



Singapore
Accreditation
Council

ACCREDITATION SCHEME FOR LABORATORIES

Technical Notes MED 002
Specific Criteria for Cytogenetics
Section

Technical Notes MED 002 - Cytogenetics, 29 March 2019
The SAC Accreditation Programme is managed by Enterprise Singapore

© All rights reserved

1. Introduction & Scope

- 1.1 a) This document describes the specific requirements to be complied by cytogenetics section to be accredited.
- b) The International Standard 'ISO 15189 Medical laboratories – Particular requirements for quality and competence', other MEDICAL Series Technical Notes published by SAC-SINGLAS shall be studied in conjunction with this document.

2. General Technical Note : Medical 001

2.1 Please refer **General Technical Note: Medical - 001** for the following:

- Personnel
- Accommodation & Environmental Conditions
 - Physical Facilities and Laboratory Safety
- Laboratory Equipment – Calibration & Maintenance
- Pre-examination Procedures
 - Requisitions, Collection and Handling of Specimens
- Examination Procedures
 - Test Methods and Method Validation
- Assuring Quality of Examination Procedures
 - Quality Control, Proficiency Testing, Reagents and Reference Materials
- Post-examination Procedures
 - Retained Samples and Waste Disposal
- Reporting of Results

3. Personnel

3.1 Refer to Personnel in **General Technical Note: Medical - 001**. . In addition to that the following is applicable to cytogenetics laboratory.

3.2 A Cytogeneticist with a minimum of four years' experience and specialized training shall direct laboratories that provide Cytogenetics services.

He/She should preferably be a member of an appropriate body such as the American Board of Medical Genetics, the Royal College of Pathologists of United Kingdom and Australasia, the Human Genetics Society of Australasia, or other relevant certified body as specified by SAC-SINGLAS, and must also be capable of acting as the technical supervisor responsible for the technical performance of the laboratory.

3.3 The technical work of the laboratory shall be performed by technologists

qualified to first degree or diploma level in a relevant subject and work under the supervision of the director or technical supervisor. Preferably at least one technologist should be, or undergoing training to be, certified as described above.

- 3.4 All personnel should undergo continuous assessment and training and this will ultimately be the responsibility of the cytogeneticist.

4. Accommodation and Environmental Conditions

- 4.1 Refer to Accommodation & Environmental Conditions - Physical Facilities and Laboratory Safety in **General Technical Note: Medical - 001**.

5. Laboratory Equipment

- 5.1 Refer to Laboratory Equipment in **General Technical Note: Medical – 001**. In addition to that the following is applicable to cytogenetics laboratory.
- 5.2 All instruments must be routinely maintained and schedules for this are available. They must also be of an adequate standard to match the job being performed. This will include e.g. microscopes of sufficient quality and age to be capable of defining a band level of 550 or above.

6. Pre-examination Procedures

- 6.1 Refer to Pre-examination Procedures in **General Technical Note: Medical – 001**. In addition to that the following is applicable to cytogenetics laboratory.

6.2 Sample Collection, Sample Transport & Sample Receipt

- 6.2.1 Fresh samples should arrive at the laboratory as soon as possible and not frozen.
- 6.2.2 Prenatal specimens should also include the Gestational age.

7. Examination Procedures

- 7.1 Refer to Examination Procedures in **General Technical Note: Medical - 001**. . In addition to that the following is applicable to cytogenetics laboratory.
- 7.2 The services provided by a Cytogenetic laboratory would aim to include both short and long term cultures with all currently used techniques appropriate to the specimen referred. The procedures used should conform to internationally recognized standards and guidelines.
- 7.3 All long-term cultures should be spilt between two incubators. Duplicate flasks should be harvested independently.

- 7.4 Where mosaicism is investigated, 30 cells or more must be counted and if in amniotic fluid / chorionic villi then between at least two flasks. Fragile - X analysis requires 75 and 50 cells examined for females and males respectively. A recommendation to the clinician for molecular testing should be considered where appropriate.
- 7.5 The minimum number of banded cells analysed is 2 for all types of tissue except bone marrow where it is 10. Ten cells counted are the minimum if mosaicism is not an issue.
- 7.6 FISH analyses should be documented by means of photographic or digitized images. All FISH analyses will include appropriate controls and an interpretation, together with declarations on the type, limitations and source of probe used.
- 8. Assuring Quality of Examination Procedures – Quality Control and Proficiency Testing**
- 8.1 Refer to Assuring Quality of Examination Procedures - Quality Control, Proficiency Testing, Reagents and Reference Materials in **General Technical Note: Medical - 001**.
- 9. Post-examination Procedures**
- 9.1 Refer to Post-examination Procedures - Retained Samples and Waste Disposal in **General Technical Note: Medical - 001**.
- 10. Reporting of Results**
- 10.1 Refer to Reporting of Results in **General Technical Note: Medical - 001**. In addition to that the following is applicable to cytogenetics laboratory.
- 10.2 The final report of all cases should be kept as a permanent record by the laboratory. Microscope slides of abnormal cases should be kept for 5 years and normal cases for 2 years. Analysis records should be kept for 5 years.
- 10.3 The laboratory should establish critical limits so that notification can be made expeditiously to whoever is ultimately responsible for patient care. All staff must be aware of these limits.
- 10.4 Reporting should be in the form of the International System for Human Cytogenetic Nomenclature. It must include all preliminary verbal results together with the final summary and interpretation.