SAPIENS	SAMPLE COLLECTION HANDBOOK

1. AIM

This manual has been prepared with the aim of establishing a specific standard for primary samples to be accepted into our laboratory.

2. SCOPE

3. ABBREVIATIONS

4. DEFINITIONS

Precious Sample: Cerebrospinal fluid (CSF), amniotic fluid, bone marrow, cord blood, CVS material, skin biopsy, embryo biopsy, and other samples requiring intervention for collection from the patient, as well as samples from patients where obtaining repeat samples is difficult, are examples of examples that require intervention.

5. RESPONSIBLE PARTIES

*Preanalytical Coordinator*Sample Acceptance, Patient Admission Personnel, Laboratory Representatives of Contracted Institutions and Organizations, Contracted Courier, and Laboratory Coordinator are responsible.

Current Status: The information contained in this manual is reviewed with the Laboratory Quality Systems Manager and Laboratory Coordinators. In case of any changes, this should be done by the Laboratory Quality Systems Manager.**Sampling Handbook**It is transmitted to laboratory personnel via a shared network.

6. ACTIVITY FLOW

6.1. COMPLETING THE CONSENT FORM AND IDENTIFYING THE SAMPLES

For a reliable laboratory result, accurate sample identification is a critical step. It should be remembered that the pre-analytical phase is the period where laboratory errors most frequently originate.

Except for institutions that register through LBYS and send samples with the institution's consent form, institutions that send samples without registration will have their samples recorded by our laboratory for the required analyses and necessary information.**Genetic Testing Information Text and Explicit Consent Form**This form has been prepared.

The form must contain mandatory information about the patient and/or their family member. It is crucial that the institution's负责人 (responsible person) who requested the form ensures it is completed accurately and legibly.

Institutions that register through LBYS must send copies of the delivery note printouts generated after registration.

On the sample material**Genetic Testing Information Text and Explicit Consent Form**Patient information contained within must be identified. After the sample reaches our laboratory, it is barcoded and accepted by the Sample Acceptance Unit.

Every item sent by the institutions**Genetic Testing Information Text and Explicit Consent Form**It is accepted and processed as an agreement.

For outpatients visiting our laboratory, genetic counseling is followed by consultation with a Medical Geneticist.**Genetic Testing Information Text and Explicit Consent Form**The form is completed and sent to the blood collection unit, where the process described in section 6.1 is applied.

6.2. FACTORS AFFECTING THE ANALYSIS RESULT

Proper transport and analysis alone are not sufficient to obtain reliable and medically assessable results. The factors affecting the analysis results can be briefly summarized as follows.

Factors that remain unchanged:

- Gender

- Race

- Heredity

Changing factors:

- Use of medication

- Having undergone a bone marrow transplant

- Pregnancy

-Endogenous factors

-Exogenous factors (Pharmacotherapy)

The laboratory can only assess a very limited portion of the factors that may affect the accuracy of analysis results if there is a lack of information regarding the patient and sample collection conditions. Therefore, providing the laboratory with clinical information about the patient is extremely important so that the clinician can make interpretations and assessments that can assist them.

6.3. REFERENCE RANGE

The reference range specified for the tests represents the group containing 95% of the values obtained from healthy individuals and provides a general basis for evaluating the test result. These values may vary from patient to patient depending on various factors. The reference range may also change depending on the analysis method. The reference values in the patient's report are the valid values.

6.4. OUR LABORATORY'S WORKING PROGRAM

Inside our laboratory**Test List**All tests included in the application (except those sent to the application laboratory) are being processed.

The working day and reporting dates of all tests performed in our laboratory.**Test List**This is indicated opposite the relevant test. General concepts related to these are summarized below;

Tests**Test List**Work is performed and reported within the specified timefrar

6.5. SAMPLE COLLECTION AND PREPARATION PROCEDURE

I-BLOOD SAMPLES

Collection of Blood Samples

Venous Blood Sampling

During blood collection, the patient should be in a lying or sitting position and should rest in this position for at least 20 minutes.

The needle tip should be as wide as possible.

The tourniquet should not remain tightened on the arm for more than 30 seconds.

The vessel should be compressed with a maximum pressure of 60 mmHg.

The tourniquet should be released after the needle has been successfully placed in the vein.

When drawing blood with a syringe, forceful aspiration of blood into the tube should be avoided.

Blood samples should be taken in the following order:

For cytogenetic and molecular cytogenetic (FISH) tests, samples must be collected in heparinized (green-capped) tubes.

For molecular genetics and microarray testing, samples must be collected in EDTA-containing (purple-capped) tubes.

