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NHS North West NHS Genomic Laboratory Hub

ACCEPTANCE CRITERIA, REQUIREMENTS FOR CYTOGENETIC ANALYSIS, AND TISSUE DISPOSAL POLICY FOR SOLID TISSUE SAMPLES FOLLOWING LOSS OR TERMINATION OF PREGNANCY

PLEASE NOTE:
WITH EFFECT FROM 1/4/2019 ALL PREGNANCY LOSS SAMPLES FOR MOLECULAR CYTOGENETIC ANALYSIS SHOULD BE SENT TO THE NORTH WEST GENOMIC LABORATORY HUB (LIVERPOOL) AT LIVERPOOL WOMEN'S HOSPITAL, CROWN STREET, LIVERPOOL, L8 7SS.
RESULTS OF ANY MICROARRAY ANALYSIS WILL BE REPORTED BY THE NORTH WEST GENOMIC LABORATORY HUB (MANCHESTER).

Acceptance Criteria

Samples are accepted for testing from the following referral categories only:

- Structural fetal abnormality. **It is essential that full clinical details are clearly recorded on the referral form.** Please specify any suspected syndromes.
- A third or subsequent consecutive miscarriage. Please include the dates of each miscarriage on the referral form.
- Samples requested for follow up investigations. Please note that routine confirmations of prenatal results are not performed.
- IUD when the gestational age is 24 weeks or greater (TESTED BY QF-PCR ONLY).
- Confirmed neonatal deaths will be processed for microarray following QF-PCR if appropriate.
- Postnatal samples for culture prior to export for further testing (skin biopsy only).
- Samples received where there is confirmation of **recurrent** neural tube defects (more than one occurrence within the family) **WILL** be processed for molecular cytogenetic analysis.

Samples not meeting acceptance criteria or where no clinical information is provided will not be processed.

Note: Samples referred for isolated neural tube defects only (single event, no other structural abnormalities), which do not meet the acceptance criteria described above, will NOT be processed for molecular cytogenetic analysis.

If you require further information please contact the laboratory directly by telephone and ask to speak to the Duty Scientist.

Sample Requirements

Fresh tissue samples are required (less than seven days old for post mortem samples) and should not exceed the sample sizes given below. The most appropriate sample types are:

- A full depth skin sample (0.5cm^3).
- A sample of umbilical cord tissue approximately 2-3 cm in length.
- A sample of placental tissue approximately 1-2 cm^3 in size which includes placental villi.
- If possible, a sample of cardiac or cord blood in EDTA (0.5ml collected in a paediatric tube).
- A sample of products of conception in a sterile 20ml universal container.

Other tissue types should only be sent in exceptional circumstances. Duplicate samples will not be processed unless the primary sample is unsuitable for testing.

Please Note

- **Whole fetuses cannot be accepted by the laboratory under any circumstances**. The referring centre will be contacted to arrange collection as soon as possible.
- Tissue samples that are more than 7 days post mortem or appear necrotic on arrival in the laboratory may not be suitable for testing. Please state the date of delivery on the referral form.
- Samples that have been preserved in formalin are unsuitable for molecular cytogenetic studies. Samples that have been frozen are unsuitable for cell culture but are suitable for molecular cytogenetic analysis.
- **Do not** include cord clips, dressings or any other medical device with the sample.

- **Please do not** send the entire products of conception from an early pregnancy loss. Please examine the tissue at delivery and only send sufficient material for testing (in a sterile 20ml universal container). Where excessive material, larger container or the entire products of conception is sent, the referring centre will be contacted to arrange collection as soon as possible.
- Products of conception **will only be accepted from clinically confirmed pregnancies**. **All products of conception samples where there are no identifiable fetal tissues at delivery must be accompanied by a maternal blood sample (1-5ml in EDTA) to exclude maternal cell contamination. In some instances, products of conception samples may be entirely maternal in origin in which case a result is not possible.**

Transport Requirements

- Solid Tissue samples should be sent dry, or in a small volume of sterile saline, in a sterile 20ml universal container. Samples can be stored overnight in a small volume of sterile saline solution in a sealed specimen container (to prevent leakage). Samples sent in specimen containers larger than specified above will be rejected, and the referring centre will be contacted to arrange collection as soon as possible.
- Samples MUST be sent with a fully completed Genetic Test Request Form, on which the consent statement has been signed by the referring clinician. For early pregnancy loss samples, a record of discussion and consent form is also required. Please do not send documentation for any other department with samples for genetic analysis.
- **All packaging must conform to UN3373 standards, details of which can be found via the link below.**
- https://mft.nhs.uk/nwglh/test-information/general-requirements/transport-and-packing-requirements/**.**
- **Inappropriately packaged specimens received may be rejected and reported as Trust incidents.**

Tissue Disposal Policy

Disposal of surplus fetal tissue is governed by the Human Tissues Act 2004.

The laboratory will respectfully dispose (by sensitive incineration) any remaining definitively non-fetal cord, placenta, or membrane samples within 12 weeks from the date we received the test request.

The laboratory does not have facilities for the handling or cremation of fetal material so samples should not exceed the requirements listed above.

Where excess identifiable *fetal* material is sent, the sample will be returned to the referring centre to fulfil patient wishes approximately 12 weeks after receipt regardless of whether a record of discussion and consent was received.

Where there is excess *products of conception* the laboratory will act according to the woman's wishes on the record of discussion and consent form. If no form is provided within 12 weeks of the referral the laboratory will sensitively dispose.

Essential Referral Information

All samples for genetic analysis must include the following information in order to be processed:

- Referring Consultant and Referral Centre clearly indicated.
- Full patient details including maternal NHS number and maternal Date of Birth.
- Full clinical details including the reason for request (please detail abnormalities), gestational age, date of delivery and date of sampling.
- The site of origin of the sample.

OTHER TISSUE SAMPLES REFERRALS

- Skin biopsy samples requiring fibroblast cell culture should be sent to the North West Genomic Laboratory Hub Manchester, St Mary's Hospital, Oxford Road, Manchester, M13 9WL.
- If a skin biopsy from a living patient requires testing for tissue specific mosaicism or if the tissue requires cell culture prior to export for molecular or biochemical testing, please telephone the laboratory (0161 276 6553) to request fresh transport medium. Please also comply with transport requirements above.
- Solid tumour samples for cytogenetic testing should be sent to the Oncology Cytogenetics Laboratory at the CHRISTIE NHS FOUNDATION TRUST (0161 446 3165).

Last updated: September 2024