KOÇ ÜNİVERSİTESİ
HASTANESİ

TISSUE TYPING LABORATORY TEST GUIDE

2023

https://www.kuh.ku.edu.tr/tissue-typing-laboratory

This test guide is designed as a guide for patients and users to provide information about the organization and services of **Koç University Hospital Tissue Typing Laboratory**.

Organization of the Tissue Typing Laboratory

- Supervisor: Sebahat Akgül, PhD
- Assistant Supervisor: Emre Arpalı, MD, PhD
- Quality Assurance Specialist: Talin Çatalbaşyan
- Test & Analysis Specialist: Ümit Aslanhan, MSc
- Technical Personnel: Talin Çatalbaşyan; Ezgi Dinçer, MSc; Demir Kaan Demir, MSc
- Medical Secretary: Pınar Yıldız

Contact Info

Address : Koç Üniversitesi Hastanesi Doku Tipleme Laboratuvarı, M Blok 3. Kat
Davutpaşa Caddesi No:4 30010 Topkapı / Istanbul TURKIYE

Phone Number : +90 850-2508250 (Internal Extension: 23244)

Email : KUH-DTL@kuh.ku.edu.tr

Business Hours

- Monday–Friday; 8.00 am – 5.00 pm
- 24-hour emergency service is provided for kidney transplantation from deceased donors

Clinical Services

- **Determination of Tissue Compatibility** between the patient and the donor before **Solid Organ Transplantation** and **Immune Monitoring** after transplantation
- **Determination of Tissue Compatibility** between the patient and the donor before **Allogeneic Stem Cell Transplantation** and **Immune Monitoring** after transplantation
- Determination of **HLA Alleles Associated with Diseases** such as Behçet and Ankylosing Spondylitis
- Identification of **HLA Alleles Associated with Drug Hypersensitivity**

Contents

1. Tests Offered by the Tissue Typing Laboratory

- **1.1.** Tissue Typing
- **1.2.** Anti-HLA Antibody Detection (Panel Reactive Antibody, PRA / Donor-Specific Antibody, DSA)
- **1.3.** Crossmatch Tests
- **1.4.** Typing Tests for Disease- and Drug Hypersensitivity-Associated HLA Alleles
- **1.5.** In-House Organ and Bone Marrow Transplant Test Packages

2. Tissue Typing Laboratory Test Request and Registration

3. Tissue Typing Laboratory Sampling Rules

4. Transport and Storage of Samples

5. Sample Acceptance and Rejection Criteria

6. Tests Requiring Preliminary Preparation Process

7. Laboratory Test Results

8. Laboratory Critical Test Values

9. Obtaining Consent for Typing of Disease- and Drug Hypersensitivity-Associated HLA Alleles

1. Tests Offered by the Tissue Typing Laboratory

All procedures pertinent to sample preparation, handling, storage and transfer are compliant with national and international accreditation and standardization institutions' standards.

1.1. Tissue Typing

Tissue typing tests for Human Leukocyte Antigen (HLA) Class I (A, B, C) and Class II (DRB1/3/4/5, DQA1, DQB1, DPA1, DPB1) alleles are performed at low-resolution by the **Polymerase Chain Reaction Sequence-Specific Oligonucleotide (PCR-SSO)** method (Table 1) and at high-resolution by the **Next Generation Sequencing (NGS)** method (Table 2).

Table 1. Low-Resolution HLA Typing Tests

CURRENT CODE	SUT CODE	TEST NAME	SAMPLE TYPE	TARGET MATERIAL	SAMPLE AMOUNT	TUBE	METHOD	WORKING TIME	TURN-AROUND TIME
763269	L103270	HLA-A	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	PCR-SSO	Business hours	10 Business days
755573	L103280	HLA-B	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	PCR-SSO	Business hours	10 Business days
752341	L103290	HLA-C	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	PCR-SSO	Business hours	10 Business days
762721	L103330	HLA-DRB1	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	PCR-SSO	Business hours	10 Business days
760502	L103310	HLA-DQA1	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	PCR-SSO	Business hours	10 Business days
763680	L103320	HLA-DQB1	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	PCR-SSO	Business hours	10 Business days
765796	L103300	HLA-DPA1	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	PCR-SSO	Business hours	10 Business days
760615	L103400	HLA-DPB1	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	PCR-SSO	Business hours	10 Business days

The HLA typing of the deceased donor is studied immediately after the samples are delivered to the Tissue Typing Laboratory, finalized within 3-4 hours, and reported to the Ministry of Health via the Transplantation, Dialysis and Monitoring Systems (TDIS).

