Specimen Collection, Labeling, Packaging, and Transport Manual

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Purpose
Laboratory test results are dependent on the proper collection and handling of patient specimen. It is important that all specimens be properly labeled and requisition forms are filled completely. Please follow the instructions for specimen collection, packaging, and transport as outlined in this manual. This manual is reviewed at least annually by the Laboratory Director to ensure that all procedures are up to date. In the event that there are any questions or concerns when collecting, packaging, or transporting a specimen, please email info@viafet.ae or call +971 4 344 3222 to have your concerns addressed.

Policy Statements

Cancellation of Tests
Cancellations received prior to test setup will be honored at no charge. Requests received following test setup cannot be honored. A report will be issued automatically and charged appropriately.

Compliance Policies
Viafet Genomics Laboratory is committed to compliance with the applicable laws and regulations in each of our operating regions.

Confidentially of Results
Viafet Genomics Laboratory is committed to maintaining confidentiality of patient information. To ensure compliance with the College of American Pathologists (CAP) for the appropriate release of patient results, the following policies are in place:

Phone Inquiry Policy – One of the following unique identifiers will be required:
• Viafet Test ID or Viafet Patient ID; or
• External ID along with patient name; or
• Identification by the individual that he or she is the referring physician identified on the requisition form

Definition of Minimum Sample Requirements (Not applicable to embryo biopsies)
Minimum sample requirements are defined based on the amount of specimen required to perform an assay once, including instrument and container dead space. Submitting the minimum specimen volume makes it impossible to repeat the test or perform confirmatory testing. In some situations, a minimum specimen volume may result in a Quality Not Sufficient (QNS) result, requiring a second specimen to be submitted.

Disclosure of Results
Viafet Genomics Laboratory will release results to ordering physicians or other health care providers responsible for the individual patient’s care. Third party requests or requests from patients for results are directed to the ordering facility.

Informed Consent Certification
Submission of an order for any tests contained in this manual constitutes certification to Viafet Genomics Laboratory by ordering physician that the ordering physician has obtained informed consent of subject patient.
Record Retention
Viafet Genomics Laboratory retains all test requisitions and patient test results at a minimum for the retention period required to comply with and adhere to the CAP. A copy of the original report and requisition forms is available in Viafet's Laboratory Information System (LIS).

Requisition Form
A requisition form (either soft or hard copy) is required for all specimen sent to Viafet Genomics Laboratory.

Specimen Identification Policy
In compliance with and adherence to the CAP, Viafet Genomics Laboratory’s policy states that before collecting a specimen, personnel should confirm the patient’s identity by checking at least two patient-specific identifiers. Following collection, the specimen should be labeled with at least TWO patient-specific identifiers on the primary specimen container, the innermost container that holds the original specimen prior to processing and testing. Patient specific identifiers may include: patient’s first and last name, medical record number, or date of birth. Specimens are considered mislabeled when there is a mismatch between the patient specific identifiers on the specimen and information accompanying the specimen. When insufficient or inconsistent identification is submitted, Viafet Genomics Laboratory will recommend that a new specimen be obtained, if feasible.

Supplies
Any supplies that are required for specimen collection, as specified in this manual, are provided without charge. Supplies can be requested by emailing info@viafet.ae.
Pre-Implantation Genetic Screening & Diagnosis (PGS & PGD)

Please inform Viafet of your upcoming cases by emailing info@viafet.ae on or before the day of Egg Retrieval.

In the case of Pre-Implantation Genetic Diagnosis (PGD) for a Single Gene Disorder, patient reports must be submitted to the laboratory before the start of the IVF cycle to ensure that all quality control procedures are complete before receiving the patient’s specimen(s). A clinical coordinator will confirm when we are prepared for the IVF cycle to begin.

Please note, diagnosis for a Single Gene Disorder cannot be performed in conjunction with 5-Chromosome FISHAnalysis.
24-Chromosome PGS and/or PGD for a Single Gene Disorder

In-Country Specimen for Pick Up by a Trained Viafet Courier

Required Materials
1. Four-well dishes
2. Gamete culture media

Preparation
1. Prepare the four-well dish by putting 20 µl of gamete culture media in each well.
2. After completion of embryo biopsy, pipette each biopsied cell directly into the correctly labeled well.
3. Label the four-well dishes as per the Specimen Labeling instructions below.
4. Each dish should contain a maximum of four biopsied cells.

Specimen Labeling
1. Each four-well dish should contain two acceptable patient identifiers along with the embryo ID alongside each corresponding well on the dish. Embryo ID should include both alphabetical and numerical values; e.g. E1, E2, E3, E4, etc.
2. Once a dish is labeled and all biopsies are complete, place the cover on the dish and label with two acceptable patient identifiers.
3. Labeling should be performed using permanent, NOT dry-erase, marker.

