DKMS Life Science Lab

Instruction

List of Services

DKMS Life Science Lab gGmbH
St. Petersburger Str. 2, 01069 Dresden
Tel. (0351) 89993-000
Fax: (0351) 89993-001
Email: info@dkms-lab.de

Opening hours for receipt of materials: Mon – Fri 08.00 a.m. – 4.00 p.m.

Dated: 05/2022
Publisher: DKMS Life Science Lab gGmbH

List of Services

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1 Abbreviation

1.1 Methods

ELISA	Enzyme-linked immunosorbent assay
LCT	Complement-dependent (micro)lymphocytotoxicity test
LCT+DTT	Complement-dependent (micro) lymphocytotoxicity test using DTT for inactivation of the IgM antibodies
NGS-E	Next generation sequencing of typing-relevant exons using short PCR amplicons (<1kb)
NGS-LR	Next generation sequencing of long-range PCR amplicons (>1kb)
PCR	Polymerase chain reaction
SSO	Sequence-specific oligonucleotide
XMAP-M	Antibody detection/screening by means of bead array technology (Luminex, antigen mix)
XMAP-SA	Antibody specification by means of bead array technology (Luminex technology, single antigen)

1.2 General abbreviations

*	Molecular genetic analysis
µg	Microgram
µl	Microlitre
ACD	Acid citrate dextrose
AB	Antibodies
CE-IVD	In vitro diagnostic products with CE marking in compliance with EU standards
CPDA	Citrate phosphate dextrose adenine
DTT	Dithiothreitol
EDTA	Ethylenediaminetetraacetic acid or its salts
g	Gram
GenDG	Genetic Diagnostics Act – a German law concerning the genetic testing of humans
HD	High throughput laboratory
HLA	Human leukocyte antigens
KL	Clinical laboratory
mg	Milligram
min.	Minimum
Min.	Minute
ml	Millilitre
mm	Millimetre
ng	Nanogram
TAT	Turnaround time (processing time for a sample in working days from the beginning of the workflow); individual agreements can be made with a contract
Unorm	Units normalised to a protein content of 1 mg/ml
WD	Working days (high throughput area: 20 working days (Mon-Fri) corresponding to 28 calendar days as the standard TAT)

2 Commissioning, material extraction, pre-analytics, communication of results

2.1 Sample material

2.1.1 Blood

The alphabetical list of services shows the test materials needed for the analyses you require. You can freely select from the sample containers listed below.

Several samples of the same type should be sent in if they need to meet a very exacting scope of analysis, if you are requesting analyses with high material requirements or if the pre-analytics differs in the case of identical material. Therefore, if applicable, please note the pre-analytical information for the individual analyses.

Sequence	Material	Monovettes (cap colour)	Vacuettes (cap colour)	Application	Storage temperature when shipping
1	Serum	Serum gel (brown)	Serum (red)	e.g. serology, immunology	Room temperature
2	Whole blood with no additives	Neutral tube (white)	Neutral tube (white)	Immunohaematology	Room temperature
3	EDTA blood	EDTA (red)	EDTA (purple)	e.g. immunohaematology, blood type analytics, DNA analyses	Room temperature
4	(preferably)	Citrate (green)	Citrate (blue)	e.g. DNA analyses	Room temperature
5	Citrated blood	Li-heparin (orange)	Li-heparin (green)	e.g. DNA analyses	Room temperature
6	Heparin blood	-	ACD-B (yellow)	e.g. blood type analytics, DNA analyses	Room temperature
7	ACD blood	CPDA (yellow)	CPDA (yellow)	e.g. blood type analytics, DNA analyses	Room temperature

2.1.2 Swabs

Sample container	Description	Application	Storage temperature
Donor swab (swab)	**Swab** without transport medium, **in transport envelope**	DNA analyses and/or CMV status determination for potential stem cell donors or study participants	Room temperature
Patient or donor swab (swab)	**Swab** without transport medium, **in transport envelope**	DNA analyses	Room temperature

2.1.3 Other

Sample container	Description	Application	Storage temperature
Reaction tube 1.5 ml	With safety cap	Extracted DNA	Room temperature
Reaction tube 2 ml	With safety cap	Extracted DNA	Room temperature
96-well microplates	Preferably: 330 µl, 96 round wells, V-bottom plate, polypropylene	Extracted DNA	Room temperature

2.2 Materials for sample collection/sample transport

After consulting with the laboratory, the materials can be provided for sample collection or sample transport for swabs or DNA samples. Order forms can be sent in along with test specimens via a courier service. Any changes to sample materials, the introduction of new methods or changes to evaluation criteria must be notified in good time.

