DCG LABORATORY USER MANUAL

1.0 PURPOSE

The purpose of this document is to detail all relevant information for Users with regards the service provided in the Department of Clinical Genetics Laboratory. Information in this document will be used to update the Lab App.

2.0 SCOPE

2.1. In-Scope:

2.1.1. Relevant information and guidelines required for the Users of all services provided by the DCG laboratory with the exception of those listed in section 2.2.

2.2. Out of Scope:

2.2.1. Information and guidelines for Cystic Fibrosis National Newborn Screening programme.

2.2.2. Laboratory instructions on how to implement the information provided in this document. Please refer to MP-LAB-Labelling.

3.0 RESPONSIBILITIES

Role	Responsibility
All Staff	• To notify Divisional and/or Laboratory management of any discrepancies in this document • To actively promote the use of the Lab App to Users • To read and acknowledge this document in a timely manner
Divisional Management	• To ensure consistent application of the criteria described in this document • To actively promote the use of the Lab App to Users
Laboratory Management	• To ensure all information in this document is relevant and accurate • To ensure any updates to this document are reflected in the Lab App when required • To actively promote the use of the Lab App to Users

4.0 POLICY

4.1 To ensure all relevant details described in this document are also available on the Lab App.

5.0 PROCEDURE

5.1. ABOUT US

The Department of Clinical Genetics (DCG) provides a public genetic service to referring clinicians for patients and families in the Republic of Ireland affected by, or at risk of, a genetic disorder. It is estimated that European populations have a 6%-8% lifetime prevalence of having a rare disease, the majority of which are genetic. Services are provided to the majority of public hospitals in the Republic of Ireland, where applicable a signed service level agreement should be in place (see MP-LAB-SLA).

The Department comprises two integrated divisions:

- Clinical Genetics
- Genetics Laboratory (Cytogenetics and Molecular Genetics)

Private Hospitals

In limited circumstances, the laboratory may accept samples from private hospitals. Please contact the Laboratory Manager for further information.

5.2. CONTACT DETAILS

For general laboratory queries please email genetics.lab@childrenshealthireland.ie

Position	Name	Email
Lab Manager	Jennifer McDaid	jennifer.mcdaid@childrenshealthireland.ie
Quality Manger	Julie Egan	julie.egan@childrenshealthireland.ie
Cytogenetics Chief Scientist	David Betts	david.betts@childrenshealthireland.ie
Cytogenetics Principal Scientist	Linda McArdle	linda.mcardle@childrenshealthireland.ie
Molecular Principal Scientists	Aileen Butler	aileen.butler@childrenshealthireland.ie
	Trudi McDevitt	trudi.mcdevitt@childrenshealthireland.ie

Please note, the laboratory requests that patients do not contact the laboratory directly. All communication relating to patient testing and results MUST be channelled through the patient's health care professional.