Whole Blood with EDTA

Tube: Vacuum-sealed plastic tube with purple cap containing EDTA.

Example:

Whole blood is collected up to the mark in purple-capped EDTA tubes. To prevent clots from forming in the tubes, the tubes are gently inverted 5-6 times immediately after blood collection to mix the blood. Shaking should be strictly avoided.

During blood collection, particular attention should be paid to ensuring the blood sample is filled up to the marked line.

Samples are stored in the refrigerator (at 2-8 °C).

Points to Note:

If blood has not been collected up to the marked line on the tube, or if a clot has formed in the tube, a new sample must be taken!

Whole Blood with Heparin

Tube: Vacuum-sealed plastic tube with green cap containing lithium heparin.

Example:

Blood samples are collected in green-capped tubes containing lithium heparin.

To ensure the blood sample mixes with lithium heparin, the tubes should be inverted very slowly 5-6 times to ensure complete contact of the blood with the anticoagulant.

Preservation of Blood Samples

After blood collection, the sample is kept at room temperature, away from direct sunlight, until the clotting process is complete. This usually takes about 30 minutes. The presence of clotting-accelerating agents in the blood collection tube can shorten this time to 15 minutes. After this time, the serum needs to be separated from the clot using centrifugation.

TUBES RECOMMENDED BY OUR LABORATORY

TUBE	COVER COLOR	DIMENSIONS (MM)	VOLUME (ML)	AREA OF USE
EDTALI TUBE	PURPLE	13 X 75	2-5	MOLECULAR GENETİC TESTS (DNAİNSULATİON)
HEPARIN-CONTAINING TUBE (PLASTIC)	GREEN	13 X 75	2-5	CYTOGENETİCS AND FISHTESTS

II. TISSUE CULTURES

Abortion samples, amniotic fluid, chorionic villus sampling, and CVS are valuable specimens.

Chorionic villus biopsy material (20-30 mg), skin biopsy (1-2 cm3), abortion material (1-2 cm3), (skin biopsy, placental biopsy) samples should be sent to the laboratory in transport medium.

Amniotic fluid (approximately 20 ml) should be collected in a sterile syringe without a seal and delivered in the same syringe without transferring it anywhere.

III. PARAFFIN BLOCK

Paraffin block samples are collected for molecular testing and FISH tests.

Paraffin block samples can be sent either as sections of at least two 4-6 µm thick plates fixed on slides, or as paraffin blocks containing the tumor tissue.

IV. EMBRYO BIOPSY MATERIAL

Embryo biopsy material should be suspended in 2.5 µl of 1xPBS in 0.2 mL PCR tubes. Samples should be shipped with ice packs.

6.6. EXAMPLE STORAGE CONDITIONS

For successful testing and reliable results, it is extremely important that samples taken from patients are stored under appropriate conditions. Therefore, the laboratory staff of the institution sending the samples are responsible for the preservation of the samples from the moment they are collected until they are delivered to SAPIENS Genetics and Health Services Inc. couriers and cargo carriers.

Unless otherwise specified under the relevant test, samples must be stored within the temperature ranges outlined in the SAPIENS Genetics and Health Services Inc. Test Guide from the time of collection until delivery to the SAPIENS Genetics and Health Services Inc. Courier.

Our laboratory is not responsible for any errors in results that may arise due to any mistakes made during the period until the results are delivered to the courier of SAPIENS Genetics and Health Services Inc.

6.7. SAMPLE BAG PREPARATION GUIDELINES

Bag and Material Specifications

SAPIENS Genetics and Health Services Inc. Sample Shipping Bag contains double-layered thermal insulation material;

Our laboratory transport bags are designed to ensure your samples reach us in the most suitable condition.

Our case has a rigid outer structure that maintains the temperature inside and protects the samples from external impacts.

The compartment inside the carrying case should be used for sending delivery note printouts and Sample Submission Forms.

Once the samples are placed in the bags, the bag covers must be closed. Closing the zippers on the bag covers is mandatory, as bags with open covers may open during transport and the samples inside may be lost.

Our laboratory is not responsible for sample loss in bags sent without the cases being sealed. Please attach the datalogger sent to you to the sample bag. This is necessary for us to determine whether the sample has arrived at the correct temperature.

Bag Organization.

The "Genetic Testing Information Text and Explicit Consent Form" or "Delivery Note Printouts" related to the samples in the box are placed in the compartments inside the carrying case.

NOTE: Please use the materials (tubes, transport medium, etc.) sent to you by our laboratory when sending samples to our laboratory. Samples sent without screw caps may spill during transport, causing delays in analysis.