Table 2. High-Resolution HLA Typing Tests

CURRENT CODE	SUT CODE	TEST NAME	SAMPLE TYPE	TARGET MATERIAL	SAMPLE AMOUNT	TUBE	METHOD	WORKING TIME	TURN-AROUND TIME
758323	L103470	HLA-A	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	NGS	Business hours	20 Business days
756789	L103480	HLA-B	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	NGS	Business hours	20 Business days
765601	L103490	HLA-C	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	NGS	Business hours	20 Business days
762238	L103510	HLA-DRB1	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	NGS	Business hours	20 Business days
763626	L103440	HLA-DRB3	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	NGS	Business hours	20 Business days
765057	L103450	HLA-DRB4	Peripheral blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	NGS	Business hours	20 Business days
752317	L103460	HLA-DRB5	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	NGS	Business hours	20 Business days
753844	L103410	HLA-DQA1	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	NGS	Business hours	20 Business days
759218	L103500	HLA-DQB1	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	NGS	Business hours	20 Business days
760906		HLA-DPA1	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	NGS	Business hours	20 Business days
755510	L103400	HLA-DPB1	Peripheral Blood Swap Bone Marrow	DNA	5-10 ml	EDTA (purple cap)	NGS	Business hours	20 Business days

1.2. Anti-HLA Antibody Detection (Panel Reactive Antibody, PRA / Donor-Specific Antibody, DSA)

Determination of antibodies specific to HLA Class I (A, B, C) and Class II (DRB1/3/4/5, DQA1, DQB1, DPA1, DPB1) antigens is conducted by **Screening** and high-resolution **Single Antigen Bead** method in a sensitive Luminex flow cytometry system (Table 3).

Table 3. Anti-HLA Antibody (PRA) Tests

CURRENT CODE	SUT CODE	TEST NAME	SAMPLE TYPE	TARGET MATERIAL	SAMPLE AMOUNT	TUBE	METHOD	WORKING TIME	TURN-AROUND TIME
754444	L105880	Class I Screening	Peripheral Blood	Serum	5 ml	Without anticoagulant (yellow/red cap)	Luminex	Business hours	5 Business days
755931	L105900	Class II Screening	Peripheral Blood	Serum	5 ml	Without anticoagulant (yellow/red cap)	Luminex	Business hours	5 Business days
766306	L100930	Class I Single Antigen	Peripheral Blood	Serum	5 ml	Without anticoagulant (yellow/red cap)	Luminex	Business hours	5 Business days
752988	L100940	Class II Single Antigen	Peripheral Blood	Serum	5 ml	Without anticoagulant (yellow/red cap)	Luminex	Business hours	5 Business days
766126	L101880	C1q-Binding Class I Single Antigen	Peripheral Blood	Serum	5 ml	Without anticoagulant (yellow/red cap)	Luminex	Business hours	5 Business days
754183		C1q-Binding Class II Single Antigen	Peripheral Blood	Serum	5 ml	Without anticoagulant (yellow/red cap)	Luminex	Business hours	5 Business days
765294	L105870	Specific to Class I Antigen	Peripheral Blood	Serum	5 ml	Without anticoagulant (yellow/red cap)	Luminex	Business hours	5 Business days
753104	L105890	Specific to Class II Antigen	Peripheral Blood	Serum	5 ml	Without anticoagulant (yellow/red cap)	Luminex	Business hours	5 Business days

1.3. Crossmatch Tests

Crossmatch tests are performed between patients and donor candidates by complement-dependent cytotoxicity (CDC) and flow cytometry (FC) methods to show the absence or presence of donor-specific antibodies (DSA) (Table 4).