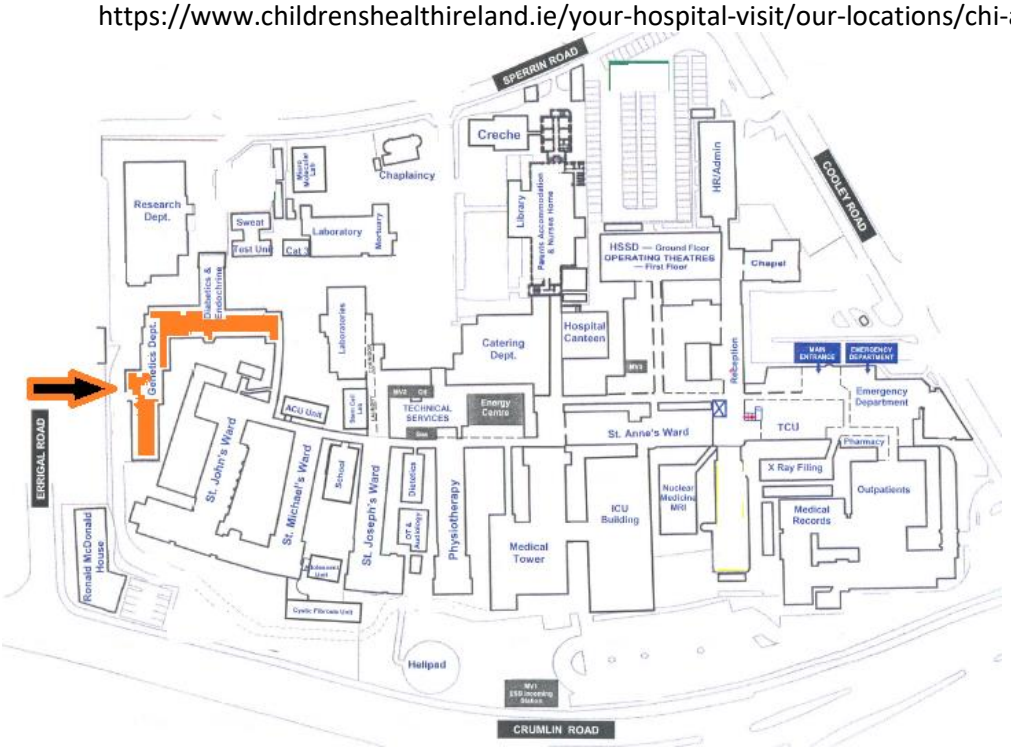
Patient/guardians have the right to access a copy of personal data held by Children's Health Ireland including information held in the Department of Clinical Genetics. Details on how to request access to this data can be found at https://www.childrenshealthireland.ie/policies-statements/healthcare-record-personal-data-requests/.

5.3. OPENING HOURS

- The laboratory is open Monday - Friday: 09.30 - 17.00
- There is no service on a Saturday or Sunday
- Public Holidays: No service
- The DCG laboratory does **NOT** provide an on-call service.

5.4. LOCATION

- The Department of Clinical Genetics is based in Children's Health Ireland at Crumlin which is located on Cooley Road, Dublin D12 N512.
- Delivery access is via **Gate 5** at the **rear** of the hospital on Errigal Gardens or through the main hospital.
- There is **NO** patient access to the Department via Gate 5. Patient access is via main hospital entrance.
- For information on travelling to CHI at Crumlin, see website https://www.childrenshealthireland.ie/your-hospital-visit/our-locations/chi-at-crumlin/



Map of the CHI at Crumlin site. Clinical Genetics shown in orange.

5.5. SAMPLE COLLECTION GUIDELINES

- There are no special requirements or preparation of the patient prior to taking blood samples for genetic tests. Fasting is not required.
- Once samples have been collected, do not freeze or expose the samples to excessive heat (>40°C).
- Do not place the sample in direct sunlight.
- If your patient has recently had a blood transfusion or bone marrow transplant, please refer to the Transfusion and Transplant section for guidance (see section 5.8).
- Please ensure samples are received by the laboratory in a timely manner.
- Please refer to the individual test in the "Clinical Genetics Tests" section of the Lab App for more information on sample requirements and acceptance criteria.
- Ensure all sample collection containers are within their expiry date, using out of date tubes may compromise the patient result.

- In the interest of patient safety and ensuring a genetic result is not compromised, please do not send blood samples to the DCG laboratory that have been previously processed/analysed on another instrument. Such samples will not be processed by the DCG laboratory.
- If there is a requirement to separate/divide a sample, please contact the DCG laboratory for guidance.

Sample Types

DNA based testing (sequencing/microarray):

- Use EDTA tubes only (pink or purple top).
- A minimum of 1ml is required for adults, children and neonates (please note: 3-5ml is preferred for children and adults if possible).
- Mix well to avoid clotting.
- Can be stored overnight at 4°C if required.

