**Collection and Custody Chain Form** for the Preimplantation Genetic Testing (PGT-A).

The doctor requesting the service is responsible for recording in the sensitive fields the requested information, printing two copies, and singing them prior to sample collection.

**DATA OF THE DOCTOR IN CHARGE**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Requested collection data:** |  | **Quote No.:** |  | **Sample No.** |   |
| **Clinic or Institute:** |  |
| **Sample responsible(s):** |  |
| **Email(s) (Separated by commas)** |  |
| **Phone(s) (Separated by commas)** |  |

**SERVICE DATA**

**Results delivery time:** Up to 30 working days from batches of 24 samples and the laboratory acceptance.

**What to deliver:** Online record (\*.PDF).

The assigned people in this form are the only ones authorized for receiving the results by email (please check the recorded applicant data well).

**Payment terms:** They will be stipulated in the corresponding service quote. Delivering results will be contingent upon the full payoff of the service.

NOTE: Preferably, for faster delivery of results, please request your sample collection until ALL of them are under the conditions mentioned below.

**SAMPLE DATA**

Embryo biopsies for **EmbryoTest PlusTM** **(ETP)** will be suspended in 2.5ul of phosphate-buffered saline (PBS 1X) in microtubes of 0.2ml (low retention) or else, in materials and reagents delivered by **Semper Genomics (SG)** in the sample collection kit.

Each microtube must be coded and labeled with a permanent marker, recording the **Patient Identification Number (PIN)** and embryo number; also perfectly sealed and centrifuged (preferably). Hereunder, the samples (microtubes) must be placed in the tube rack (one row per patient) , and frozen at -4ºF until the collection time by the **Semper Genomics** staff.

**SAMPLE EXCLUSION CRITERIA**

1. The ID code of the samples must match the recorded data herein. Otherwise, the sample(s) will be rejected.
2. The laboratory staff of SG must ensure the physical presence (volume) of each sample. Thus, it is recommended to centrifuge them before freezing them.
3. If the sample is not amplified, either for lack of genetic material, some inhibitor, or sample biology, it will be excluded from the test.

NOTE: If one or all the samples are excluded, the client will be notified in the emails recorded in this form.

**TEST DATA**

Factors and limitations that affect the test or its results:

1. Possibility of cell absence in the biopsy or the "tubing" (transfer).
2. Sample degradation for incorrect storage or handling of the samples (cold chain).
3. The test is limited to a qualitative analysis of aneuploidy detection of the embryonic genome.

**DELIVERABLE RESULTS**

Digital records in files (\*.PDF) with methodological description and result tables (aneuploidies) for each sample. The records will be sent by email to the address(es) recorded in this form.

NOTE: **Semper Genomics** will terminate the service in accordance with the results 72 hours after the file sending if no notification is received from the client.

**DATA PRIVACY**

The test results will be protected under strict privacy, and they can be provided by email only to the assigned people herein. The data and records privacy will be 90 calendar days from the sending of results to the client. After that date, they will be eliminated from the SG server.

**TABLE OF SAMPLE RECORD**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Cons.** | **Sample Identification Number (PIN) up to 5 digits.** | **Embryo No.** | **Tissue Type** | **Biopsy day** | **Embryo grading: ex. 5AA** | **Biopsy embryologist** | **Transfer made by:** | **Witness** |
| **1** |  |  |  |  |  |  |  |  |
| **2** |  |  |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |  |  |
| **4** |  |  |  |  |  |  |  |  |
| **5** |  |  |  |  |  |  |  |  |
| **6** |  |  |  |  |  |  |  |  |
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| **22** |  |  |  |  |  |  |  |  |
| **23** |  |  |  |  |  |  |  |  |
| **24** |  |  |  |  |  |  |  |  |

Filling instructions: The doctor is responsible for recording the requested data in the table above, consecutively writing for each sample, without missing rows, only the initials of the requested people in the last three columns. **TE:** Trophoblast,  **NC:** Negative Control.

**CONFORMED SIGNATURES AND DATES OF CUSTODY CHAIN TRANSFER:**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Doctor's name and signature (Delivery) | SG Logistics Signature (Collection) | SG Laboratory signature (Reception) |
| DATE: | DATE: | DATE: |

|  |
| --- |
| **Observations / Incidents** |
|  |

Record the observations or incidents with some sample or during the process, from sample collection to its entry at SG laboratory, by any of those involved therein.

NOTE: For clarifications or inquiries during the process, please contact us at the email ventas@sempergenomics.com

**PRINT TWO COPIES OF THE HEREIN FOR DATA RECORD AND SAMPLE CUSTODY TRANSFER.**