All Wales Clinical Biochemistry Audit Group

Standards for the Use of Automated Immunoassay Analysers

INTRODUCTION

The results of a survey undertaken in July 1999, presented at an audit meeting in September 1999, showed that automated immunoassay analysers are now widely used in Wales, but that policies and procedures for their use (e.g. in the determination of reference ranges) differ significantly between laboratories. It is likely that the use of automated analysers will increase as more assays become available. The following standards are therefore recommended to ensure that laboratories using these analysers provide a satisfactory quality of service.

STANDARDS

1. Choice of Analyser:

Laboratories should ensure that each system (analysers and reagents) is obtained from a reputable supplier, preferably adhering to ISO 9000 and/or FDA regulations and ideally whose system has been assessed by the Medical Devices Agency (MDA).

2. Staffing:

a) Laboratory staff should understand the principles and technology of the analytical systems they use and any resulting constraints on the operation of the systems.

b) Laboratories should employ sufficient staff who have received an appropriate level of training such that they are competent to carry out necessary maintenance and initial trouble-shooting procedures.

c) Staff should be encouraged to attend EQA and User Group meetings to ensure that they keep up-to-date with best current practice.

3. Operational Procedures:

a) Maintenance schedules should be followed and completed according to the manufacturer's recommendations.

b) Local changes to the manufacturer's recommended operational procedures should be documented and applied in consultation with the manufacturer.

c) Laboratories should ensure that calibration is carried out in line with manufacturer's specifications, particularly when a new reagent lot is introduced. The new calibration should be checked using quality control materials before its use for clinical samples.

d) After the introduction of a new reagent lot, the assay working range, analytical sensitivity limits and correct dilution set points re-checked.[1,2]

e) Laboratories should ensure that reference ranges which they quote are evidence-based and should not just accept reference ranges supplied by the manufacturer.

4. Quality:

a) Each laboratory should ensure that appropriate internal quality control procedures are in place. Quality control materials used should be obtained from a supplier who is independent of the analyser manufacturer. Quality control materials should be used to validate calibrations before patient samples are assayed and at appropriate intervals during sample runs. Analyte concentrations in quality control materials should give an assessment of performance close to key decision points.

b) All assays should be checked regularly by participation in CPA accredited external quality assessment (EQA) schemes and meet the schemes' analytical quality criteria.

c) Results should be technically and clinically validated by appropriately trained staff before reporting; any questionable result should be investigated.

5. **Recognition of Artefactual Results**:

Staff should be trained to recognise artefactual results and be able to carry out:

(i) simple dilution studies to identify cross-reactivity with similar molecules,[3] the effect of antigen excess[4] and anomalous "free" hormone results.

(ii) gamma globulin addition to neutralise the effect of heterophilic antibodies.[5]

(iii) precipitation techniques to remove macroisoforms.[6]

(iv) solvent extraction techniques to improve specificity.[7]

If these procedures fail to explain an anomalous result, the sample should be referred to another laboratory, which measures the analyte using different technology. Anomalous results should be reported to the equipment manufacturer.

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