Blood samples for constitutional karyotype/FISH (culture):

- Use lithium heparin tubes only (orange or green top).
- A minimum of 1ml is required for neonates, children and adults (please note: 3-5ml is preferred for children and adults if possible).
- Mix well to avoid clotting.
- Due to the culture requirement, lithium heparin bloods must be received by the DCG laboratory within 48 hours of venepuncture.
- Can be stored overnight at 4°C if required.

Blood samples for haematology/oncology testing:

- For karyotype/FISH ~5ml blood should be taken in lithium heparin.

Bone marrow samples for karyotype/FISH:

- Bone marrow aspirates (~5ml) should be taken into RPMI/heparin medium.
- Sample should be sent to the laboratory within 24 hours of being taken, to arrive at the laboratory between 9:30am and 5pm Monday to Friday.
- The samples may be refrigerated overnight (4°C) if necessary.
- Please note that samples with a cell concentration of $<1x10^6$/ml and heavily blood stained aspirates are less likely to yield a reportable result.

Skin biopsy for fibroblast cell culture:

- Skin biopsy for fibroblast culture can only be processed by prior arrangement with the laboratory.
- Skin biopsies should be taken into tissue transport medium available from the Cytogenetics division prior to the procedure.
- Samples may also be collected in sterile saline.
- Sample should be sent to the laboratory as soon as possible following sampling, to arrive at the laboratory between 9:30am and 5pm Monday to Thursday, and between 9:30am and 3pm Friday.

- May be refrigerated overnight (4°C) if necessary.
- Fibroblasts are not stored in the laboratory, DNA may be extracted from the fibroblast and stored in the DCG laboratory if there is consent to do so.

Solid tissue:

- Only accepted by prior arrangement. Please contact the laboratory to confirm acceptance and appropriate sampling/transport requirements.

5.6. REQUESTING A GENETIC TEST

Genetic tests are usually only carried out once in an individual's life, placing a special emphasis on ensuring that the correct genetic test results go to the correct patient. Accurate patient and sample identification are crucial first steps in achieving this objective.

In order to ensure that the correct analysis is performed on the correct patient sample, and to avoid reporting results incorrectly, samples must conform to the criteria given below.

- A fully completed request form must accompany each sample. The most recent version of the DCG request form (MF-LAB-DCGRequest) can be obtained:
  - Via the CHI website, (https://media.childrenshealthireland.ie/documents/consent-form-for-genetic-anylsis.pdf)
  - By contacting the laboratory
  - Via the LabApp (on the Lab App please refer to the form titled 'GENETICS – DCG Request for Genetic Analysis' in files tab on mobile version or Files2Download on desk top version).
- The consent section of the DCG request form must be completed as per information in section 5.7.
- A minimum of two items of unequivocal identifying information must be provided for the patient on both the request form and sample tube, e.g. patient full name, date of birth, and/or MRN.

  NOTE: For referral of a baby, where the baby's first name is not present on both the request form and sample tube (i.e. indicated as Baby, Infant, Baby of Mary, Mary's baby, Twin one or no first name provided), the surname, date of birth and MRN must be provided on both the request form and sample tube. Pathology numbers are not considered a unique identifier.

- **Appendix 1 provides guidance on how to complete the DCG request form.**
- The patient identifiers on the request form and sample tube(s) MUST match.
- All patient identifiers on the request form and the sample tube MUST be clear and legible.
- The clinical diagnosis and test required/clinical indication must be provided on the request form.
- The name and contact details of the referring consultant to whom the report should be sent MUST be provided. If additional copy holder(s) are required, this must be clearly stated on the request form.
  NOTE: the DCG laboratory can only issue reports to the referring clinicians clearly stated on the request form.
- Samples must be submitted in the appropriate sample receptacle (see MP-LAB-TestScope or 'Clinical Genetics Tests' section on the LabApp).
- The date and time the sample was taken should be recorded on the request form.

