

# LABORATORY EQUIPMENT, INFORMATION SYSTEMS AND CONSUMABLES

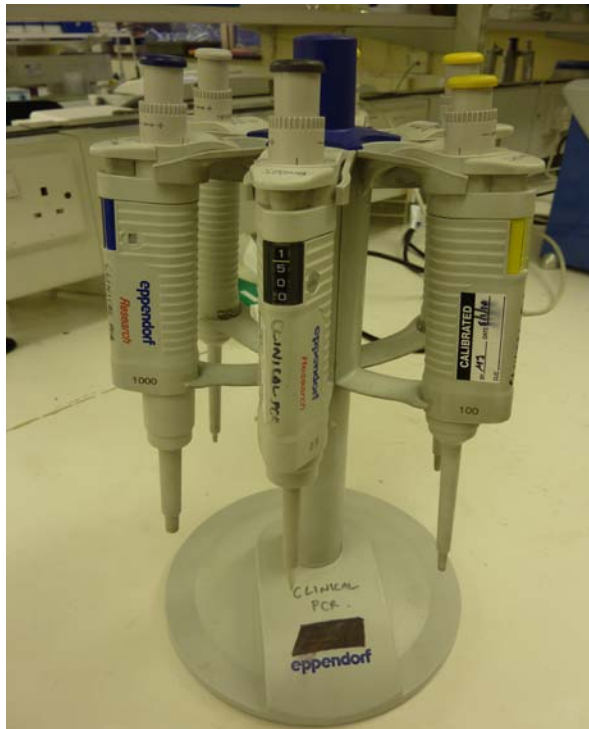
SEEMA DHANJAL  
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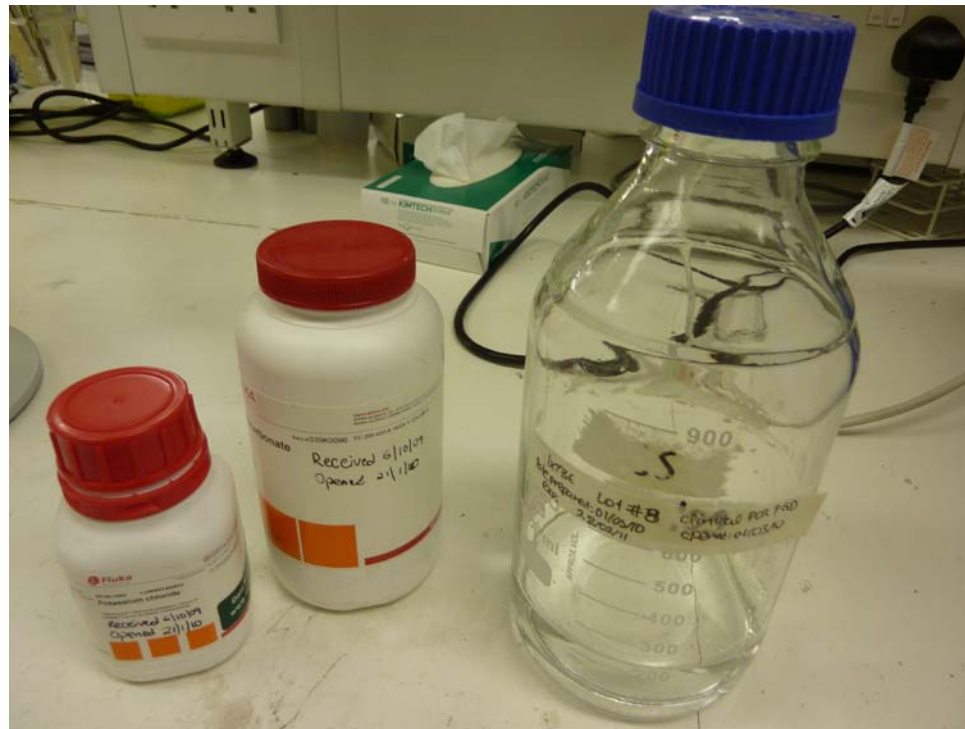
ISO 15189  
Section 5.3  
Laboratory Equipment



