at: 12/21

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**HLA-DQ2/DQ8**

sample types: EDTA blood  
sample volume: 1,5 ml  
method: EUROARRAY  
frequency: biweekly  
reference value: see result report  
remarks: Declaration of consent for human genetic diagnostics required.  
as at: 12/21

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**HPV**

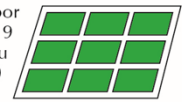
sample types: cervical swab  
sample volume: n/a  
method: EUROARRAY  
frequency: biweekly  
reference value: see result report  
remarks: The analysis is not covered by the accreditation of our laboratory.  
as at: 12/21

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**Haemochromatosis (HFE) (4 SNP+)**

sample types: EDTA blood  
alternative sample types: isolated genomic DNA  
sample volume: 1,5 ml  
method: EUROARRAY  
frequency: biweekly  
reference value: see result report  
remarks: Declaration of consent for human genetic diagnostics required.  
The analysis is not covered by the accreditation of our laboratory.  
as at: 12/21

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**Lactose-/ fructose (aldolase B) intolerance**

sample types: EDTA blood  
alternative sample types: isolated genomic DNA  
sample volume: 1,5 ml  
method: EUROARRAY  
frequency: biweekly  
reference value: see result report  
remarks: Declaration of consent for human genetic diagnostics required.  
The analysis is not covered by the accreditation of our laboratory.  
as at: 11/24

**MTHFR**

sample types: EDTA blood  
alternative sample types: isolated genomic DNA  
sample volume: 1,5 ml  
method: EUROARRAY  
frequency: biweekly  
reference value: see result report  
remarks: Declaration of consent for human genetic diagnostics required.  
The analysis is not covered by the accreditation of our laboratory.  
as at: 12/21

**Mullerian-duct repression hormone (MRH)**

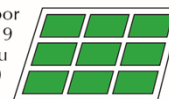
sample types: serum, heparin plasma  
sample volume: 1,5 ml  
method: ELISA  
frequency: daily (mo-fri)  
reference value: see result report  
remarks: The analysis is not covered by the accreditation of our laboratory.  
as at: 01/19

**Neurofilament (pNf-H) ELISA**

sample types: serum CSF sample volume: 1,5 ml  
method: ELISA  
frequency: biweekly  
reference value: see result report  
remarks: Please note the instructions for preanalytics. The samples must be submitted frozen.  
This analysis is not covered by the current accreditation scope.  
as at: 11/24

**Neurofilament (Nf-L) ELISA**

sample types: CSF sample volume: 1,5 ml  
method: ELISA  
frequency: biweekly  
reference value: see result report  
remarks: Please note the instructions for preanalytics. The samples must be submitted frozen.  
This analysis is not covered by the current accreditation scope.  
as at: 11/24

**pTau(181)**

sample types: CSF  
sample volume: 1,5 ml  
method: ELISA  
frequency: weekly  
reference value: see result report  
remarks: Please note the instructions for preanalytics. The samples must be submitted frozen.  
This analysis is not covered by the current accreditation scope.  
as at: 11/24

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**SARS-CoV-2**

sample types: throat swab  
alternative sample types: purified RNA  
sample volume: -  
method: PCR EURORealTime  
frequency: biweekly  
reference value: see result report  
remarks: The analysis is not covered by the accreditation of our laboratory.  
as at: 03/24

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**sCD163**

sample types: urine  
sample volume: 1,5ml method: ELISA  
frequency: biweekly  
reference value: see result report  
remarks: The analysis is not covered by the accreditation of our laboratory.  
as at: 10/19

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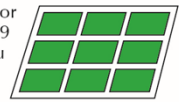
**STI-11**

sample types: swab  
alternative sample types: urine  
sample volume: 1,5 ml  
method: EUROARRAY  
frequency: biweekly  
reference value: see result report  
remarks: The analysis is not covered by the accreditation of our laboratory.  
as at: 12/21

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**Total Tau**

sample types: CSF  
sample volume: 2,0 ml  
method: ELISA  
frequency: weekly  
reference value: see result report  
remarks: Please note the instructions for preanalytics. The samples must be submitted frozen.  
This analysis is not covered by the current accreditation scope.  
as at: 11/24



**Uromodulin**

sample types: serum, heparin plasma  
sample volume: 1,5 ml  
method: ELISA  
frequency: biweekly  
reference value: see result report  
remarks: The analysis is not covered by the accreditation of our laboratory.  
as at: 01/19

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**$\beta$ -amyloid (1-40) ELISA**

sample types: CSF sample volume: 2,0 ml  
method: ELISA  
frequency: weekly  
reference value: see result report  
remarks: Please note the instructions for preanalytics. The samples must be submitted frozen.  
This analysis is not covered by the current accreditation scope.  
as at: 11/24

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**$\beta$ -amyloid (1-42) ELISA**

sample types: CSF sample volume: 2,0 ml  
method: ELISA  
frequency: weekly  
reference value: see result report  
remarks: Please note the instructions for preanalytics. The samples must be submitted frozen.  
This analysis is not covered by the current accreditation scope.  
as at: 11/24