- Samples which present an identified infection hazard (e.g. HIV, Hepatitis B, vCJD) must be clearly identified and submitted in accordance with established protocols. Please read our High-Risk Sample Guidelines for details.
- If a result is required urgently, this must be clearly detailed on the DCG request form.
- Verbal requests for testing are not accepted, all requests must be in writing using the DCG request form.
  NOTE: It is the responsibility of the referring Clinician to ensure all relevant details (e.g. phenotype, previous results and/or family history) required for accurate testing are included on or with the genetic request form.

5.7. CONSENT

The Department of Clinical Genetics laboratory requires informed consent in order to comply with section 71 (2) (b) of the Irish Data Protection Act 2018, enacted to adopt the EU General Data Protection Regulation (GDPR) into Irish law. Please also refer to Article 9 'Processing of Special Categories of Personal Data' in the GDPR. Consent for genetic testing is also a requirement of Children's Health Ireland.

Consent is incorporated into the DCG request form. Below are general guidelines for completing the consent section of the DCG laboratory request form. Please also refer to Appendix 1.

- Informed consent for genetic testing may only be obtained by a hospital Consultant (any speciality), Specialist Registrar (in Genetics) or Genetic Counsellor. A legible signature MUST also be provided. The inclusion of a Medical Council Registration number is recommended, however, it is not mandatory.
- The consent section MUST be signed by the patient, parent or guardian
- The consent for genetic testing (consent statement 1 on the request form) MUST be selected as "YES" or the sample will not be processed
- If the other consent statements are not answered it will be assumed that consent was NOT obtained for these purposes
- A person has the right to amend their consent at any time, including choosing not to go through with the genetic test. This is achieved by contacting their healthcare provider who in turn will notify the laboratory in writing of the change. A patient, parent or guardian must not contact the laboratory directly.

The DCG request form contains the following consent statements:

I consent to be tested for the genetic test(s) and understand the implications of the test

This statement relates to consenting to the requested genetic test. The individual obtaining consent must ensure the patient (or guardian) understands the nature, limitation(s) and consequences of the test. Further information on each test and limitations is described under the relevant test in the Clinical Genetics Test Section of the Lab App.

<u>This consent statement MUST be answered "YES" for testing to proceed. If "YES" is not selected the sample will be rejected.</u>

I consent for the DNA from this sample to be stored

This statement relates to long-term storage of the patient's DNA sample (i.e. for DNA to be stored in the Department of Clinical Genetics indefinitely or until the patient removes consent for storage). The

benefit of storing DNA is that it can be used for further genetic testing if required and a repeat blood sample is not required from the patient.

NOTE: stored DNA will only be used for purposes for which consent has been obtained. There is no obligation to provide consent for DNA storage; however, without consent the DNA sample will be discarded.

I consent for this sample to be used for quality assurance and audit purposes

This statement relates to the use of the patient sample in quality assurance process and/or audits. Quality assurance and audits are an integral part of the quality management system of any diagnostic laboratory and are frequently used to introduce new technology and/or improve testing methods. The use of patient samples greatly improves the data generated from quality assurance testing and audits. **NOTE:** the patient sample will never be compromised if/when it is used for quality assurance testing. There is no obligation to provide consent for the use of patient sample for quality assurance and audit purposes.

I consent for the results of this test to be available to assist in testing other family members

This statement relates to the use of the patient results in assisting the testing of family members. For example, the patient's genetic result/sample may be used to establish the most appropriate genetic testing for other family members in order to determine their genetic risk. In certain circumstances, the inability to use patient results/sample in testing family members may result in the inability to offer and appropriate test and/or delayed testing of other family members. There is no obligation to provide consent for this statement.

5.8. TRANSFUSION AND TRANSPLANT

It is imperative to record the details of transfusions & transplants including number of days since the event.

Genetic tests are designed to look at the constitutional genetic makeup of a patient by studying their DNA or chromosomes from lymphocytes. If you send us a blood sample from a patient who has recently had a blood transfusion or bone marrow transplant, the result may be compromised because we are studying the lymphocytes of the donor and not the patient.