# Equipment



# Reagents



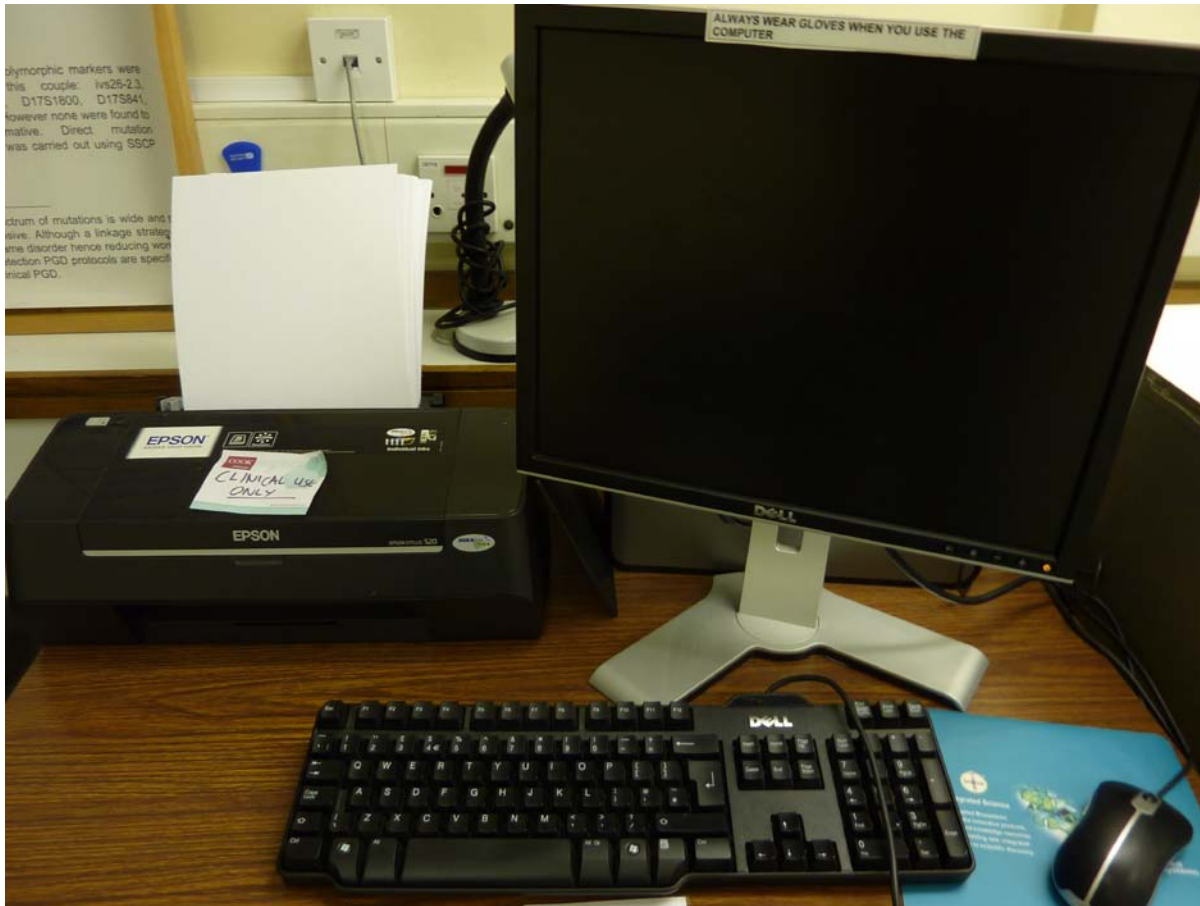
# Consumables



# Reference materials



# Computer software



## 5.3.1

- Must have access to all equipment needed
  - Primary sample collection
  - Sample preparation
  - Sample processing
  - Sample examination
  - Sample storage



## 5.3.1

For example for PCR PGD

- Pre pre PCR area
- Pre PCR area
- PCR area
- Post PCR area
- micro pipettes
- centrifuges
- tubes
- tips
- PCR machines
- Genetic analyser
- Separate fridges/freezers for DNA and PCR products

## 5.3.1

- If equipment not available or in case of a breakdown
  - Access to external equipment pre-organised
  - Out of hours/ weekend access
  - QM must ensure equipment complies with standards
  - PGD-Important due to short time available to report results and inability to retest single cells

## 5.3.2

‘Equipment shall be shown (upon installation and in routine use) to be capable of achieving the performance required and shall comply with specifications relevant to the examinations concerned.’

## 5.3.2

- The purpose of each examination should be reviewed to decide equipment required
- Exact performance specifications for equipment must be defined- acceptable ranges must be set e.g. pipettes
- Before use the equipment must be tested and validated using internal quality control samples

## 5.3.2

- Regular monitoring and calibration is essential to show that specifications are being met
  - E.g. Temperature monitoring of fridges/incubators
  - Assigned person
- Intervals can be different for different equipment, as long as clearly specified e.g. Weekends?
- Preventative maintenance- service contracts
- Records kept of all maintenance and faults

[illegible]

Item	Model Number	Lab code	Company Name	Contact number	Serial Number	Purchase Date	Location	Service contract Y/N?	Last serviced	Repairs	Assigned person
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## 5.3.5 and 5.3.6

- Used by authorised personnel only
  - trained and regularly tested
  - retraining after long absences
- Maintained in safe working conditions
  - SOPs include risk assessments
- Instructions readily available
  - Manuals/SOPs next to equipment



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Document number: SOP039

SOP039\_Running and maintenance of the autoclave

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Date of Issue: 25/03/09

## 2 APPENDIX

### Astell Autoclave – Instructions for use

Water level should be up to (NOT higher than) horizontal metal plate, covering copper coil entirely. Fill with TAP WATER (not distilled water).

