

ONE LINERS

Laboratory staff are major users of in vitro diagnostic medical devices (IVDs). Laboratories may also be involved in training others in the use of IVDs and investigating or managing problems with IVD use. The aim of this news sheet is to detail briefly some of the device problems that are reported to the Medicines and Healthcare products Regulatory Agency (MHRA), and to draw wider issues to the attention of other IVD users.

You are encouraged to report problems relating to medical devices, or associated with the use of medical devices, to the MHRA. Please report online via our website www.mhra.gov.uk

Eight Out Of Ten!

Some reagent kits claim a performance that may not meet laboratories' clinical needs. A recent MHRA investigation of a reported false negative result revealed that a kit had a claimed sensitivity that indicated it could miss two out of ten positives. It was, however, being used alone for routine screening for an infectious disease.

Check the performance claims supplied with kits and ensure that these meet your needs.

Once Byte-n, Twice Shy?

MHRA has received a number of reports from manufacturers highlighting software problems with laboratory analysers. The manufacturers are providing interim manual solutions until a software fix can be made available.

Ensure that you are aware of applicable interim manual solutions and that you receive the latest software fixes and upgrades for your analyser hardware.

Monkey Business?

Reports of false negative RhD results investigated by MHRA were found to express weak D.

Care must be taken in handling and interpreting weak and partial RhD reactions. Follow the UK guidelines for RhD grouping.

Niess-Error?

There is a risk of false negative gonococcal results owing to the increasing isolation of strains that lack the enzyme prolyliminopeptidase.

Be aware of tests that rely upon the detection of this enzyme for a positive result. Confirm results using another test method such as a serological test.

Tube Or Not Tube?

Some combinations of blood collection tubes used with specific assays have been found to cause a bias in the assay result.

Check with the tube and assay manufacturer to ensure that interference is not a problem.

Blue Line Blues

We have received some reports of false results due to uncertainty about the use of pregnancy test kits, particularly in interpretation of the result, length of time that the test should be read and interpretation of a feint line.

Ensure that you and other pregnancy test users are familiar with the instructions for use provided by the manufacturer.

Pick 'n' Mix

Some reports of false negatives have revealed that the combination of assay and instrument have not been validated. This is particularly an issue with open system analysers.

When automating an assay, ensure that you can verify that the combination of assay and instrument has been properly validated. Be sure that the relevant software protocol has been used in validation.