If your patient has recently had a blood transfusion:

- Please indicate the date of any recent transfusion on the request form.
- If possible, wait at least two weeks before taking a blood sample from a patient who has had a blood transfusion. If not possible you may send an unused portion of the transfusion pack with the patient sample.
- Alternatively, check with your pathology laboratory in case there is a pre-transplant sample stored.
- We may request a second sample type to confirm our results.

If your patient has had a bone marrow/stem cell transplant, please contact the laboratory for advice.

5.9. SAMPLE ACCEPTANCE AND REJECTION CRITERIA

Laboratory Criteria for Specimen Acceptance

Samples and request forms must conform to the criteria detailed in section 5.5, 5.6, 5.7, and 5.8 of this document. Trained, competent and authorised laboratory personnel will evaluate the specimens/forms to ensure compliance with acceptability criteria relevant for the requested examination(s).

It is the responsibility of the requesting clinician and person collecting patient specimens to ensure the criteria in section 5.5, 5.6, 5.7 and 5.8 are adhered to. Requests that do not conform to the acceptance criteria will not be accepted for testing.

Laboratory Criteria for Rejection of Samples

Samples that do not conform to the acceptance criteria will be rejected and will not be processed by the laboratory. A record of the specimen will be made in the relevant Laboratory Information System and the reason for its rejection noted. A report/letter will be sent to the requesting clinician detailing the reason for rejection.

NOTE: For urgent referrals (e.g. pregnancy-related, urgent neonatal), the requesting clinician or their team will additionally be notified by phone call or email from the DCG laboratory.

Reasons for Rejecting a Specimen may include (not exhaustive)

- Specimen received unlabelled
- Specimen incorrectly labelled
- Request form illegible
- Specimen label illegible
- The consent section of the request form is not adequately completed
- Request is not made by a Consultant, Specialist Registrar in Genetics or a Genetic Counsellor
- Incorrect patient or sample identification:
  - Specimen and form do not contain the required minimum identifiers
  - Specimen and form do not contain the same identifiers
- Specimen that has leaked extensively
- Incorrect type of specimen for test request
- Insufficient volume of specimen for test requested
- Specimen extensively clotted
- Sample instability, too old for analysis due to delay in transport, etc.
- Insufficient information received to proceed with testing
- Inappropriate container(s)
- Incorrect storage or handling temperature
- No Service Level Agreement in place with the referring hospital
- Test requested not within the services provided by the DCG laboratory

Exceptions to Rejecting a Specimen

In exceptional circumstances, the laboratory may consider a deviation from some of the above acceptance criteria (e.g. labelling errors or inadequate consent). Exceptional circumstances may be if the sample is deemed non-recollectable (e.g. deceased patient or precious samples such as those samples obtained under surgical procedures).

In the case of labelling errors, a deviation from policy form (MF-LAB-Deviation) is required to be completed by the requester. All deviations are reviewed by a Senior Clinical Scientist (or above) to ensure there is sufficient evidence to verify the correct identity of the patient for testing. The final report will indicate the nature of the deviation and a copy of the completed deviation form will be attached to the report.

5.10. REQUESTING ADDITIONAL TESTING ON SAMPLES STORED IN THE DCG LABORATORY

- The ability to request additional tests on a sample stored in the DCG laboratory is dependent on the original sample type as some stored material is more stable than others. E.g. Stored DNA is stable for long periods but fixed cells for chromosome analysis deteriorate after 3 months. Please refer to MP-LAB-ClinMat for sample retention times.
- Please contact the laboratory for information and advice on requesting additional tests.
- Please note: verbal requests for additional testing are not accepted, all requests must be in writing using the DCG request form.