Our laboratory ensures that samples are received in bags belonging to our laboratory; otherwise, the relevant institutions are notified. Please inform the responsible parties for the replacement of damaged bags. Our laboratory and the authorized representative of the institution using the bags are responsible for the disinfection and sterilization of the bags to prevent any risk of contamination.

6.8. CRITICAL / PANIC VALUES

The critical and panic values for the tests performed in our laboratory are determined by our Laboratory Experts and based on information from various current sources.**Panic Diagnosis List**It has been prepared. When a critical panic value is detected in any test result, the relevant unit specialist will communicate this value to the institution's authorized person (patient's doctor, laboratory manager or laboratory personnel, etc.) via communication channels (WhatsApp, etc.) or email.**Panic Value Statement Form**He/She informs with.

6.9. EXAMPLE ACCEPTANCE-REJECTION CRITERIA

Some of the factors that can be determined as rejection criteria for samples are as follows:

Samples sent in the wrong sample container/tube

Samples that arrived at the laboratory more than 72 hours later.

Clotted blood samples

Damaged sample tubes/sample containers

Samples sent with incorrect indications (decision to be made in consultation with the doctor)

Examples where patient identification information is missing.

Samples where the Sample Submission Form and Informed Consent Form are missing or not fully completed.

Frozen samples

Tissue samples such as abortion and CVS material being placed in alcohol or formalin

Insufficient samples taken

OUR EXAMPLE REJECTION-ACCEPTANCE AREA

SAPIENS Genetics and Health Services Inc. examines the suitability of all samples received from institutions in the sample acceptance area, taking into account our Rejection-Acceptance Criteria. Our personnel have received training on sample rejection and acceptance as part of their professional orientation training.

Rejected samples are stored in the refrigerator in this area.

Samples that have been rejected may be analyzed if deemed appropriate by a specialist upon written request from the institution.

Samples that do not pass the acceptance process are sent to the rejection area and stored under appropriate conditions.

Information regarding rejected samples is relayed to the relevant laboratories by Patient Admissions Staff or Sample Acceptance during working hours.

6.10. RECEIPT OF ADDITIONAL TEST REQUESTS AND CONDITIONAL SAMPLE ACCEPTANCE

Additional Test Requests

When institutions make verbal requests such as adding new tests, canceling tests, repeating samples, or requesting the return of samples, a written statement (fax, email, etc.) is requested from the institution. Requests received from the customer with written confirmation are evaluated and the necessary actions are taken.

Samples remaining from completed tests are stored under appropriate conditions, and requests for additional analyses on the same sample are evaluated considering the sample's stability period. Accordingly, requests for additional analyses for all samples are accepted based on the stability periods specified in the Sample Storage Period List. In cases outside these specified periods, a new sample is requested.

Conditional Acceptance

Working with a Rejected Sample (Conditional Acceptance):

Samples rejected in our laboratory are processed by personnel from our contracted institution upon request. If the relevant specialist approves, the Patient Admissions Staff or Sample Acceptance and Patient Registration Staff will contact the institution to inform them that the analysis will be performed. Samples approved for analysis are then collected from the rejection area and processed by the relevant technician.

6.11. REVIEW OF SAMPLE QUANTITIES

The sample quantity required for each test performed in our laboratory.**Test List**This information is communicated to our clients. Changes in the sample quantities required for testing are related to changes in working methods. When there are changes in working methods, institutions are informed via external announcements.

6.12. PRESERVATION OF SAMPLES FOR A SPECIFIC PERIOD OF TIME

In some cases (customer request, verification test, etc.), samples that have been processed and whose results have been obtained in our laboratory need to be re-processed. In such cases, the samples to be re-processed are stored at temperature ranges appropriate to the parameters of the test to be performed.

6.13. LIST OF SERVICES WE OFFER

In our laboratory, according to the technical equipment capabilities and agreements with our clients;

Cytogenetic Tests

Molecular Genetic Tests

Tests are being conducted under these headings. The number of tests conducted under these headings can be increased or decreased depending on the current circumstances. The test information we are working on will be delivered to you.**Test List**in It is currently available.

6.14. REPORTING QUALITY CONTROL RESULTS

External quality control results for test parameters processed in our laboratory are sent to institutions upon request. Institutions wishing to receive these results should contact our laboratory's quality unit and inform them in writing via email, to the email address they will receive from the quality unit, which tests and date range they require external quality control results for. The quality unit will then send the requested information to the institutions via email.

7. RELATED DOCUMENTS

SG.FR.27 Sample Submission Form

SG.LS.06 Complete Test List

SG.FR.125 Genetic Testing Information Text and Explicit Consent Form