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Specification List Molecular Genetics and Special Immunodiagnostics

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Allgemeine Hinweise

Dieses Leistungsverzeichnis enthält alle vom Klinisch-immunologischen Labor angebotenen Untersuchungen mit Angaben über die Methoden, die Probenarten und –volumina, die Häufigkeit der Untersuchung, Grenzwerte und ggf. präanalytische Besonderheiten. Das aktuelle Leistungsverzeichnis kann auf unserer Homepage unter www.labor-stoecker.de heruntergeladen werden.

Bearbeitungsdauer:

Die Proben werden am Tag des Eingangs im Laboratorium registriert und die Untersuchungen wenn möglich am gleichen Tag durchgeführt oder begonnen, so dass der Befundbericht in der Regel spätestens am Tag nach dem Probeneingang an den Empfänger übermittelt werden kann. Wenn Untersuchungen nicht täglich durchgeführt werden sowie durch eventuell notwendige Wiederhol- und/oder Verdünnungsanalysen kann sich die Bearbeitungszeit in Einzelfällen verlängern.

Grenzwerte/Referenzbereiche:

Die im Leistungsverzeichnis enthaltenen Grenzwerte entsprechen den Herstellerempfehlungen der verwendeten Testsysteme und dem aktuellen Stand der Wissenschaft und Technik. Durch neue wissenschaftliche Erkenntnisse und technische Fortschritte in der Analysentechnik können sich diese Grenzwerte ändern. Ausschlaggebend für die Befundinterpretation sind die im Befundbericht angeführten Grenzwerte und sonstigen Hinweise.

Messunsicherheit:

Das Klinisch-immunologische Labor führt regelmäßige Kontrollen durch und ergreift kontinuierlich Maßnahmen, um Schwankungen und verfahrensbedingte Abweichungen der Messergebnisse zu minimieren. Aufgrund der vorhandenen Messunsicherheit sind grenzwertige und schwach positive Ergebnisse bzw. Ergebnisse, die in der Nähe der Grenzwerte oder sonstiger medizinischer Entscheidungsgrenzen liegen, vorsichtig zu interpretieren. Auf Anfrage kann für jede quantitative Untersuchung die individuelle Messunsicherheit zur Verfügung gestellt werden. Die meisten der vom Klinisch-immunologischen Labor durchgeführten Untersuchungen (Antikörperdiagnostik) sind jedoch als qualitativ einzustufen.

Vergleichbarkeit von Untersuchungsergebnissen:

Die Ergebnisse verschiedener Testmethoden (z.B. Immunfluoreszenz, ELISA, Blot-Techniken) zum Nachweis der gleichen Antikörper in einer Probe können unterschiedlich ausfallen. Ursache hierfür können unterschiedliche Antigene sein oder die unterschiedliche Immobilisierung des gleichen Antigens auf den verschiedenen Trägermaterialien, die durch Konformationsänderungen des Antigens oder durch sterische Inhibierung die Bindung der Antikörper an das Antigen beeinflussen.

Laboreigene diagnostische Tests (LDT):

Die eingesetzten Untersuchungsverfahren sind üblicherweise CE-gekennzeichnet. Nicht CE-gekennzeichnete Verfahren, die durch das Labor selbst validiert wurden, sind im Leistungsverzeichnis als laboreigene diagnostische Tests (LDT) gekennzeichnet und unterliegen nicht der Akkreditierung des Klinisch-immunologischen Labors.

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.

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 send 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 difffer. 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.

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25-OH-vitamin D ELISA

sample type: serum
sample type 2: EDTA, heparin, citrat plasma
sample volume: 1,5ml
method: ELISA
frequency: biweekly
reference value: see result report
remark: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

APOE

sample type: EDTA blood
sample type2: isolated genomic DNA
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: Declaration of consent for human genetic diagnostics required.
remark 2: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

Calcitonin hormone assay

sample type: serum
sample type 2: EDTA, heparin, citrat plasma
sample volume: 1,5 ml
method: ELISA
frequency: biweekly
reference value: see result report
remark: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

Cortisol Saliva

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

dermatomycosis

sample type: skin material
sample type 2: hair material
sample type 3: nail material
sample type 4: culture material
sample type 5: purified DNA
sample volume: culture material 1 cm^2
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

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FII+

sample type: EDTA blood
sample type 2: isolated genomic DNA
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: Declaration of consent for human genetic diagnostics required.
remark 2: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

FV

sample type: EDTA blood
sample type2: isolated genomic DNA
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: Declaration of consent for human genetic diagnostics required.
remark 2: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

HLA-B27

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

HLA-B57

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

HLA-Cw6

sample type: EDTA blood
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: Declaration of consent for human genetic diagnostics required.
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HLA-DQ2/DQ8

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

HLA-DRB1 shared epitopes

sample type: EDTA blood
sample type2: isolated genomic DNA
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: Declaration of consent for human genetic diagnostics required.
remark 2: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

HPV

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

Haemochromatosis (HFE) (2 SNP+)

sample type: EDTA blood
sample type2: isolated genomic DNA
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: Declaration of consent for human genetic diagnostics required.
remark 2: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

Haemochromatosis (HFE) (4 SNP+)

sample type: EDTA blood
sample type2: isolated genomic DNA
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: Declaration of consent for human genetic diagnostics required.
remark 2: The analysis is not covered by the accreditation of our laboratory.
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Intact PTH hormone assay

sample type: serum
sample type 2: EDTA, heparin, citrat plasma
sample volume: 1,5 ml
method: ELISA
frequency: biweekly
reference value: see result report
remark: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

Lactose intolerance

sample type: EDTA blood
sample type2: isolated genomic DNA
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: Declaration of consent for human genetic diagnostics required.
remark 2: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

MTHFR

sample type: EDTA blood
sample type2: isolated genomic DNA
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: Declaration of consent for human genetic diagnostics required.
remark 2: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

Mullerian-duct repression hormone (MRH)

sample type: serum
sample type 2: heparin plasma
sample volume: 1,5 ml
method: ELISA
frequency: daily (mo-fri)
reference value: see result report
remark: The analysis is not covered by the accreditation of our laboratory.
as at: 01/19

SARS-CoV-2

sample type: throat swab
sample type 2: purified RNA
sample volume: -
method: EURORealTime
frequency: biweekly
reference value: see result report
as at: 12/21

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sCD163

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

STI-11

sample type: swab
sample type 2: urine
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

STI-6

sample type: swab
sample type 2: urine
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

STI-7

sample type: swab
sample type 2: urine
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

STI-CT/NG

sample type: swab
sample type 2: urine
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

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STI-CT/NG/TP/TV

sample type: swab
sample type 2: urine
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

STI-HSV1/2

sample type: swab
sample type 2: urine
sample type 3: mouth/pharyngeal lavage
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: The analysis is not covered by the accreditation of our laboratory.
as at: 08/2020

STI

sample type: swab
sample type 2: urine
sample volume: 1,5 ml
method: EUROARRAY
frequency: biweekly
reference value: see result report
remark: The analysis is not covered by the accreditation of our laboratory.
as at: 12/21

Uromodulin

sample type: serum
sample type 2: heparin plasma
sample volume: 1,5 ml
method: ELISA
frequency: biweekly
reference value: see result report
remark: The analysis is not covered by the accreditation of our laboratory.
as at: 01/19