2.3 Sample labelling

Each sample container must be clearly labelled. When it is necessary for particular analyses, the corresponding order must also be labelled with an identical and unique sample barcode. Certain requirements apply in these cases, and these are provided in advance as a basis of the contract and are discussed with the customer.

The following guidelines apply for the sample barcode:

Barcode type (Code 128)	
Legible characters	Sample number should be printed beneath the barcode. Must be readable to the human eye!
Print quality	Black printed on a white background Smudge-proof and resistant to abrasion
Barcode quality	Well defined individual bars Easily distinguishable Immediately readable with a hand scanner

2.4 Testing request/requisition

Where required according on the type of analysis, each sample must have an accurately completed laboratory order attached. This applies equally to both paper-based and electronic orders. The following patient-specific information is required for clinical investigations:

mandatory	**Necessary for correct diagnosis and plausibility check**
• Surname, first name, date of birth (gender optional) or unique identifier (e.g. barcode/GRID of donor)	• Clinical diagnosis or symptoms
• Depending on the order (e.g. privately insured), address of the patient	• Information on previous findings
• Test materials with date of sample collection.	• Medication, if applicable
• Scope of testing requested	
• Sender (plus ward or department in the case of hospitals) with doctor's signature	

For samples in the high throughput area, the following information is required:

mandatory	**Optional**
• Unique barcode	• Requisition with barcode in paper form accompanying the sample
• Scope of testing requested	
• Sender	
• List with number of samples and identifiers in digital form	

Samples that cannot be uniquely identified, e.g. if labelling is missing or unclear or there is no barcode, can only be processed if the sender creates a clear assignment before further processing. To this end, written confirmation is obtained from the person responsible for the identification, and documented.

For studies or anonymous donor typing, separate arrangements are agreed with the sender and put into writing.

2.5 Special features for genetic analyses (German Genetic Diagnostics Act)

- The Genetic Diagnostics Act has been in effect since 01/02/2010 and concerns testing that is directed at inherited or prenatally acquired characteristics of human genetic material (chromosomes, DNA, genes). The law also applies to gene products if the testing is directed at the genetic make-up.
- In the case of genetic testing for medical purposes (diagnostic or predictively with disease association), it is absolutely imperative that the patient is informed and provides a signed declaration of consent. This must contain the subject and scope of the testing, the consent to the sample collection and to the testing, and to the findings being noted or being destroyed as well as the decision regarding retention of the sample following the analysis. Prior to the declaration of consent, the nature, scope and implications of the testing must be clarified and documented. In the case of persons who are not able to consent (children or those under supervision), the signature of the legal representative must be obtained.
- If there is no declaration of consent, the laboratory must not begin the aforementioned analyses.
- Otherwise, the provisions of the current version of the German Genetic Diagnostics Act apply.

2.6 Collection of the test material

2.6.1 General

- Please inform the test subjects of any particular preparatory measures that they need to observe for the sample collection or beforehand (e.g. avoid eating food or taking medicines, and suchlike).
- Please use the prescribed sample containers and tag or label them during the sample collection. It may be helpful to show the test subject the filled tubes bearing their name.
- If several samples are collected for one requisition, they must be labelled individually.
- In general, medication should not be taken until after blood sample collection.
- Samples should never be exposed to direct sunlight.
- Contaminated materials should be disposed of properly.
- Avoid injuries by using appropriate materials (safety cannulas, safety lancets, sharps containers).
- If there is no centrifuge available, please rapidly send in non-centrifuged material that is to be frozen on an ice pack.

2.6.2 Serum

- Serum is the fluid portion of the blood after the process of blood clotting is completed.
- After taking a sample, leave the blood standing in the serum tube to clot for at least 20 minutes.
- Centrifuge it beforehand if necessary (approx. 10 minutes at approx. 3000 rpm). Then transfer the supernatant (the serum) into aliquot containers intended for this purpose and label it as serum.
- Store the material in accordance with the instructions for the test parameter in question.

2.6.3 Whole blood (neutral tube)

- Invert the neutral tube carefully several times and store in accordance with the instructions for the test parameter in question.

2.6.4 Acid citrate dextrose blood (ACD)

- Fill the ACD tube to the fill line.
- Invert the tube carefully several times and store in accordance with the instructions for the test parameter in question. If you forget to invert it, the ACD and the blood will not be sufficiently mixed and this will result in blood clot formation. This means that determinations may be distorted or rendered impossible.

