



Practice Guidelines for Internal Quality Control within the Molecular Genetics Laboratory.

These guidelines have been prepared following the internal quality control best practice meeting held at the International Centre for Life, Newcastle-upon-Tyne on February 26th 2003

1.0 INTRODUCTION

Draft Guidelines for Internal Quality Control of Sample Reception and DNA Extraction.

2.0 SAMPLE RECEPTION

1. Staff in sample reception should receive specialist training for that area of work.
2. Staff involved in sample reception, booking-in and DNA extraction should have the minimum of interruption while working.
3. Samples and their accompanying documentation should be dealt with one at a time.
4. The paperwork should have the required legible information which matches the information on the tube.
5. Each sample should have a minimum of two identifiers.
6. Any discrepancy in the information should be noted as a permanent record.
7. A written protocol should be in place for acceptance/rejection of samples. This should include the level of responsibility needed to reject a sample and a definition of which 'critical samples' will not be rejected.
8. Rejected samples should be safely stored for a defined period before actual disposal to allow the opportunity to clarify the situation with the referring clinician.

3.0 SAMPLE BOOKING IN

Critical consideration should be given to the use of a hand written 'day book'. The less hand written transfer of information the better.

1. Data should be entered on the computer from the original documentation that arrived with the sample.
2. The time between arrival of the sample and booking-in/entry on the computer should be minimised as much as possible. (Consensus seemed to be working towards a maximum of 10 hours).
3. Where possible sample and DNA numbers should be computer generated.
4. Where possible sample and DNA identifying labels should be computer generated.
5. If possible do not cover the original information on the tube with a laboratory label
6. All data entered on the computer should be checked for accuracy by a second trained member of staff as soon as possible. A checked 'minimum data set' defined by the

laboratory protocol should be available before the sample is tested.

4.0 DNA EXTRACTION

1. Individual laboratories should consider the costs and benefits of storing blood spots on filter paper from each sample. This material may be useful as a back-up for diagnostic purposes, to investigate clinical incidents and for auditing the effectiveness of IQC procedures (for the sensitivity of this strategy see Appendix).
2. Computer generated DNA extraction worksheets contribute to the accuracy of the procedure.
3. The DNA extraction method chosen should minimise the number of tube transfers as far as possible. Clearly fully automated systems provide the gold standard in this respect requiring tube order to be checked only at the start and finish.
4. The integrity of the labelling should be maintained throughout the extraction process.
5. Suitably qualified staff should check the tube order after each transfer step and document the check with their signature.
6. Any discrepancies in tube order found and rectified should be recorded.
7. Where possible only have one tube lid open at a time.
8. Establish the optimum sample batch size which does not overburden the operator.
9. Labelling the lid as well as the side of the tube provides a useful visual check on the order.
10. If two tubes of blood or DNA from the same patient are to be pooled a documented procedure should be in place to avoid error.

Where samples have been pooled this information should be in a permanent record.

APPENDIX

For those who might want to consider an audit these are a few figures:

For a 1% error rate, testing 290 samples gives a 95% probability of finding 1 or more.

For a 0.1% error rate you need to test 3000 to get the same pick up and for 0.001% it is 30,000. These figures were worked out for us by Andy Curtis in Newcastle but an article in The Probe by David Barton and Rob McMahon as early as 1995 quoted similar figures.