5.11. PACKING AND TRANSPORT REQUIREMENTS

All packing and transport should adhere to the HSE National Guidelines for the Preparation for Transport of Patient Specimens and other Biological Materials. (See https://assets.hse.ie/media/documents/ncr/Guidelines_for_the_Preparation_for_Transport_of_Patient_Specimens_and_othe_uUk13xH.pdf)

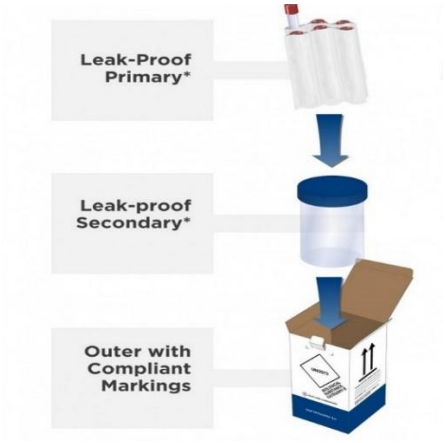
Packaging

The sample and referral form should be sealed separately in a biohazard bag to prevent contamination of paperwork in the event of leakage.

Blood samples should be packaged according to UN3373 standards. (See https://www.un3373.com/category-biological-substances/category-b/)

Briefly:

- The packaging must be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport.
- Packaging must be constructed and closed to prevent any loss of contents that might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity or pressure.
- The packaging must consist of three components:
  a) a primary receptacle(s);
  b) a secondary packaging; and
  c) a rigid outer packaging.
- Primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packaging must be secured in outer packaging with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.



High risk samples must be clearly labelled and all packaging must conform to PI620. Please refer to section 3.0 of the HSEs *Guidelines for the Preparation for Transport of Patient Specimens* (https://assets.hse.ie/media/documents/ncr/Guidelines_for_the_Preparation_for_Transport_of_Patient_Specimens_and_othe_uUk13xH.pdf)

Transport and Delivery

- Samples should be sent to the laboratory as soon as possible.
- Please avoid samples arriving at weekends or public holidays; samples arriving during this time may be compromised and no result possible as staff are not present in the laboratory to receive and process the samples.
- Samples may be delivered by hospital porter, by hand, by external post, and by courier. All deliveries should be handed directly to sample reception of the DCG laboratory.
  NOTE: The DCG laboratory only assumes responsibilities for samples once received by the DCG sample reception.

5.12. REPORTS

- Reports are issued as paper copies (by post) for each sample received.
- Reports are only issued to the Clinicians/departments listed on the request form.
  Note: Reports may also be issued to Departments/individuals where there is a prior arrangement that a copy of the report is issued to them e.g. an array report will go to the pathology lab for billing reason, even if the lab isn't referenced on the report.
- Target and current turnaround times can be found on the Lab App.
- The DCG laboratory retains a copy of all reports.
- Amended/revised reports will be clearly marked.
- Request for copies of reports from Consultants that are not the original requesting clinician can only be issued once there is written evidence the Consultant has taken over care of the patient.
  NOTE: an email sent directly from new Consultant clearly stating they have taken over patient care is sufficient.
- The reports from samples sent to external referral laboratories will be issued directly to the referring Clinician from the referral testing laboratory.
- The laboratory will **never** communicate results or issue reports directly to patients or their family members. It is the responsibility of the requesting clinician to ensure the results and any other relevant information are provided to the patient in a timely manner and that appropriate counselling is provided to their patients.

Note: If patients wish to receive a copy of their report this can be requested via the referring clinician or by following Children's Health Ireland process for healthcare record and personal data requests. For further information on this process please refer to https://www.childrenshealthireland.ie/policies-statements/healthcare-record-personal-data-requests/

- A copy of our reporting policy (MP-LAB-Reporting) is available on request.

5.13. TURNAROUND TIMES

The DCG laboratory aims to report all genomic tests within reporting time guidelines as stated in the 'Clinical Genetics Tests' section of the LabApp. Reporting times will vary depending on the test type and referral type.

Information on current reporting times for all tests can be found in the 'Current Turnaround Times' section of the Lab App.