Acceptable Specimen Labeling

Unacceptable Specimen Labeling

Requisition and Patient Consent
1. A consent and requisition form should accompany each patient’s specimen.
2. The checkbox for “Blastomeres in dishes” should be selected. The location of each blastomere should be mentioned on the requisition form using the embryo ID. Embryo ID should include alphabetical and numerical values; E1, E2, E3, E4, etc.

Blastomeres in dishes
Label the embryo ID in the correct location.
3. Enter the date and time of the embryo biopsy as well as the day of embryo development on which the biopsy was taken. The individual(s) who performed embryo biopsy and specimen labeling should sign the form.

### Specimen Packaging and Transportation

1. Specimen should be kept at room temperature until picked-up by a Viafet Courier.
2. The Viafet Courier will place the four-well dishes into the specimen transport box.
3. Results will be released within 24-36 hours of receiving the specimen.

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**Sample Collection**

<table>
<thead>
<tr>
<th>Collection Date:</th>
<th>Time:</th>
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</thead>
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I certify that I collected the accompanying sample from the above mentioned patient, whose identity was confirmed, and that I labeled the sample immediately following collection.

Name: __________________________ Designation: ______________________

Signature: __________________________
24-Chromosome PGS and/or PGD for a Single Gene Disorder

Out-of-Country Specimen Mailed via International Courier

Required Materials
1. 0.5 ml Eppendorf safe-lock tubes (catalog #30121023)
2. Global Total Culture Media (do not use after expiry)
3. Mineral Oil

Preparation
1. Pipette 3.5 µl of Global Total into a 0.5 ml safe-lock tube.
2. After performing embryo biopsy, wash the blastomere with 100 µl of Global Total.
3. Pipette the blastomere, with as little Global Total as possible, into the prepared 0.5 ml safe-lock tube.
4. Top off each tube with 550 µl of mineral oil and close firmly.
5. Label each tube as per the Specimen Labeling instructions below.

Specimen Labeling
1. Label each tube with two acceptable patient identifiers (or patient label) and embryo ID. Embryo ID should include alphabetical and numerical values; E1, E2, E3, E4, etc.
2. Labeling should be performed using permanent, NOT dry-erase, marker.

Requisition and Patient Consent
1. A consent and requisition form should accompany each patient’s samples.
2. The checkbox for “Blastomeres in tubes” should be selected. The embryo ID should be mentioned for the number of tubes sent.

Sample Collection

Collection Date:     Time:     
I certify that I collected the accompanying sample from the above mentioned patient, whose identity was confirmed, and that I labeled the sample immediately following collection.

Name:  Designation:  
Signature:  

DXB-AD-DOC-02
Effective Date: 06/06/16
Version: 02
Specimen Packaging and Transportation

1. The samples should remain at room temperature.

2. Tubes containing biopsies for each respective patient should be placed together into a small container; e.g. a urine sample container. The container should be stuffed with tissue or gauze to ensure that the tubes remain in a compact space during transport.

3. Mail immediately by international courier (DHL) using the account number provided by Viafet. Inform a Viafet Clinical Coordinator of the DHL Tracking Number as well as the contents of the package being sent. Please ship to the following address:

   DHL Main Office Terminal 2
   Dr. Ali Hellani
   +971 50 514 1569

4. Results will be released within 24-36 hours of receiving the specimen.
5-Chromosome FISH Analysis

In-Country Specimen for Pick Up by a Trained Viafet Courier
See instructions for “In-Country Specimen for Pick Up by a Trained Viafet Courier”, 24-Chromosome PGS and/or PGD Single Disorder on page 6.

Out-of-Country Specimen Mailed via International Courier

Required Materials provided by Viafet
1. Engraved slides
2. 1.5 ml Eppendorf safe-lock tubes (catalog #30120086)
3. Lysing solution A, B, and C. To be stored at room temperature
4. 1.5 ml Viafet FISH Washing Solution. To be stored at 4°C

Preparation
1. Before performing embryo biopsy, ensure that the Lysing Buffer (LB) is prepared. Each batch is useable for 3 days and is to be stored at room temperature:
   a. In a 1.5 ml tube, add 1 µl of solution A and 1 µl of solution B to 990 µL of distilled water.
   b. Mix the solutions by vortexing at maximum speed for one minute
   c. Add 10 µl of solution C to the mixture and vortex at maximum speed for one minute.
2. Pipette 1 µl of LB for each blastomere onto the circles of the provided engraved slide. The side of the slide with numbers 1, 2, 3, and 4 should be facing upwards. The first blastomere should be pipetted into the circle below the number 1, the second one into the circle below the number 2, and so on until the first one is filled (i.e the blastomeres should be pipetted horizontally, filling the row before moving onto the row below).
3. Pipette each blastomere, with as little washing solution as possible, onto the slide with LB solution.
4. Wait until the cytoplasm starts lysing and then aspirate the LB solution.
5. The nucleus should be seen clearly. Minimal traces of cytoplasm will not affect the result.
6. Repeat for all blastomeres.
7. Label the slides as per the instructions in Specimen Labeling below.

