



european society of human reproduction & embryology

Personnel: Competency

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Competency: definitions (1)

- a knowledge, skill or attitude that enables one to effectively perform the activities of a given occupation or function to the standards expected in employment.
- means having the requisite abilities, skills, or a specified level of mastery
- a standardized requirement for an individual to properly perform a specific job. It encompasses a combination of knowledge, skills and behavior utilized to improve performance. More generally, competence is the state or quality of being adequately or well qualified, having the ability to perform a specific role. (Wikipedia)
- describes the work related skills and behaviour needed to effectively perform in a role. Core competencies are required for all role profiles



ISO 15189:2007 Medical laboratories – Particular requirements for quality and competence.

- **5.1 Personnel**
 - **B 1.5** The laboratory director or designee(s) shall have demonstrable **competence** to assume responsibility for the services provided in order to:
 - b) ensure that there are appropriate numbers of staff with the required education, training and **competence** to provide a service that meets the needs and requirements of the users (B2)
- **NOTES**
- 1 **Competence** is demonstrated by academic; postgraduate and continuing education and by evidence of continuing practice and experience that may be demonstrated by successful annual joint review.
- 2 The Laboratory Director would be expected to have Medical Consultant status or equivalent and have **competence** at the level of the Membership of the Royal College of Pathologists or equivalent. Exceptions to this may occur for highly specialised services, but the need for clinical as well as managerial **competence** must be met.



ISO 15189:2007 Medical laboratories – Particular requirements for quality and competence.

• B9 Staff training and education

– **B9.3** Competency to perform assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary. Records of competency assessments shall be kept (B6).

• Employer must demonstrate that their employees are adequately trained and experienced enough to carry out their job function(s)

- Procedures
- Equipment



Demonstrating Competency

• Assessment by:

- Witness procedure
- Written questions
- Achieve set level of success: cell biopsy, cell collection, amplification.

• Levels of competency:

- Not competent
- Competent with supervision
- Competent
- Competent to troubleshoot and train others



Assessment: procedures (1)

Assessment record: Collection of biopsied blastomeres	
Member of staff undergoing assessment _____	
Grade _____	
Name of assessor _____	Grade _____
SOP Number(s): EP-D-FI2-Blastomeres Collection EP-D-FI2-Care Set up EP-D-FI2-Checklist-Care Set up	
Risk assessment: MF-D-FI2-C&E/8	
Knowledge	
<ul style="list-style-type: none"> • Use of binocular microscope • If hand drawn glass pipettes are used, selection of pipette with appropriate diameter • Cell quality measures: cell number, embryo grade, visible nucleus, vacuoles, blebs, cell morphology, zona quality • Understands the importance of minimal liquid volume transfer • Describes collection method for removal of culture media through wash drops • Understands potential sources of DNA contamination and need for appropriate precautions • Sample checking procedure • What to do if a cell lyses or is 'lost' during collection • Health and safety issues associated with this procedure • Who to report to if there is a problem 	
Competence vs skills to:	Trainer's signature
• If used, Set up mouth pipette <input type="checkbox"/>	_____
• If used, Safe disposal of glass pipettes <input type="checkbox"/>	_____
• Set up microscope <input type="checkbox"/>	_____
• Collect cells and transfer through wash drops <input type="checkbox"/>	_____
• Deposit & observe cell in 0.2ml tube containing lysis buffer <input type="checkbox"/>	_____
• Achieve 10% amplification with no contamination <input type="checkbox"/>	_____
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Maintaining competency (1)

- Mechanism when a change is implemented (procedure/equipment) all appropriate people have been informed and assessed as required.
- Compliance
 - Evidence updated SOPs have been read and are in use (document control: excel spreadsheets, commercial software)
 - Assessments
 - Examination Audits



Compliance: updated SOPs

Sections	SOP	Description	Read by	Date
Lab + Equipment	AP-PC-001-01-01-01	PC-001: Safety and Hygiene		
	AP-PC-001-01-01-02	PC-001: Safety and Hygiene		
	AP-PC-001-01-01-03	PC-001: Safety and Hygiene		
	AP-PC-001-01-01-04	PC-001: Safety and Hygiene		
	AP-PC-001-01-01-05	PC-001: Safety and Hygiene		
	AP-PC-001-01-01-06	PC-001: Safety and Hygiene		
	AP-PC-001-01-01-07	PC-001: Safety and Hygiene		
	AP-PC-001-01-01-08	PC-001: Safety and Hygiene		
	AP-PC-001-01-01-09	PC-001: Safety and Hygiene		
	AP-PC-001-01-01-10	PC-001: Safety and Hygiene		
	AP-PC-001-01-01-11	PC-001: Safety and Hygiene		
	AP-PC-001-01-01-12	PC-001: Safety and Hygiene		
General	AP-PC-001-01-02-01	PC-001: Safety and Hygiene		
	AP-PC-001-01-02-02	PC-001: Safety and Hygiene		
	AP-PC-001-01-02-03	PC-001: Safety and Hygiene		
	AP-PC-001-01-02-04	PC-001: Safety and Hygiene		
Organic DNA extract	AP-PC-001-01-03-01	PC-001: Safety and Hygiene		
	AP-PC-001-01-03-02	PC-001: Safety and Hygiene		
PCR assay	AP-PC-001-01-04-01	PC-001: Safety and Hygiene		
	AP-PC-001-01-04-02	PC-001: Safety and Hygiene		
	AP-PC-001-01-04-03	PC-001: Safety and Hygiene		
	AP-PC-001-01-04-04	PC-001: Safety and Hygiene		



Document control: commercial software (1)

IPassport

Address: http://www.genpathology.com/ipassport_index.html

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 Tel: +44 (0)151 841 8339
 Fax: +44 (0)151 841 8331
 Email: info@genpathology.com
 Web: www.genpathology.com

IPassport Quality Management System - Software Modules
 Support an integrated laboratory operation

- Compliance Checklist
- Task Management
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- Document Imaging
- Checklists
- Incident Reporting
- Audit Reporting
- Equipment & Materials
- Reagents
- COC/BI
- MDCS
- Health & Safety Audit
- Meeting Management
- Personnel Management
- Laboratory Management



Document control: commercial software (2)

Q Pulse

Q-Pulse Overview

The Q-Pulse Assessment Framework is an integrated solution to manage all of your compliance needs.

Click on each section to find out how Q-Pulse can help you to work smarter, be more efficient, save resources and improve. Manage self-training and competence and plan and measure your improvement opportunities across your organisation.

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Q-Pulse offers a comprehensive system to manage all of your compliance needs across your entire organisation.

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Define and document policies and standards. 4th and 5th ed. 2011

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Maintaining competency (2)

- When someone is assessed and deemed to be competent –for how long is this valid?
 - Does it depend on:
 - Frequency of performing procedure?
 - Complexity of the procedure?
 - Change in personal circumstances?
- Need to re-assess if technique not performed in X months?



Re-assessment

Written by: _____

The skills listed below are absolutely essential for being safe for ourselves, others, knowledge and confidence in the procedure.

Assessor's signature: _____

Trainee's signature: _____

Date: _____

Competency Review

Competency Review	Competency Review 1	Competency Review 2	Competency Review 3	Competency Review 4
Knowledge on fundamentals	SAU	SAU	SAU	SAU
Competency in skill				
Competency in practical business context				

Questionnaire – BestColour

Answer the following questions:

1. What protective clothing is worn?
2. What is the purpose of washing the cell? Describe the method used.
3. What action would you take if a cell lyses during biopsy?
4. What action would you take if the cell is 'lost' during the washing steps?
5. What are the best colour tubes for cell collection?


