



european society of human reproduction & embryology

Personnel and their records

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Overview

- ISO requirements
- Personnel Document
- Documents that need to be kept
- Staff
- Training specific to PGD
- Training Log
- Continued Professional Development
- Competency Log
- Annual Appraisals
- Training courses



ISO 15189

- **Section 5.1**
- Documentary evidence
- **5.1.1** Laboratory management shall have an organizational plan, personnel policies and job descriptions that define qualifications and duties for all personnel.
- Sufficient competent personnel to meet the needs of the laboratory
- Personnel documents for each person
- Training and competency log books
- Continued professional development



Personnel Document

- 5.1.1. Describing personnel management
- Professional direction
 - who directs unit and hierarchy
- Outline of staffing of PGD centre
 - Who is employed, in which positions
 - Replacements
 - Recruitment
 - Personnel records (what they are and where they are stored)



Documents that need to be kept

- 5.1.2. Educational and professional qualifications, training and experience, and competence of all personnel
- staff orientation and induction
- job title
- job descriptions
- contracts, terms and conditions
- line management and accountability
- education and continual professional development
- records of absence, accidents, occupational health, disciplinary action
- staff meetings and annual reviews
- Training log book
- Competency log book



Laboratory Director



- **5.1.3** The laboratory shall be directed by a person or persons having executive responsibility and the competence to assume responsibility for the services provided.

- Commonly specified by national professional group



The Royal College of Pathologists
Pathology: the science behind the cure

- In UK – has to be a member of the Royal College of Pathologists

- **5.1.4** The responsibilities of the laboratory director or designees shall include professional, scientific, consultative or advisory organizational, administrative and educational matters. These shall be relevant to the services offered by the laboratory.

- The laboratory director need not perform all responsibilities personally

- But - laboratory director remains responsible for overall operation and administration of laboratory, for ensuring that quality services are provided for patients.



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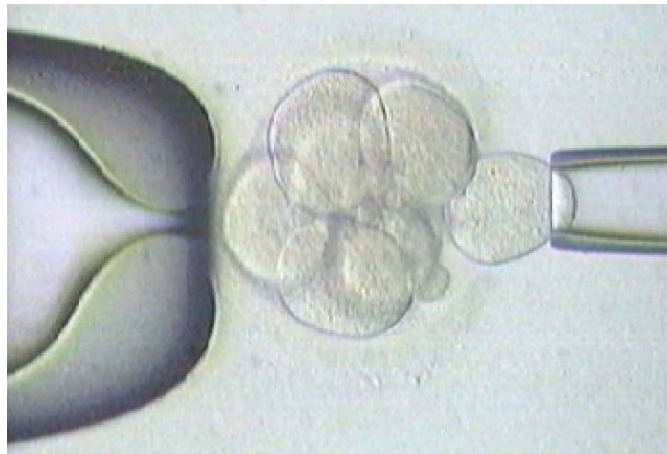
Quality Manager

- Delegated responsibility and authority to oversee compliance with the requirements of the quality management system
- Report directly to laboratory management
- Does not have to be one of PGD team performing diagnosis
- May be better to be an administrator
- Responsible for QMS, planning audits, chairing QM meetings, managing update of documents, etc



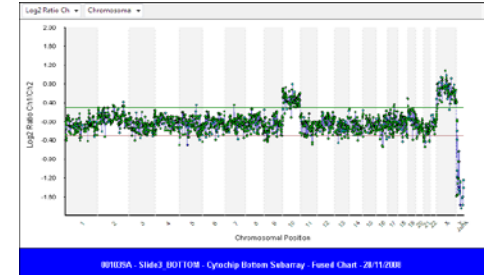
Personnel carrying out biopsy

- Registered clinical embryologist
- Daily working with embryos
- Appropriate training in biopsy
- Needs to perform biopsies regularly
- Need to have thorough knowledge of genetics and PGD



Personnel carrying out PGD

- Needs to be a suitably qualified person
- PCR and arrays – molecular training
- FISH – cytogenetic training
- No recognised training schemes exist for PGD
- In UK – need to be state registered clinical scientist registered with the Association of Clinical Scientists and the Health Professional Council
- Can achieve by portfolio
- UCL Centre for PGD trying to be registered training centre



Training programmes



- **5.1.12** The personnel making professional judgements with reference to examinations shall have the applicable theoretical and practical background as well as recent experience.
- **5.1.6** Personnel shall have training specific to quality assurance and quality management for services offered
- **5.1.13** Confidentiality of information regarding patients shall be maintained by all personnel.
- Needed for all staff: laboratory, management, administrative
- Initial induction and continuous training and competence
- Use of equipment, SOPs, data protection, training in the IVF unit, and health and safety
- Personnel involved in internal audits must have training.

