

Urgent Field Safety Notice
Presage ST2 Assay
FSCA 19-002
Field Safety Notice – Immediate Action Required

Date: 14 June 2019

Attention:

This is a retrospective Field Safety Corrective Action. The event occurred, a limitation was added to the Instructions for Use, and customers were notified on 18 March 2018. We are now fulfilling our regulatory obligation to report this Field Safety Corrective Action to the relevant competent authorities.

Details on affected devices:

Presage ST2 Assay BC-1065E – All Lots manufactured until March 2018

Description of the problem:

Following an investigation into lab to lab variability of results from identical patient samples, it was determined that running the Presage ST2 Assay with an automated plate washer may cause falsely elevated results if run in strip mode. Using the automated plate washer in strip mode results in a lower slope due to decreased signal which will result in artificially high calculated results for specimens on columns on the right side of the plate. It is believed that this effect on signal is due to drying of the plate when the washer is used in strip mode.

Using the automated plate washer in plate mode is comparable to the manual wash technique and does not cause the plate to dry out as it does in strip mode.

We believe the risk to patients associated with previous use of affected devices in combination with an automated plate washer to be minimal. The results of identical specimens obtained via plate mode and strip mode showed a mean difference of 15%. “Normal” individuals not at risk of heart failure generally have an ST2 concentration of less than 20 ng/mL, so results using an automated plate washer in strip mode would produce a falsely elevated result of 23 ng/mL, well below the clinically relevant cutoff of ST2 concentration 35 ng/mL. The potential for false positives around the cutoff is increased, but these individuals would be considered high risk heart failure patients, and would receive similar treatment regardless.

Advise on action to be taken by the recipient:

Please take note of the limitation regarding the use of an automated plate washer in the Presage ST2 Assay IFU.

Please complete the attached confirmation form to acknowledge your receipt of this FSN and return to Critical Diagnostics immediately.

Transmission of this Field Safety Notice: (if appropriate)

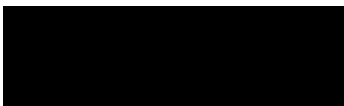
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Contact reference person:

Greg Cerra
Critical Diagnostics
3030 Bunker Hill St / Suite 117A
San Diego, CA 92109

The undersign confirms that this notice has been notified the appropriate Regulatory Agencies.



CONFIRMATION OF NOTIFICATION

It is important that your organisation confirms that you have received the attached field safety notice. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions. Please complete the sections below and provide a scanned copy to: gcerra@criticaldiagnostics.com

Organisation Name: _____

Address: _____

Contact Name: _____

Telephone number: _____

Email: _____

I confirm receipt of the Field Safety Notice and that I read and understood its content.

Print Name: _____

Signature: _____

Date: _____

The deadline for returning this confirmation form is 21 June 2019, please email a completed copy to Critical Diagnostics Immediately upon completion.