2.6.5 Citrated blood

- Fill the citrate tube to the fill line, as an incorrect mixing ratio of blood and citrate may result in incorrect readings.
- Invert the filled tube carefully several times and store in accordance with the instructions for the test parameter in question. If you forget to invert it, the citrate and the blood will not be sufficiently mixed and this will result in blood clot formation. This means that determinations may be distorted or rendered impossible.

2.6.6 Citrate phosphate dextrose adenine blood (CPDA)

- Fill the CPDA tube to the fill line.
- Invert the tube carefully several times and store in accordance with the instructions for the test parameter in question. If you forget to invert it, the CPDA and the blood will not be sufficiently mixed and this will result in blood clot formation. This means that determinations may be distorted or rendered impossible.

2.6.7 EDTA blood

- Fill the EDTA tube to the fill line.
- Invert the tube carefully several times and store in accordance with the instructions for the test parameter in question. If you forget to invert it, the EDTA and the blood will not be sufficiently mixed and this will result in blood clot formation. This means that determinations may be distorted or rendered impossible.

2.6.8 Heparin blood

- Fill the Li-heparin tube to the fill line because underfilling it may potentially result in incorrect readings.
- Invert the tube carefully several times and store in accordance with the instructions for the test parameter in question. If you forget to invert it, the heparin and the blood will not be sufficiently mixed and this will result in blood clot formation. This means that determinations may be distorted or rendered impossible.

2.6.9 Plasma (citrate plasma, EDTA plasma, heparin plasma)

- Plasma is the fluid portion of the blood before the onset of blood clotting.
- Draw the blood into the relevant sample tubes (citrate, EDTA or heparin tubes).
- Carefully invert and centrifuge immediately (approx. 10 minutes at 3000 rpm)
- Withdraw the supernatant (the plasma) and transfer it into sample tubes intended for this purpose. Label the tube with the type of plasma.
- Store the material in accordance with the instructions for the test parameter in question (e.g. deep-frozen, protected from light).

2.6.10 Swabs

Patient or donor swab

- Open the swab packaging and remove the swab. Make sure not to touch the head of the swab with your fingers. Use each swab only once.
- Please take a swab with each of the enclosed swabs.
- To do this, wipe the inside of the cheeks using pressure for at least 60 seconds (including the folds at the upper and lower jaws). Move high and low as well as rotating to collect sufficient cells from the buccal mucosa. Saliva by itself is insufficient!)
- Please let used swabs dry for two minutes and then put them in the cardboard envelope without the plastic cover.

2.6.11 Materials not listed

- Consultation in writing requested via Typing@dkms-lab.de.

2.7 Communication of results or findings

Results or findings are generally communicated electronically via an agreed delivery channel, by secure email, by post or during a consultation in person. The contact person for receiving communications regarding the results or findings will be specified in the contract.

2.8 Other information

You can request detailed information about methods used from Typing@dkms-lab.de.

2.9 Complaints

Any complaints received are recorded and handled by complaint management. In order to identify any systematic problems and introduce improvements, they are classified and analysed regularly.
Contact:
Typing@dkms-lab.de / Clinical laboratory and search unit: searchunit_dd@dkms-lab.de

3 Alphabetical list of services

Item	Test	Material/quantity	Evaluation criteria	Method	Application area	TAT (in WD)
1	**Antibodies HLA class I**, complement-dependent (IgG+IgM)	Serum/whole blood with no additives 1 ml	Negative	LCT	**KL**	As per contract
2	**Antibodies HLA class I**, complement-dependent (IgG)		Negative	LCT+DTT		
3	**Antibodies HLA class I and II** complement-independent		Negative	XMAP-M		
4			See findings	XMAP-SA		
5	**CMV virus antibodies (IgG)**	Swab 2 units	Negative: 0- 8 Unorm Borderline: 8 – 20 Unorm Positive: > 20 Unorm	ELISA	**HD** With commercial kit	20
6	**HLA base profile exon** HLA class I (HLA-A*; HLA-B*; HLA-C*) and HLA class II (HLA-DRB1*; HLA-DQB1*; HLA-DPB1*; HLA-DRB3/4/5*; HLA-DQA1*; HLA-DPA1*) **Optional additional profile (ABO*, RhD*, CCR5Δ32*)**	Swab 2 units	See findings	NGS-E	**HD** With reagents developed **in-house**	20
7		EDTA blood* 2 ml				
8		Extracted DNA Volume: > 100 µl DNA concentration: minimum 20 ng/µl				
9	**HLA base profile + CMV exon** HLA class I (HLA-A*; HLA-B*; HLA-C*) and HLA class II (HLA-DRB1*; HLA-DQB1*; HLA-DPB1*; HLA-DRB3/4/5*; - HLA-DQA1*; HLA-DPA1*) **CMV virus antibodies (IgG)** **Optional additional profile (ABO*, RhD*, CCR5Δ32*)**	Swab 3 units	See findings See CMV	NGS-E ELISA	**HD** With reagents developed **in-house** With commercial kit	20