NOTE: As patient's circumstance is specific to the patient, the DCG laboratory may not have awareness of the clinical urgency of a case or the date by which a report is required. The responsibility is on the referring clinician to advise the DCG laboratory if a report has not been received within a clinically required timeframe.

5.14. CONFIDENTIALITY AND DATA PROTECTION

The DCG laboratory in CHI at Crumlin takes the protection of patient personal information (including results, demographic information etc.) very seriously and is compliant with GDPR and CHI data protection policies. All staff are informed of their responsibilities regarding patient confidentiality. It is mandatory for staff to complete training in GDPR and Cybersecurity on an ongoing basis.

The laboratory policy is described in MP-LAB-Confid which is available on request.

HSE policy and procedure with regards to Data Protection can be obtained through the following link, https://www.hse.ie/eng/gdpr/

5.15. CLINICAL ADVICE

The DCG laboratory are happy to provide advice on any scientific and technical issues. Please contact the laboratory directly by email and telephone.

It is the policy of the laboratory to evaluate, maintain and regularly review measurement uncertainty (MU). MU is considered for all assays introduced into the laboratory. Please refer to MP-LAB-MU.

Please contact the laboratory if further information on the measurement uncertainty is required.

There is an on-call Consultant Clinical Geneticist who can provide clinical advice for genetic testing if needed. Please contact the Clinical Genetics Service 01-409 6739 (voicemail checked daily).

5.16. SAMPLE RETENTION AND STORAGE

The DCG laboratory adheres to the HSE policy on the sample and record retention 9(HSE Records Retention Policy) . For further information, please contact the laboratory (please refer to MP-LAB-ControlRecord and MP-LAB-ClinMat).

5.17. QUALITY

Accreditation

The DCG laboratory is accredited to the ISO 15189:2022 standards (Medical Laboratories – Requirements for Quality and Competence). Reg. no.: 417MT.

External Quality Assessment (EQA)

The DCG laboratory participates in the external quality assurance schemes run by:

- The Genomic Quality Assessment (GenQA)
- The European Molecular Genetics Quality Network, EMQN.

Copies of our ISO 15189 certificate is available upon request or via the INAB website. Copies of EQA results are also available on request.

Risk Management

It is our policy to manage risks throughout the laboratory with particular focus on risks to patient care. The laboratory uses risk assessment as a tool to develop actions to address both risks and opportunities for improvement. This approach involves proactively identifying risks that threaten the achievement of objectives and patient safety, e.g., the delivery of high-quality safe care, accuracy of results and compliance with legal and regulatory requirements. A copy of risk management policy is available on request (MP-LAB-Risk).

Risk communication is the sharing of information about residual risk and risk management between the risk owners/decision makers and other personnel and laboratory users. Users will be notified if residual risk cannot be controlled at an acceptable level.

For questions/queries relating to risk management or residual risk ratings within the DCG laboratory, please contact the Quality Manager at julie.egan@childrenshealthireland.ie

For more information please contact the DCG Laboratory Quality Manager, Julie Egan (julie.egan@childrenshealthireland.ie).

5.18. IN-HOUSE TESTS

All in-house tests provided by the DCG laboratory are detailed in the 'Clinical Genetics Tests' section of the Lab App. This information is as per MP-LAB-TestScope.

5.19. REFERRAL LABORATORIES

- The laboratory of the Department of Clinical Genetics at CHI at Crumlin provides a service for genetic tests (germline) that are not available in-house. Referral to external testing laboratories occurs in cases where there is a request for:
    - Provision of a genetic tests not available in the DCG laboratory.

- Backup service in the event of an unplanned interruption of the DCG service.

NOTE: As a patient's circumstance is specific to the patient, the DCG laboratory may not have awareness of the clinical urgency of a case or the date by which a report is required. The responsibility is on the referring clinician to advise the DCG laboratory if a report has not been received within a clinically required timeframe.

- Please refer to MP-LAB-TestScope for further information on the referral service provided by the DCG laboratory. This information is also provided in 'Clinical Genetics Test Referred Out' section of the LabApp.