Specimen Labeling
1. Use one slide per patient.
2. Label the slide with at least two patient specific identifiers (for example, the patient’s name and medical record number).
3. Labeling should be performed using a pencil, NOT a marker.
Requisition and Patient Consent

1. A consent and requisition form should accompany the shipment for each patient.
2. The checkbox for “Blastomeres on slides” should be selected. The location of each blastomere on the slide should be mentioned on the requisition form using the embryo ID. Embryo ID should include alphabetical and numerical values; E1, E2, E3, E4, etc.

3. Enter the date and time of the embryo biopsy as well as the day of embryo development on which the biopsy was taken. The individual(s) who performed embryo biopsy and specimen labeling should sign the form.

Specimen Packaging and Transportation

1. The samples should remain at room temperature.
2. Place the slide in a slide holder and pack the slide holder into an envelope.
3. Mail immediately by international courier (DHL) using the account number provided by Viafet. Inform a Viafet Clinical Coordinator of the DHL Tracking Number as well as the contents of the package being sent. Please ship to the following address:

   DHL Main Office Terminal 2
   Dr. Ali Hellani
   +971 50 514 1569

4. Results will be released within 24 hours of receiving the specimen.
Blood Collection for Whole Exome Sequencing, Carrier Screening, Gene Screening Panels, HLA Typing, Linkage Analysis, and/or Targeted Mutation Screening

Required Materials
1. EDTA Tubes (purple top)

Preparation
1. 2.5 cc of blood is required for each individual completing testing.
2. Label each tube as per the Specimen Labeling instructions below.

Specimen Labeling
1. Label each tube with two acceptable patient identifiers (or patient label).
2. Labeling should be performed using permanent, NOT dry-erase, marker.

Requisition and Patient Consent
1. A consent and requisition form should accompany each patient’s samples.
2. The checkbox for “Blood in EDTA tube” should be selected.

Specimen Packaging and Transportation
1. The samples should remain at room temperature.
2. The tube(s) should be placed inside a biohazardous bag.
4. The Viafet Courier will place the biohazardous bag(s) into the specimen transport box OR mail immediately by international courier (DHL) using the account number provided by Viafet. Inform a Viafet Clinical Coordinator of the DHL Tracking Number as well as the contacts of the package being sent. Please ship to the following address:

   DHL Main Office Terminal 2
   Dr. Ali Hellani
   +971 50 514 1569

5. Turn-around-time will vary based on the test requested.
Chromosomal Analysis of Amniotic Fluid, Chorionic Villus Sampling, and Products of Conception

Required Materials
1. 1.8-2 ml Screw Cap Tube (for example, USA Scientific 1.8 ArcticIce Cryogenic Tube - catalogue number 1418-7310)
2. Saline (Not required for Amniotic Fluid specimen collection)

Preparation
1. Maternal blood sample is required in order to rule out maternal contamination with the sample. 2.5 cc of EDTA blood is requested. Label the tube as per the Specimen Labeling instructions below.
2. **For Chorionic Villus Sampling or Products of Conception:** Place the tissue into 1 ml of saline solution in a 1.8-2 ml Screw Cap Tube. For POC, a tissue the size of a kidney bean is required (approximately 3 cm$^3$). Label the tube as per the Specimen Labeling instructions below.
3. **For Amniotic Fluid:** After aspirating the fluid, put it in a 15 ml tube. Label the tube as per the Specimen Labeling instructions below.

Specimen Labeling
1. Label each tube with two acceptable patient identifiers (or patient label).
2. Labeling should be performed using permanent, NOT dry-erase, marker.

Requisition and Patient Consent
1. A consent and requisition form should accompany each patient’s samples.
2. The checkboxes for “Blood in EDTA tube” and “Amniotic Fluid” or “Saline (CVS, Products of Conception)” should be selected.

Specimen Packaging and Transportation
1. The samples should remain at room temperature.
2. Place the sample into a biohazardous bag.
3. **If out-of-country:** Mail immediately by international courier (DHL) using the account number provided by Viafet. Inform a Viafet Clinical Coordinator of the DHL Tracking Number as well as the contents of the package being sent. Please ship to the following address:

   **DHL Main Office Terminal 2**
   Dr. Ali Hellani
   +971 50 514 1569

4. **If in-country:** The Viafet Courier will place the biohazardous bag(s) into the specimen transport box.
5. Turn-around-time will vary based on the test requested.