HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Tosoh Automated Glycohemoglobin Analyzers:
HLC-723G7 (Variant Analysis Mode)
HLC-723G8 (Variant Analysis Mode)


Priority 2 – Warning

HPRA Safety Notice: SN2014(37) **Issue Date: 08 September 2014**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Tosoh Corporation	V21588

ISSUE
The Health Products Regulatory Authority (HPRA) has been notified of erroneously high HbA1C results (between 3-5 mmol/mol higher) generated on Tosoh Automated Glycohemoglobin Analyzers (G7 & G8, Variant Analysis mode). The erroneously high results are not detected by internal and external QC.

ACTION OR RECOMMENDATIONS

The HPRA advises the following;

Laboratory personnel:

1 Be aware of the potential for erroneously high results using these devices in the Variant Analysis Mode.

2 When issuing/communicating results, consider the need to include a comment that HbA1c results should be interpreted in combination with the patients' own glucose monitoring values.

3 Ensure that all relevant staff are informed of this information.

4 Report any concerns regarding these devices to the HPRA.

Hospital Clinicians / General Practitioners;

1 HbA1c results should be interpreted in combination with the patients' own glucose monitoring values.

2 Ensure that all relevant staff are informed of this information.

3 Report any concerns regarding these devices to the HPRA.

TARGET GROUPS

Risk Managers	Diabetic departments
Laboratory Managers	Endocrinology units
Chief Medical Scientists	Endocrinology Consultants
Diabetic Clinics/ outpatients	Paediatric wards
Diabetic nurse specialists	General practitioners

BACKGROUND

Erroneously high HbA1c results (between 3-5 mmol/mol higher) have been reported for patient samples using Tosoh Automated Glycohemoglobin Analyzers (G7 and G8, Variant Analysis mode).

This issue may have the following clinical implications:-

- Risk of severe hypoglycaemia particularly in type 1 diabetic patients where an inaccurately high HbA1c may lead to excess or inappropriate use of insulin, therefore HbA1c must be interpreted in combination with the patients' own glucose monitoring values.

- Potential over diagnosis of type 2 diabetes in the community by GPs who use the ADA diagnostic criterion of HbA1c > 48mmol/mol (6.5%) – resulting in potentially inappropriate further testing (e.g. oral glucose tolerance testing)

The manufacturer is currently investigating this issue. Users are advised to exercise caution using these devices pending completion of the manufacturer's investigation.

The HPRA will issue an updated communication following completion of the manufacturer's investigation.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Tosoh Europe N.V. Transportstraat 4, 3980 Tessenderlo, Belgium	Telephone: Fax: E-mail: Website:	+32 13 61 85 92 +32 13 61 85 09 info.raqa@tosoh.com www.tosohbioscience.eu

Enquiries to the **distributor** should be addressed to:

Aquilant Scientific Aquilant House 21 Fonthill Business Park, Fonthill Road, Clondalkin, Dublin	Telephone: Fax: E-mail: Website:	+353 (1) 4048300 +353 (1) 4048333 info@unitech.ie www.aquilantscientific.ie

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2	Telephone: Fax: E-mail: Website:	+353-1-6764971 +353-1-6344033 devicesafety@hpra.ie www.hpra.ie