Table 4. Crossmatch Tests

CURRENT CODE	SUT CODE	TEST NAME	SAMPLE TYPE	TARGET MATERIAL	SAMPLE AMOUNT	TUBE	WORKING TIME	TURN-AROUND TIME
731872	L106970	CDC Crossmatch (Total, T, B Lymphocyte)	Peripheral Blood of the Patient	Serum	5 ml	Without anticoagulant (yellow/red cap)	Business hours 08:00-12:00	2 Business days
700389	L106980			Lymphocyte	16 ml	With Li heparin (green cap)		
759270	L106990							
700388	L101300		Peripheral Blood of the Donor	Lymphocyte	16 ml	With Li heparin (green cap)		
731873	L101310							
762476	L107000	Flow Crossmatch (T, B Lymphocyte)	Peripheral Blood of the Patient	Serum	5 ml	Without anticoagulant (yellow/red cap)	Business hours 08:00-12:00	2 Business days
				Lymphocyte	8 ml	With Li heparin (green cap)		
			Peripheral Blood of the Donor	Lymphocyte	16 ml	With Li heparin (green cap)		

1.4. Typing Tests for Disease- and Drug Hypersensitivity-Associated HLA Alleles

HLA alleles associated with diseases such as Behçet, ankylosing spondylitis, celiac, and drug hypersensitivity are determined (Table 5).

Table 5. Detection of Disease- and Drug Hypersensitivity-Associated HLA Alleles

CURRENT CODE	SUT CODE	TEST NAME	SAMPLE TYPE	TARGET MATERIAL	SAMPLE AMOUNT	TUBE	METHOD	WORKING TIME	TURN-AROUND TIME
764798	L103200	HLA-B2 (PCR)	Peripheral Blood	DNA	5-10 ml	EDTA (purple cap)	RT-PCR	Business hours	5 Business days
754396	L103210	HLA-B5 (PCR)	Peripheral Blood	DNA	5-10 ml	EDTA (purple cap)	RT-PCR	Business hours	5 Business days
763142	L103220	HLA-B57 (PCR)	Peripheral Blood	DNA	5-10 ml	EDTA (purple cap)	PCR-SSO	Business hours	5 Business days
755935	L103230	HLA-DQ8 (DQB1*03:02)	Peripheral Blood	DNA	5-10 ml	EDTA (purple cap)	RT-PCR	Business hours	5 Business days
765808	L103240	HLA-DQB1*0201	Peripheral Blood	DNA	5-10 ml	EDTA (purple cap)	RT-PCR	Business hours	5 Business days
753768		HLA-A29 (PCR)	Peripheral Blood	DNA	5-10 ml	EDTA (purple cap)	PCR-SSO	Business hours	5 Business days
763038		HLA-DQB1*06:02	Peripheral Blood	DNA	5-10 ml	EDTA (purple cap)	PCR-SSO	Business hours	5 Business days
762611		HLA-C*06 (PCR)	Peripheral Blood	DNA	5-10 ml	EDTA (purple cap)	PCR-SSO	Business hours	5 Business days
760798	L103250	HLA-DR4 (PCR)	Peripheral Blood	DNA	5-10 ml	EDTA (purple cap)	PCR-SSO	Business hours	5 Business days

1.5. In-House Organ and Bone Marrow Transplant Test Packages

9100008/HLA-A, -B, - C, -DRB1, -DRB3, -DRB4, -DRB5, -DQA1, -DQB1, -DPA1, -DPB1, High-Resolution Tissue Typing Panel, Transplant

9100001/HLA-A, -B, -C, -DRB1, -DQB1 High-Resolution Tissue Typing Panel (KIT), Transplant

9100002/HLA-A, -B, -DRB1 Low-Resolution Tissue Typing Panel, Transplant

9100009/HLA-A, -B, -DRB1 Low-Resolution Tissue Typing Confirmation Panel, Transplant

9100003/Anti HLA Class I Screening, Class II Screening, Transplant

9100004/Anti HLA Class I (Single antigen), Transplant

9100005/Anti HLA Class II (Single antigen), Transplant

9100006/CDC Crossmatch Package, Transplant DONOR

9100011/CDC Crossmatch Package, Transplant RECIPIENT

9100007/Flow Crossmatch, Transplant DONOR

9100010/Flow Crossmatch, Transplant RECIPIENT

2. Tissue Typing Laboratory Test Request and Registration

Tissue Typing Laboratory tests are requested via the **Hospital Information Management System (HIMS)-Nucleus**, under the "Directives and Results -> Directive Entry" tab. In parallel, the relevant **Test Request Form** is filled by the doctor and given to the patient. The polyclinic/TTL registry secretary accepts the doctor's request through the Laboratory Information Management System (LBYS), makes the necessary records and prints the request barcodes. The printed barcodes are given to the patient, and the patient and donors are directed to the Blood Collection Unit. The barcode, which includes the protocol number and the tests to be conducted, is affixed to the appropriate tubes by the nurse who draws the blood. The patient's identity is verified (No. 2ST.1000.008 "Patient Safety") and the blood collection is performed in accordance with the "Blood Collection Instruction".

