Laboratory ONE LINERS

IN VITRO VERITAS! 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 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 either by telephone or via our website (www.mhra.gov.uk).

Which Measure-ment?

The MHRA has received reports of measurement units on analysers reverting to default values without warning. This occurred following power loss or major maintenance such as change of a circuit board and resulted in incorrect patient results being issued. The change went undetected as the units of measurement on the analyser's on-board QC charts also changed.

After power loss or major maintenance, always check assay parameters. Consider using manual QC charts.

High and Dry!

We have received reports of false negative results for antibody screening when using blood group screening cards and cassettes. The cards and cassettes had been stored inappropriately and had dried out.

Follow manufacturers' instructions for use and storage and check cards and cassettes for suitability prior to use.

Salmonella Type-us!!?

We have had reports of false negative results when testing Salmonella spp using antisera.

Be aware of which strains of Salmonella the antisera can detect. Antisera may not detect all strains and may not have been tested against newer strains.

Surface Tension!

The MHRA has received reports of incorrect results generated because samples have surface bubbles. Some laboratory analysers may not detect bubbles.

Make sure that you follow the manufacturer's advice on appropriate sample handling. Be aware that sampling issues may cause erroneous results.

Size Matters!

The MHRA has received occasional reports of false results with laboratory analysers. Some of these reports have come from laboratories using consumables such as sample tubes that have different dimensions to those specified by the analyser manufacturer.

Before purchasing a laboratory analyser, ensure that you know the analyser manufacturer's specifications for all the consumables including sample tubes.

Do the Two-Step!

We have received a report of a false negative viral antibody result observed when using a one-step dilution process on an automated ELISA analyser. The manufacturer recommended a two-step dilution process.

Be sure that you follow the manufacturer's instructions for using one-step or two-step dilution on automated systems.

MHRA
Medicines and Healthcare products Regulatory Agency

If you would like to discuss or report an adverse incident, including 'near misses' involving a device, either contact your Trust Medical Devices Liaison Officer, or contact us directly on: 020 7084 3123 (medical), 3128 (nursing) or e-mail: devices@mhra.gsi.gov.uk
To discuss laboratory-related issues, please call us on 020 7084 3066.

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