ACCREDITATION SCHEME FOR LABORATORIES

Technical Notes MED 002

Specific Criteria for Cytogenetics Section

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1. Introduction & Scope

1.1 This document describes the specific requirements to be complied by cytogenetics section to be accredited.

1.2 The document shall be read in conjunction with ISO 15189 Medical laboratories – Requirements for quality and competence', SAC-SINGLAS documents, Proficiency Testing Technical Note 001, and other MEDICAL Series Technical Notes published by SAC-SINGLAS.

2. Personnel

2.1 Refer to Personnel in **General Criteria for Medical Testing Laboratories Technical Note MED 001**. In addition to that the following is applicable to cytogenetics laboratory.

2.2 Director/ Laboratory Supervisor :

(a) The Director/ Laboratory Supervisor of a cytogenetics laboratory should be a senior physician or a senior scientist with appropriate qualifications.

(b) He/ She should have with a minimum of four years' experience and specialized training shall direct laboratories that provide Cytogenetics services.

(c) 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.

2.3 The technical supervisor shall be a technologist qualified to first degree or diploma level in a relevant subject with a minimium of three years of experience in clinical cytogenetics under a qualified director.

2.4 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.

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

2.5 The laboratory is recommended to process not less than a total of 500 samples and not less than 30 samples per test in a year to ensure and maintain staff competency.

3. Laboratory Equipment

3.1 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.

4. Pre-examination Procedures

4.1 Sample Collection, Transport, Receipt and Handling

4.1.1 Fresh samples should arrive at the laboratory as soon as possible and not frozen.

4.1.2 All unprocessed cultures must be kept for at least two days after a final result is issued or validated to enable follow-up studies and verification of specimen identity, if necessary.

4.1.3 Prenatal specimens should also include the Gestational age.

5. Examination Procedures

5.1 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. Duplicate or independently established cultures are prepared for all specimen types, whenever possible.

5.2 All long-term cultures should be spilt between two incubators with independent electrical power supply or emergency power supply, independent gas sources and alarms.

5.3 Duplicate or independently established cultures are recommended for all specimen types, when adequate specimen is available.

5.4 Duplicate cultures should be harvested independently. For prenatal samples (amniotic fluid and chorionic villus samples), cultures from the same patient shall not be harvested in the same batch.

5.5 All chorionic villus studies shall be included in the analysis of long-term cultures.

5.6 Chromosome Analysis

5.6.1 In general, routine cytogenetic analysis should consist of a minimum of:

(a) 5 banded cells analysed

(b) 10 cells counted [in addition to (a)].

5.6.2 For prenatal analysis performed on primary colonies and sufficient colonies are available, at least 15 metaphases from at least 10 colonies are counted between at least two cultures. At least five banded metaphases are analysed from two cultures. If there are insufficient colonies or if only one culture is analysed, then a comment to this effect should be made in the report.

5.6.3 Fragile X testing must be carried out by molecular methods rather than cytogenetic methods.

5.6.4 For neoplastic samples (e.g. bone marrow, unstimulated blood or solid tumour), at least 20 metaphases are analysed, if possible.

5.6.5 Two of the fully analysed metaphases should be archived as images.

5.6.6 A minimum of 550-band level resolution is recommended for peripheral blood studies when evaluating patients for intellectual disabilities, dysmorphic features, or birth defects.

5.7 FISH Analysis

5.7.1 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.

5.7.2 For FISH analysis, sufficient numbers of metaphases, interphases or nuclei from cultured or uncultured cells must be analysed to ensure the statistical validity of the result. Signals must be scored by two independent analysts.

5.7.3 When used as the first line of analysis, the following minimum levels apply:

(a) For locus-specific probes, 10 cells should be scored to confirm or exclude an abnormality.

(b) For prenatal interphase screening for aneuploidy, signals should be counted in a minimum of 50 cells for each probe.

(c) For interphase screening for mosaicism or malignant clones, a minimum of 60- 200 cells should be scored, according to international guidelines.

5.8 Microarray Analysis

5.8.1 Microarray technology needs to be validated prior to incorporating Microarray into diagnostic service.

5.8.2 The quality of critical assay component is reviewed and verified in each assay run.

5.8.3 The laboratory should set the number of clones/probes to define an abnormal threshold for microarray genomic copy number assessment.

6.0 Ensuring the Validity of Examination Results

6.1 Success Rates

Laboratory should audit and document their success rates for types of tissues where a diagnostic service is provided. The success rates for various tissue should be achieved annually as below:

(a)	amniotic fluid Specimens	99%
(b)	chorionic villi Specimens	98%
(c)	peripheral blood Specimens	98%
(d)	bone marrow Specimens	85%

7. Reporting of Results

7.1 The chromosome constitution should be reported using the most recent International System for Human Cytogenetic Nomenclature as far as possible. It must include all preliminary verbal results together with the final summary and interpretation.

7.2 FISH report should include the probe name and source. Any limitation of the probe should also be addressed in the report.

7.3 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.

7.4 Laboratory should produce 90% of the results within the times indicated:

(a)	Lymphocyte analysis	28 days
(b)	Bone marrow and tumour analysis	21 days
(c)	Amniotic fluid and Chorionic Villus analysis	15 days

7.5 The Microarray report should include the platform used, genome build used, methods and resolution.

8. Clinical Records and Storage

8.1 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.

8.2 For chromosome analysis, two representative banded metaphases must be stored, either as slides, photographic negatives or digitized images over the required period.

8.3 For FISH analysis, at least one representative FISH image must be stored, either as photographic negatives or digitized images over the required period.

8.4 For Microarray analysis, the experimental condition of the assay, image analysis file and data interpretation files must be stored digitally over the required period.