In **Tissue Typing Laboratory Organ Transplantation Test Request Form 'Patient (Recipient)'** (Form No: 27070.013) and **Tissue Typing Laboratory Organ Transplantation Test Request Form 'Donor'** (Form No: 27070.014) as well as at **HBYS (Nucleus)**, patient and donor's name and surname, TR ID number, patient's protocol number (and/or barcode number), patient and donor's date of birth, sex and blood group, donor's relation to the patient, patient's diagnosis, requesting institution and doctor information, request date and time, sampling date, sample type, and the test or tests to be conducted must be fully and accurately specified. In the request form it should be noted for alloimmunization evaluation whether any blood transfusions were performed, the number of transfusions (if any), the last transfusion date (if any), the number of pregnancies and the last pregnancy date in female patients (if any), the previous transplant history, the number and the last transplant date (if any), and the date of transplant nephrectomy (if any). The DTL registry secretary confirms the information in the HBYS by directly asking the patient and/or donor or by deducting it from the test request forms and corrects the missing or erroneous information by contacting the coordinator.

In **Tissue Typing Laboratory Bone Marrow Transplantation Test Request Form 'Patient (Recipient)'** (Form No: 27070.009) and **Tissue Typing Laboratory Bone Marrow Transplantation Test Request Form 'Donor'** (Form No: 27070.008) as well as at **HBYS (Nucleus)**, patient and donor's name and surname, TR ID number, patient's protocol number (and/or barcode number), patient and donor's date of birth, sex, blood group, donor's relation to the patient, patient's diagnosis, requesting institution and doctor information, the request date and time, the sampling date, the sample type, and the test or tests to be conducted must be fully and accurately specified. Whether the patient has been transfused or not, (if so, number, last transfusion date),

white blood cell (WBC) count and test date should be stated on the Test Request Form. The TTL registry secretary confirms the information in the HBYS by directly asking the patient and/or the donor or by deducting it from the request form and corrects the missing or erroneous information by contacting the coordinator.

In the **"Tissue Typing Laboratory Disease/Drug Hypersensitivity-Drug Hypersensitivity-Related HLA Test Request Form"** (Form No: 27070.007) as well as at **HBYS (Nucleus)**, patient's name – surname, TR ID number, protocol number (and/or barcode number), date of birth, sex, diagnosis, the requesting institution and doctor information, the date and time of the request, the date of sampling, the sample type and the test or tests to be conducted must be fully and accurately specified.

3. Tissue Typing Laboratory Sampling Rules

Blood samples of kidney transplant recipients and donors are taken at the Organ Transplantation Center Intervention Room.

Blood samples of recipients and donors which are prepared for bone marrow transplantation are taken in the Bone Marrow Transplantation Unit Blood Collection Room.

Blood samples of patients from other outpatient clinics (Rheumatology, Gastroenterology, Ophthalmology, Infection, etc.) are taken in the Blood Collection Room of the Clinical Laboratory, Pediatrics Polyclinic or Bone Marrow Transplant Unit.

Samples of inpatients are taken by the inpatient service nurse in the inpatient service they are in.

Personnel collecting the sample should make sure that the patient/donor's identity matches the barcode label. The patient/donor should be fully informed about the procedure to be performed. The patient should be positioned suitably. The patient's arm should be kept straight, and the wrist should be straight. A tourniquet is usually required. The tourniquet should be applied 7.5–10 cm above the area where blood will be drawn and should not be held tight for more than 1 minute. Blood can be drawn from any of the superficial veins at the bend of the elbow, on the forearm, or on the hand. The area where the blood will be taken is cleaned by wiping with 70% isopropanol or ethyl alcohol solution, with circular movements from the inside to the outside. Unsterile objects should not touch the - cleaned area. Sterile, disposable needle and syringe are used in all procedures. After the blood is drawn for all tubes, a sterile gauze or cotton is pressed to the area where the blood is taken, and the needle is withdrawn from the patient's arm at the appropriate speed. The patient is instructed to apply pressure on the area from which the blood is drawn for 3-5 minutes. Used needles, syringes or butterfly sets, all contaminated materials are thrown into the yellow sharp- tool box. If a vacuum tube is used, the needle is removed after the protective cap is carefully attached. A band-aid is attached to the patient's arm, to the area from which blood was drawn.