5.20. QUERIES/FEEDBACK & COMPLAINTS PROCEDURE

- The Department of Clinical Genetics welcomes all constructive feedback – Feedback should be directed to the Department of Clinical Genetics Quality Manager, Julie Egan (Julie.Egan@childrenshealthireland.ie) and the Laboratory Manager (Jennifer.McDaid@childrenshealthireland.ie).
- The laboratory User Feedback Form is available for download on the LabApp in the Files tab (mobile version) or via Files2Download (desktop version).
- The laboratory has a policy relating to the management of complaints and compliments (MP-LAB-COMP&CMENT) which is available upon request.

Postal address for feedback:

Julie Egan,

Quality Manager,

Department of Clinical Genetics,

Children's Health Ireland (CHI) at Crumlin

Dublin D12 H938

For patient complaints please visit:

https://www.childrenshealthireland.ie/contact-us/feedback-complaints/

6.0 DEFINITION(S)

Term	Definition
N/A	

7.0 DOCUMENT REFERENCE(S)

7.1. Internal Document Reference(s)

Document No.	Title
MF-LAB-DCGRequest	DCG Request Form for Genetic Analysis

Document No.	Title
MP-LAB-TestScope	DCG Laboratory Testing Scope
MP-LAB-Reporting	Laboratory Reporting
MP-LAB-COMP&CMENT	Management of Complaints and Compliments
MP-LAB-Confid	Confidentiality, Impartiality and Ethics
MP-LAB-ClinMat	Control of Clinical Material (Storage, Retention and Disposal)
MP-LAB-ControlRecord	Control of Records
MP-LAB-SLA	Service Level Agreements
MP-LAB-Labelling	Labelling Requirements for Genetic Testing
MF-LAB-Deviation	Deviation from Labelling Policy Form
MP-LAB-MU	Measurement Uncertainty (MU)

7.2. External Document Reference(s)

Document No.	Title
N/A	HSE National Guidelines for the Preparation for Transport of Patient Specimens and other Biological Materials
N/A	HSE Records Retention Policy
N/A	UN3373 Standards
N/A	HSE Data Protection Policy

8.0 REVISION HISTORY

Version No.	Description
2.0	• Section 2.2.1 removed referenced to MOU • In section 5.1 removed the sentence '*A signed agreement must be in place prior to any sample being submitted and there will be a charge for these tests'* • In section 5.5 added 'avoid direct sunlight' • In section 5.5 updated all start times to 9:30. • To section 5.6 added a NOTE re: referring clinician's responsibility to provide all required information. • Section 5.9 change bullet point 'Test requested not in the scope of the DCG' to 'service not provided by DCG' • Section 5.11 next to high risk samples added reference to Section 3.0 of HSEs Guidelines for the Preparation fro Transport pf Patient Specimens and provided link. • Section 5.12 updated as per CR9934 and CR9974 (relating to copies of reports) • Section 5.13 added reference to 'Clinical Genetics Test' in LabApp in place of 'test directory' (CR10119). • Section 5.13 added 'NOTE' re clinical urgency from section 5.19. • Section 5.15 updated as per CR 9973 – reference to measurement uncertainty. MP-LAB-MU added to section 7.1 • Section 5.16 Provided the link to the HSEs recent version (2024) Record Retention Policy. • Updated section 5.17 with details of accreditation status and Reg. No. (CR10120)

Version No.	Description
	• Section 5.17 added section on risk management • Section 5.19 removed bullet points 2-5. • Minor formatting updates throughout the document
1.0	• New document incorporating policy and guidelines from MP-LAB-Consent, MP-LAB-DCGRequestFormAccept and MP-LAB-Labelling and the LabApp

9.0 APPENDIX

Appendix No.	Title
1	Guidance on Completing the DCG Request Form

APPENDIX 1: GUIDANCE ON COMPLETING THE DCG REQUEST FORM