



MOSTI

**STANDARDS**  
MALAYSIA

**SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)**  
*LABORATORY ACCREDITATION SCHEME OF MALAYSIA*

**STR 2.7 - SPECIFIC TECHNICAL REQUIREMENTS  
FOR ACCREDITATION OF  
ASSISTED REPRODUCTIVE TECHNOLOGY (ART)  
LABORATORIES**

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**MS ISO 15189**

**JABATAN STANDARD MALAYSIA**  
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## **STR 2.7 – SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF ART LABORATORY**

### **1 Introduction**

- a) This document describes the minimum specific technical requirements to be complied by any ART laboratory that wishes to be accredited by STANDARDS MALAYSIA. The minimum number of ART cycles performed by any laboratory seeking accreditation shall be 50 per calendar year.
- b) This document shall be read in conjunction with MS ISO 15189 Medical Laboratories – *Particular Requirements for Quality and Competence* and other specific criteria documents published by STANDARDS MALAYSIA.

### **2. Scope of accreditation**

The areas for which the accreditation may be offered are listed below:

- i. Semen Analysis (recognized standards e.g. WHO)
- ii. Sperm preparation  
(Fresh sample/frozen sample/MESA/PESA/TESA/Open Biopsy)\*
- iii. Sperm cryopreservation
- iv. In Vitro Fertilization (IVF)
- v. Gamete Intra Fallopian Transfer (GIFT)
- vi. Intra Cytoplasmic Sperm Injection (ICSI)
- vii. Assisted Hatching
- viii. Oocyte/Embryo/blastocyst cryopreservation

\* Micro Epididymal Sperm Aspiration (MESA)  
Percutaneous Epididymal Sperm Aspiration (PESA)  
Testicular Sperm Aspiration (TESA)

### **3. Terms and definitions**

- 3.1 Laboratory director is the person-in-charge of the laboratory who will be responsible for all operations, administration (including the performance of technical procedures) and recording of test results and for ensuring compliance with applicable regulations. This post shall be a full time resident position.
- 3.2 Clinician in attendance is the authorized doctor (see Clause 5.1.3) who is in overall charge of the patient's fertility treatment.
- 3.3 Embryologist is the qualified technical person (see Clause 5.1.4) who performs the relevant laboratory procedures for Assisted Reproductive Technology (ART) as stated in Clause 2.

### **4. Management requirements**

As in MS ISO 15189

## **5. Technical requirements**

### **5.1 Personnel (clause 5.1 of MS ISO 15189)**

- 5.1.1 The laboratory director shall have a minimum qualification of Bachelor of Science Degree in a related Biomedical field recognised by the Government of Malaysia with at least two years of post qualification supervised training and a minimum of 100 complete hands on cycles of IVF/ICSI (either as part of the degree programme or as post-degree training).
- 5.1.2 The clinician in attendance shall be a gynaecologist registered with the Malaysian Medical Council with a postgraduate qualification in O & G recognised by the Government of Malaysia and at least two years of post specialist experience in infertility and accredited by the Lembaga Akreditasi (O& G), Ministry of Health Malaysia.
- 5.1.3 The embryologist shall have a minimum qualification of Bachelor of Science Degree in a related Biomedical field recognised by the Government of Malaysia with at least one year of post qualification supervised training and a minimum of 50 complete hands on cycles of IVF/ICSI (either as part of the degree programme or as post-degree training).
- 5.1.4 A medical laboratory technologist shall be a person with at least a Diploma in Medical Laboratory Technology or an equivalent, recognised by the Government of Malaysia and at least 6 months of supervised training in related area of the laboratory services (either as part of the diploma programme or as post-diploma training).

### **5.2 Accommodation and environmental conditions**

As in MS ISO 15189 Clause 5.2.1 in addition:

- The laboratory should be in a low-traffic, secure area separated from other general laboratory activities and operating theatre.
- Minimum space requirement for this laboratory is 100 square feet.
- Design and materials used in construction should be compatible with a high level of cleaning and disinfection.
- Use of toxic chemicals, radioisotopes, aerosol and pest control substances shall not be permitted in the laboratory.
- Use of strong smelling personal hygiene products eg perfume, deodorant, hair spray, after shave lotion etc shall not be permitted in the confines of the laboratory.

- Foodstuff shall not be permitted in the laboratory area.
- Incoming air should be ducted via a split unit ceiling mounted air conditioning system. The air should be at least HEPA filtered to remove particulate matter.
- If the laboratory and operating theater are not adjacent to each other, appropriate measures should be in place for maintenance of gamete/embryo temperature and pH during transport.

A separate area should be provided for record keeping, data entry, computer data storage and related administrative functions.