4. Transport and Storage of Samples

Transport of all laboratory samples is compliant with the international and the national **Transport of Dangerous Goods** regulations. Samples taken by nurses on the patient floors and blood collection technicians in the blood collection units within the institution are sent to the Tissue Typing Laboratory with sample transport containers at room temperature **within 1 hour at maximum**. Samples sent by contracted institutions should be delivered to the Tissue Typing Laboratory **within 2 hours at maximum** after sampling at room temperature.

Internal samples are transported upright in a tube carrier within a carrying case. External samples are first put into a plastic, unbreakable, tightly closed tube with absorbent filter paper wrapped around it, and then put into a second plastic tube and repackaged to be ready for transport. The tube should be placed vertically in the carrier bag in order to prevent the samples from falling over and leaking during transportation. These containers must have a **Biohazard Mark** label on them. All samples should be placed in containers that will not leak from their lids and request forms should not be contaminated with the sample. All personnel involved in sample transfer within the institution and in contracted institutions should wear gloves at every stage of the transportation process.

Problems encountered during transportation (spill, breakage, etc.) should be reported to the sample reception personnel of the receiving laboratory, as well as the unit sending the sample, by the sample transfer personnel. These rules also apply for the samples sent by the contracted institutions and the responsibility of implementation is on the contracted institution.

For **cadaveric transplants,** sample collection from the patient, transporting them to the Tissue Typing Laboratory and keeping/transferring them under appropriate conditions is the responsibility of the Hospital Organ Donation and Transplantation Coordinator. Tissue samples (lymph, spleen) required for cadaveric transplantation must be preserved and transmitted in Organ Storage Solution or Cell Culture Medium/Phosphate Buffered Salt Solution (RPMI/PBS). **“Tissue Typing Laboratory Cadaver-Patient Information Form”** (Form No: 27070.011) filled with the necessary information about the cadaver donor (age, gender, blood type, HLA antigen information if any, cause of brain death, organ transplant institution, length of stay in hospital, treatment received) must be sent along with the samples.

Each sample coming from the internal Organ Transplantation Center Intervention Room, Bone Marrow Transplant Unit Blood Collection Room and Clinical Laboratory to the Tissue Typing Laboratory is recorded in the **"Tissue Typing Laboratory Patient Registry"** (Form No: 27070.003) by the medical secretary. Each sample coming from internal and external contracted centers is registered in the **"Tissue Typing Laboratory Sample Reception Form"** (KUH.F.7070.033), which is signed by the person delivering the sample.

The maximum storage times of the samples delivered to the Tissue Typing Laboratory under appropriate conditions are given in Table 6.

Table 6. Sample Storage Times and Conditions

SAMPLE	MAXIMUM STORAGE TIME	STORAGE CONDITIONS
Blood with EDTA	30 days hours	2–8°C
Blood without anticoagulant	72 hours	2–8°C
Serum	7 days	–20°C
Serum	Indefinite	–80°C
DNA	7 days	–20°C
DNA	Indefinite	–80°C

5. Sample Acceptance and Rejection Criteria

For the Tissue Typing Laboratory, it is very important to identify the patient correctly, label the sample correctly, and fill out the request form. If the form or samples do not meet these requirements, the request is denied; the user is informed about this, and the sample is requested again. All samples are accepted or rejected after being evaluated according to the following criteria:

- Samples without patient barcode label (indicating the name, protocol, barcode number, date of birth, sample date, requested test)

- Samples suspected of having wrong label or of coming from the wrong patient
- Samples stored in wrong tubes
- Samples not in sufficient volume
- Hemolyzed samples
- Samples containing anticoagulants with visible clots
- Samples collected at inaccurate times for the tests to be performed.
- Contaminated or leaked samples
- Samples without a doctor-stamped Test Request Paper [patient name, date of birth, diagnosis, (for CRF patients, including sensitization information such as transplant, pregnancy, transfusion and transplant nephrectomy)] are not accepted, but recorded on the **"Tissue Typing Laboratory Rejected Specimen Registration Form"** (Form No: 27070.016).

Sample rejection is done by the laboratory technical staff and/or the laboratory secretary, after the responsible personnel is informed.

6. Tests Requiring Preliminary Preparation Process

HLA Typing: DNA isolation is made in accordance with the type of incoming material.