1. Switch power ON (green switch on side of machine)
2. Press ENTER
3. Open door
4. Load autoclave
5. Close door
6. Select program:
  1. Liquid (for solutions – loosen bottle lids) (121°C for 15 minutes)
  2. Instruments and drying: Default setting – one generally used for tip boxes (121°C for 15 minutes – Purge time 10 minutes)
  3. Glassware and Drying
7. Press START (ENTER, ENTER to skip delay)
8. When cycle ends machine will beep
9. Press OPEN, wait 30 seconds, then open door  
Have to wait 30 seconds delay, then you will get 10 seconds to open door (if door is not opened within these 10 seconds, you will need to press OPEN and wait 30 seconds again)
10. Once door opens, drying option is suggested
11. Press ENTER to select drying (default time 10 minutes – can increase/decrease time with arrows) or STOP (if drying not required)
12. Once drying finished, remove autoclaved items from machine and switch power OFF (from side)

### 5.3.7

- Faulty equipment should be taken out of service, labelled until repaired/ decommissioned
- All users must be made aware of fault in weekly meetings/email
- Once repaired, before putting it back in use, must be calibrated and validated according to specified criteria
- All users notified- Ok to use

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## Equipment Fault Report

Complete form and file in Equipment folder



Date	Equipment ID	Serial Number	Location	Reported by
<b>Nature of Fault</b>				
<b>Notification of fault to staff</b>	<b>Note on Equipment date</b>		<b>Lab meeting date</b>	
<b>Repair process</b>	<b>Company</b>	<b>Telephone / FAX</b>	<b>Contact person</b>	<b>Date</b>
	<b>Record of further correspondence to repair completion</b>			
	<b>Repair Date</b>		<b>Signed By</b>	
<b>Notification of repair to staff</b>	<b>Date Equipment tested</b>		<b>Lab meeting date</b>	
<b>Problems post repair</b>				

## 5.3.11 Computer Software

- Software according to requirements
- Risk assessment for data protection
  - No data should be lost
  - All data adequately backed up
  - Authorised staff only
- SOP for reports
  - Email –secure?
  - Fax
  - Who has access
  - People left- remove access

# Reagents and consumables

- All should be logged in
  - Forms – help keep track of stocks
- Expiry dates must be noted and adhered to
- In house reagents must be given a lot number and expiry date



## In house solution logging in form

## How to start?

- Make an inventory
- Assign equipment to different staff
  - Write SOPs
  - Maintenance logs
  - Create forms
  - Training- devise tests





*Every day, a small ant arrives at work very early and starts work immediately.*



*She produces a lot and she was happy.*



*The Chief, a lion, was surprised to see that the ant was working without supervision.*



*He thought if the ant can produce so much without supervision, wouldn't she produce even more if she had a supervisor!*



*So he recruited a cockroach who had extensive experience as supervisor and who was famous for writing excellent reports.*



*The cockroach's first decision was to set up a clocking in attendance system.*



He also needed a secretary to help him write and type his reports and ...

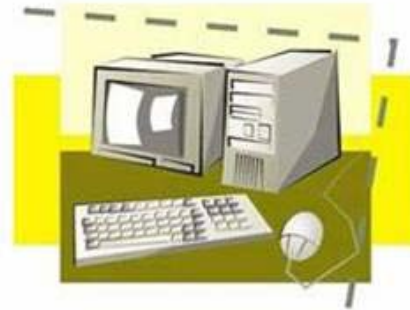


... he recruited a spider, who managed the archives and monitored all phone calls.





*The lion was delighted  
with the cockroach's  
reports  
and asked him to produce  
graphs to describe  
production rates and to  
analyse trends, so that he  
could use them for  
presentations at  
Board's meetings.*



*So the cockroach had to buy a new computer and a  
laser printer and ...*

*... recruited a fly  
to manage the IT  
department.*



*The ant, who had once been so productive and relaxed,  
hated this new plethora of paperwork and meetings  
which used up most of her time...!*



*The lion came to the conclusion that it was high time to nominate a person in charge of the department where the ant worked.*

*The position was given to the cicada, whose first decision was to buy a carpet and an ergonomic chair for his office.*



*The new person in charge, the cicada, also needed a computer and a personal assistant, who he brought from his previous department, to help him prepare a Work and Budget Control Strategic Optimisation Plan ...*



*The Department where the ant works is now a sad place, where nobody laughs anymore and everybody has become upset...*







*It was at that time that the cicada convinced the boss, the lion, of the absolute necessity to start a climatic study of the environment.*



*Having reviewed the charges for running the ant's department, the lion found out that the production was much less than before.*



*So he recruited the owl, a prestigious and renowned consultant to carry out an audit and suggest solutions.*



*The owl spent three months in the department and came up with an enormous report, in several volumes, that concluded :  
"The department is overstaffed ..."*



*Guess who the lion fires first?*

*The ant, of course, because she  
"showed lack of motivation and had a negative  
attitude".*



***NB:***

***The characters in this fable are  
fictitious; any resemblance to real  
people or facts within the  
Corporation is pure coincidence...***