### **5.3 Laboratory equipment**

#### Basic Equipment

1. Incubator(s) shall have emergency power back-up and preferably alarm systems. The alarm system should monitor power failure and both high and low deviations from set points for temperature and percentage of CO<sub>2</sub> where applicable. Provision shall be made to access a back-up incubator should the main incubator malfunction.
2. Microscopes should be appropriate to the procedure for which they are used.
3. Appropriate warming devices and mechanisms shall be in place to ensure proper maintenance of temperature and pH of media, gametes and embryos during the various phases of all procedures.
4. Where in-house media preparation is practiced there shall be access to a pH meter and osmometer for media adjustment to defined standards using appropriate calibration. All laboratory chemicals and reagents shall be labeled to indicate date received, date opened and shelf life where applicable.
5. All equipment encountering body fluids shall be disposable and tissue culture grade plastic.
6. Gas cylinders should be placed outside or in a separate room with a backup system. Gas supplies to incubators must be of a suitable quality with mechanisms in place to ensure continuity of supply. Certificate of purity shall be available at all times.
7. Gamete and embryo manipulation shall be done in laminar flow work station.
8. Procedures shall be in place such that treatment outcome will be minimally compromised in the event of malfunction of essential equipment or non-availability of key personnel.

## **5.4 Pre-examination procedures**

### **5.4.1 Preparation of patients**

A consent form shall be signed by the patient and a copy kept in the patient's record.

A separate consent form is to be signed for cryopreservation procedures. In the case of extra embryos both partners shall give consent for freezing and future use.

Oocyte retrieval should be performed under standard sterile technique as applicable in an operating theatre. Subsequent handling of gametes shall be undertaken using aseptic techniques (e.g. with proper gowning and wearing of mask, glove and theatre cap).

### ***Laboratory Safety and Infection Control***

All patient couples shall be subjected to appropriate infectious disease screening and quarantine to ensure the gametes and embryos are free from infectious diseases. The minimum diseases to be screened for are HIV, Hepatitis B and Syphilis. HIV positive patients are referred to the appropriate medical specialist for further treatment and excluded from further ART treatment. Syphilis carriers are treated with the relevant antibiotic prior to proceeding with ART.

Hepatitis carrier patients shall be listed as the last case and the operating theatre shall subsequently be closed and cleaned using the standard hospital procedure for such cases. The laboratory personnel should handle all gametes from such patients using the standard double-gloving technique in addition to the aseptic techniques. The gametes shall be incubated separately from those of other patients.

## **5.5 Examination procedures**

The quality assurance system should be such as to detect clerical, transcriptional and analytical errors. Identity of gametes and embryos must be double checked at critical steps. Double checking should be indicated by signatures and identifications of the checkers in the records. There shall be adequate documentation to indicate this process.

### **Biosecurity**

To protect the security of gametes, only authorized personnel are allowed to enter the laboratory or storage area. Security measures shall be in place to prevent unauthorized entry.

All containers and storage for gametes shall be properly labeled and recorded. All disposables for handling gametes shall be used only once. All storage containers shall be locked and stored in secure facilities.

## **5.6 Assuring quality of examination procedures**

5.6.1 Incubator performance shall be monitored daily for temperature and gas composition and calibrated at regular intervals.

5.6.2 Water purification systems where applicable shall be maintained to the manufacturer's specifications for tissue-culture quality and performance monitored and recorded on a daily basis. Screening for pyrogens is essential.

5.6.3 In house media where applicable shall be of an accepted preparation method to ensure suitability for use with human gametes or embryos.

5.6.4 Data from the laboratory shall be regularly analysed to determine that the following minimum criteria are achieved:

- fertilisation rate of at least 60% in couples without male factor infertility;
- fertilisation rate of at least 60% following ICSI
- A minimum pregnancy rate of 25% for IVF/ICSI treatment.

## **5.7 Post-examination procedure**

Facilities shall be made available for cryopreservation of remaining viable embryos either in the same laboratory or other associated laboratory.

An established protocol shall be in place for transfer of gametes or embryos from one institution to another.

Safe disposal of tissue samples no longer required shall be carried out in accordance with existing regulations or recommendations for waste management.

### **Ethics**

Confidentiality relating to patient information shall be maintained.

## **5.8 Reporting of Results**

All laboratory issues concerning patients' treatment and the source and fate of all gametes and embryos shall be documented.

All results and reports pertaining to embryology shall be validated by the embryologist.

A summary annual report shall be prepared and made available. In addition to the data generated from clause 4.13 in the MS ISO 15189, the report shall include at least the following specific data:

- number of ART cycles
- fertilization rates

- frozen embryo thaw survival rate
- pregnancy rates from fresh and frozen-thaw cycles
- changes in staffing (laboratory and clinical)
- research projects by the laboratory



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