Determination of Anti-HLA Antibody (Panel Reactive Antibody, PRA / Donor-Specific Antibody, DSA): Blood samples taken into tubes without anticoagulant are centrifuged to obtain serum.

CDC Crossmatch: Lymphocytes are isolated from the donor, serum and lymphocytes are isolated from the recipient. For lymphocyte isolation, blood samples taken into a tube with Lithium Heparin are used in live transplants. Mononuclear cells are isolated according to the density gradient from blood samples spread on Ficoll. T and B cells are purified from mononuclear cells with the help of antibody labeled magnetic beads. Tissue samples such as lymph or spleen taken from a cadaver donor are mechanically fragmented before cell isolation and spread to Ficoll.

Flow Crossmatch: Serum and lymphocytes are isolated from the recipient and lymphocytes are isolated from the donor. For lymphocyte isolation, blood samples taken into a tube with Lithium Heparin are used in living-donor transplantations. Mononuclear cells are isolated according to the density gradient from blood samples spread on Ficoll. T and B cells are separated by labeling the cells with CD3 and CD19 antibodies.

7. Laboratory Test Results

All instructions and regulations of the Hospital and the Ministry of Health regarding the confidentiality of patient information and results are strictly followed. According to the regulations, Tissue Typing Laboratory Test Results are **not** entered into the HBYS system.

The results of the patients and their compatible donors who applied for kidney and hematopoietic stem cell transplantation are recorded in the "Turkish Ministry of Health Turkey Organ and Tissue Information System" with a password known only by the laboratory supervisor and assistant supervisor.

The results of patients and donors who applied to the Tissue Typing Laboratory for organ/bone marrow transplantation from **within and outside the institution** are uploaded to the folder created for the relevant unit/institution on the Tissue Typing Laboratory Portal. When the results are uploaded to the folder, an e-mail is sent to the person authorized by the institution for access. The authorized person accesses to the system with his/her password.

Patients applying to the Tissue Typing Laboratory are given a **"Tissue Typing Laboratory Result Card"** (Form No: 27070.017) containing the patient's identification information as well as the turnaround date of the test. The patient or donor is instructed to show this card when receiving the results. Final reports with signatures are recorded in the **"Tissue Typing Laboratory Report Follow-up Form"** (Form No: 27070.015) and delivered at the Tissue Typing Laboratory Patient Admissions Unit in person.

If there are results not suitable for the patient's clinic, the laboratory should be contacted. The test is repeated with the same sample as well as a new sample. The information in the result reports cannot be used without the permission of our laboratory.

8. Laboratory Critical Test Values

Critical test results are the results obtained in routine or emergency tests of patients which may adversely affect the patient's treatment process or put the patient at serious risk if not intervened. It is the laboratory's responsibility to regularly record and report these test results to the healthcare professionals who treat the patient. The results of the **Critical Tests** should be reported to the patient's attending physician/transplant coordinator within 24 hours after the result is confirmed.

Critical Test Values:

- CDC Crossmatch Positivity
- DSA Positivity above 10.000 MFI

The critical test results and the following information are recorded in the **"Tissue Typing Laboratory Critical Test Values Notification Form"** (Form No: 27070.012) by the laboratory staff. The following information must be written on the form:

- Name and surname of the person notified
- The date and time the result reported
- Reported test and its result
- Name and surname of the reporting personnel

9. Obtaining Consent for Typing of Disease- and Drug Hypersensitivity-Associated HLA Alleles

Patients or their relatives should be asked to read and sign **“Informed Consent Form for Disease- and Drug Hypersensitivity-Associated HLA Typing Tests”** (Form No: 27070.001) in accordance with the "Regulation of Genetic Diseases Diagnosis Centers" to determine the HLA alleles (tissue groups) associated with diseases such as Behçet and ankylosing spondylitis and drugs such as Abacavir, Ustekinumab. These forms are filled under the supervision of the medical secretary in the Patient Admissions Department and signed by both the patient and her/his doctor. Consent of pediatric patients is obtained from their legal representatives.

It is the requester's responsibility to ensure that all samples sent to the laboratory are received with full informed consent for the tests requested. Patients/donors allow any remaining material from the sample to be retained as part of necessary archiving protocols and further research for the benefit of the individual. Patients/donors should also be informed that excess material may be used anonymously for quality control purposes, service development, education, and ethics committee approved research projects.