Urgent FIELD SAFETY NOTICE
i.Laboratory 5.8.1002
Date 20th Dec 2016

To: All Organisations using 5.8.1002

FAO: Clinical Safety Officer

Issue ID: 914607

Clinical Risk Class: Medium

Dear Customer

This is a follow-up notice in respect of the Customer Safety Notice sent to customers on 9th December 2016, following a request from the Health Products Regulatory Authority, in accordance with MEDDEV 2.12/1 rev.8

CSC regards patient safety of paramount importance. As part of our clinical risk and major incident handling procedures and processes, we have developed this Field Safety notice. Field Safety Notices may be sent to you if CSC becomes aware of any issues which may affect patient safety in your health care practice.

This is a Field Safety Notice which advises you that there is a risk to patients associated with a product you are using. It describes the characteristics of the risk, as well as other details, and advises you of what is likely to be causing the risk, and makes recommendations for the actions you or others may take to mitigate this risk.

Kind regards

Product Manager

Product versions to which this applies	iLab 5.8.1002		
Problem Summary	Incorrect calculation of eGFR in EQA samples		
Date Identified	12th Oct 2016	**Issue number (for internal use only)**	
Author	N. Aikenhead		
Problem Description	There has been an issue reported where eGFR was calculated incorrectly in EQA samples when the DOB and/or Gender was altered after results were received from the analyser.		
CSC Clinical Safety Assessment	**Hazard ID and Description**	LAB-008 Clinical calculations may produce an inaccurate result.	
	Clinical Impact	Information which is presented to the user must at all times be calculated correctly. There is the potential for inaccurate eGFR to be reported on patient samples under similar circumstances, where the DOB and/or Gender are altered after results have been received from the analyser. This inaccurate result may pose a risk to patients.	
	Clinical Safety Officer	**Louise Kennington**	
Possible Cause(s)	Patient demographic data being altered after the calculation has occurred.		
Observations	Users are advised to ensure that patient demographic data is as complete and accurate as possible before analysis. For EQA samples it is recommended that a new record is created for each sample in every distribution. Where updating patient demographic data post analysis is unavoidable, all results must be reviewed by a suitably qualified staff member in line with local QMS. In line with your own laboratory's internal procedures, users should consider the need to conduct a review of retrospective results/processes to determine if this has occurred where GLP has not been followed by the user. The issue is limited to those instances where demographic data has been altered after results have been calculated.		
CSC's nominated contacts*	N. Aikenhead naikenhead@csc.com Tel: 07736 197664		

*Terms Defined	
Term	**Description**
CSC's nominated contacts	This will be the Product Owner, Author or Clinical Safety Officer in the Country of Origin