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10	**HLA base profile whole-gene** HLA class I (HLA-A*; HLA-B*; HLA-C*) and HLA class II (HLA-DRB1*; HLA-DQB1*; HLA-DPB1*)	Swab 2 units	See findings	NGS-LR	**KL** With **CE-IVD-certified** reagents Optional additional profile HLA-DRB3/4/5*, HLA-DQA1*; HLA-DPA1*	5-7
11		EDTA blood* 5 ml				
12		Extracted DNA Volume: > 100 µl DNA concentration: minimum 20 ng/µl				
13		Swab 2 units			**KL** With reagents developed **in-house**	
14		EDTA blood* 5 ml				
15		Extracted DNA Volume: > 100 µl DNA concentration: minimum 20 ng/µl				
16	**HLA base profile SSO** HLA class I (HLA-A*; HLA-B*; HLA-C*) and HLA class II (HLA-DRB1*; HLA-DQB1*; HLA-DPB1*)	Swab 2 units	See findings	SSO	**KL** With **CE-IVD-certified** reagents Optional additional profile HLA-DRB3/4/5*, HLA-DQA1*; HLA-DPA1*	2-3
17		EDTA blood* 5 ml				
18		Extracted DNA Volume: > 100 µl DNA concentration: minimum 20 ng/µl				
19	**HLA single locus** (HLA-A*; HLA-B*; HLA-C*; HLA-DRB1*; HLA-DQB1*; (HLA-DQA1*); HLA-DPB1*; (HLA-DPA1*); HLA-DRB3/4/5*)	Swab 2 units	See findings	SSO	**KL** With **CE-IVD-certified** reagents In the case of disease associations, there must be a declaration of consent.	2-3
20		EDTA blood* 5 ml				
21		Extracted DNA Volume: > 100 µl DNA concentration: minimum 20 ng/µl				
22	**HLA complete profile exon**	Swab 2 units	See findings	NGS-E	**HD**	20
23		EDTA blood* 2 ml				

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Item	Test	Material/quantity	Evaluation criteria	Method	Application area	TAT (in WD)
24	HLA class I (HLA-A*; HLA-B*; HLA-C*;HLA-E*) and HLA class II (HLA-DRB1*; HLA-DQB1*; HLA-DPB1*; HLA-DRB3/4/5*; HLA-DQA1*; HLA-DPA1*) **MIC-A*, MIC-B*, KIR*, ABO*, RhD*, CCR5Δ32***	Extracted DNA Volume: > 100 µl DNA concentration: minimum 20 ng/µl			With reagents developed **in-house**	
25	**HLA complete profile + CMV** HLA class I (HLA-A*; HLA-B*; HLA-C*;) and HLA class II (HLA-DRB1*; HLA-DQB1*; HLA-DPB1*; HLA-DRB3/4/5*; HLA-DQA1*; HLA-DPA1*) **MIC-A*, MIC-B*, KIR*, ABO*, RhD*, CCR5Δ32*** **CMV virus antibodies (IgG)**	Swab 3 units	See findings See CMV	NGS-E ELISA	**HD** With reagents developed **in-house** With commercial kit	20
26	**Cross-matching** HLA class I	From the donor: EDTA blood, ACD blood, CPDA blood 10 ml and from the recipient: serum, plasma 5 ml	See findings	LCT	**KL** Heparin blood, citrated blood, and whole blood with no additives are also accepted. Sample material must not be any older than 48 hours.	2
27	**Cross-matching** HLA class II					

* EDTA blood is preferable; alternatively, heparin blood, citrated blood or ACD/CPDA blood

4 Subsequent reporting from laboratory testing

In some circumstances, laboratory parameters can be requested later from sample material stored in the laboratory. Depending on the laboratory storage capacity and provided they are still suitable for it, the sample materials remain available for a certain time for additional requests.
For certain parameters, however, subsequent determinations should be made for a restricted time period only, due to the limited stability of the analysis. Below, you will find a table of parameters with restricted reporting periods.

Test	Recommended max. reporting period	Remarks
CMV determination	3 weeks after sample collection	A valid CMV determination can be guaranteed within 4 weeks after sample collection.
KL HLA typing	Upon consultation	DNA analyses are subject to the provisions of the German Genetic Diagnostics Act.