Documentation of training

- Training log
- Competency log
- From a specified date, the person is **competent** to perform the task
- 5.1.7 – formal authorisation of competency signed by trainee, trainer, director
- Competence involves:
 - academic
 - postgraduate
 - continuing education
 - training
 - experience



Training Log

- INTRODUCTION
- OVERVIEW OF TRAINING
- INDUCTION
- WORKING IN THE UCL CENTRE FOR PGD LABORATORIES
 - [PGD REVIEW](#)
 - [MSc LECTURES](#)
- EQUIPMENT USE
 - [TABLE 1 – EQUIPMENT TRAINING LOG](#)
- PROCEDURE TRAINING
 - [TABLE 2 - PROCEDURE TRAINING LOG](#)
- TRAINING RECORDS
- PGD WORKUP ANALYSIS (MOLECULAR/MOLECULAR CYTOGENETICS)
- OBSERVATION PGD CONSULTATION
- IVF UNIT OBSERVATION DAYS
- PGD WORKUP - MOLECULAR GENETICS/CYTOGENETICS
- JOURNAL CLUB PRESENTATIONS
- AUDIT TRAINING YEAR 2



Training Log Year 1

- Induction
- Health and safety induction
- Written PGD Review
- Attendance at MSc lectures
- Equipment training
- Procedure Training
- IT training
- PGD workup analysis
- Observation of PGD consultations
- Two observation days with at the IVF team
- Work up for 3 cases
- Design and optimisation of 1 case
- Observation of 6 cases
- One journal club presentation



Training Log Year 2

- Work up for 6 cases
- Design and optimisation of 3 cases
- Writing of one HFEA application
- Shadowing of 6 cases
- PGD of 2 cases and follow up report
- Audit training
 - One vertical audit
 - One horizontal audit
- Lab and journal club presentations
- Lab supervisor for BSc project
- Submission of abstract to internal and external meetings



Training Log Year 3

- Workup for 10 cases
- Design and optimisation of 6 cases
- Writing of three HFEA applications
- PGD for 10 cases and follow-up report
- Two vertical and two horizontal audits
- Lab and journal club presentations
- Lab supervisor for MSc project
- Submission of abstract to internal and external meetings
- Completion of Portfolio of competencies for submission to the Association of Clinical Scientists
- Completion of EQA



Part of procedure training log

2.6 TABLE 2 Procedure Training Log	SOP number	Date Read	Demo Required	Demo Date	Demon strator	Superviso n required	Supervis ion Dates	Superv isor	Compete ncy test Require d	Test Date	Exa min er	Date of Compe tence	Trai nee Signa ture	Training Officer
Identification of DNA sequence	SOP006		✓			✓			✓					
Primer design	SOP006		✓			✓			✓					
DNA extraction	SOP003, SOP034		✓			✓								
PCR	SOP032		✓			✓			✓					
PCR optimisation	SOP032		✓			✓			✓					
Agarose Gel electrophoresis	SOP004		✓			✓								
Fragment analysis	SOP013		✓			✓			✓					
Single Cell PCR	SOP032		✓			✓			✓					
Sequencing	SOP012		✓			✓								
Use of the single cell room	SOP031		✓			✓								

Molecular PGD work-up analysis

- The following molecular Genetics reports are derived from referrals to our unit. For each case:
- write a summary about the disorder including the incidence, penetrance, mode of inheritance, clinical features, gene(s) involved, chromosomal location(s) and any genotype/ phenotype relationships
- Find the gene sequence
- Identify the reported mutation
- Identify intra and inter - genic short tandem repeat markers flanking the mutation site
- Using the information in the report design a strategy that could be used for PGD
- Design appropriate primers
- Submit the PCR work-up analysis for each case for marking and discussion

Continued professional development

- **5.1.9** There shall be a continuing education programme available to staff at all levels.
- **5.1.11** The competency of each person to perform assigned tasks shall be assessed following training and periodically thereafter.
- Updating of competency
- May need to perform competency tests at regular intervals
- Keep academically and technically updated
- Attend conferences, write papers, training in new techniques, etc



Competency Log

- Academic development
- Presentations and publications
- Supervision
- Research and development
- Responsibilities
- PGD training
- Service quality and management
- Professional development
- Planned future training



Annual appraisal

- All staff need this
- Keep a formal record
- Evaluates effectiveness of training
- What has been achieved since last appraisal?
- Were there obstacles?
- Summary of training and continued development
- Future training



Training courses

- MSc courses
- UCL Centre for PGD run PGD workshops since 1996
- EuroGentest Workshops on Accreditation
- Consortium



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UCL Centre for PGD

