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FIELD SAFETY CORRECTIVE ACTION

List Number	Product description	Lot number	Expiration date	Unique Device Identifier (Primary)
09P81-25	i-STAT hs-TnI cartridge	All lots beginning with	Last lot expires In	
		A24XXX	expired	(01) 00054749003051 (17)
		A25XXX	expired	(01) 00054749003051 (17)
		B25XXX	expired	(01) 00054749003051 (17)
		B26XXX	28 November 2026	(01) 00054749003051 (17)
		C26XXX	25 February 2027	(01) 00054749003051 (17)
		D26XXX	30 June 2027	(01) 00054749003051 (17)

Dear Valued Abbott Customer,

This letter contains important information about a field safety corrective action for the *i-STAT hs-TnI cartridge* and certain limitations described in its product labeling. If your facility uses this cartridge, it may be affected by the issue described in this letter. Please review this information carefully and take the recommended actions outlined below. Customers may continue to use affected cartridges in accordance with this notification and existing labeling while transitioning to updated product as it becomes available.

DESCRIPTION OF ISSUE

Abbott has identified that lots beginning with A24, A25, B25, B26, C26, and D26 may have a reduced ability to mitigate certain forms of analytical interference, including macrotroponin and heterophile antibody-related interference, due to variability associated with the alkaline phosphatase component used during reagent manufacturing. This issue may result in falsely elevated cardiac troponin I results. There is no evidence that the issue has caused falsely low results.

Abbott has received 79 reports potentially associated with this issue at a rate of approximately 25 reports per million cartridges distributed. Cartridges can continue to be used and will perform as intended in samples containing no interferent. Serious injuries could occur due to the failure mode associated with this issue. Abbott has received 6 reports of unnecessary clinical intervention (cardiac catheterization without true evidence of myocardial injury) potentially associated with this issue at a rate of approximately 2 cases per million cartridges distributed.

BACKGROUND ON THE CARTRIDGE

The *i-STAT hs-TnI cartridge* with the i-STAT System is intended for use in the *in vitro* quantification of cardiac troponin I (cTnI) in whole blood or plasma samples in point of care or clinical laboratory settings.
The *i-STAT hs-TnI cartridge* with the *i-STAT System* is intended to be used as an aid in the diagnosis of myocardial infarction (MI).

As described in the i-STAT hs-TnI cartridge Instructions for Use (IFU), certain endogenous and exogenous substances may interfere with immunoassay measurements. These include heterophile antibodies (including HAMA) and high molecular weight complexes of cardiac troponin I and immunoglobulins (macrotroponin). Such analytical interferents may, in rare cases, lead to erroneously elevated cardiac troponin I results.

While this product contains reagents that minimize the effect of these analytical interferents and QC algorithms designed to detect their effects, the possibility of interference causing erroneous results should be evaluated carefully in cases when an elevated cardiac troponin I result is encountered (e.g. exceeding the 99th

percentile URL) in the absence of other evidence of myocardial ischemia and where there are inconsistencies in the clinical information such as a patient's signs, risk factors, physical exam, symptoms, history, and results of other diagnostic tests.

POTENTIAL RISK

Clinicians should be advised to interpret cardiac troponin I results (cTnI) in conjunction with the patient's clinical presentation (history, risk factors, physical exam, and ECG findings), and other diagnostic testing in the evaluation of suspected myocardial infarction. If test results are inconsistent with the patient's clinical presentation and consistently elevated cTnI results are observed, the possibility of interference causing erroneous results should be considered.

There is a risk due to this issue that the persistently falsely elevated cardiac troponin I results (e.g. > 100 ng/L, including results exceeding the upper reportable range (>1000 ng/L)) may influence clinical decision making. If such results are interpreted without consideration of the patient's overall clinical presentation and results of other diagnostic findings, unnecessary diagnostic procedures or clinical interventions may occur.

RECOMMENDED ACTIONS

Our records indicate that your facility received an i-STAT hs-TnI cartridge lot beginning with A24, A25, B25, B26, C26, and D26.

Please take the following actions:

- Clinicians should be advised that serial cardiac troponin I results may not be helpful to distinguish true elevation of cTnI results versus elevated results due to interference; therefore the clinician should interpret results in conjunction with the patient's signs, symptoms, risk factors, medical history, physical examination findings, and results of other diagnostic testing. If results are inconsistent with the patient's clinical presentation, the possibility of analytical interference should be considered.
- If analytical interference is suspected based on the patient's clinical presentation, retest the sample using an i-STAT hs-TnI cartridge lot beginning with A26 (when available) or test the sample using an alternative validated laboratory method.
- Complete and return the Business Reply Card included with this notification to confirm receipt and understanding.

If you have forwarded any of the *i-STAT hs-TnI cartridges* to another facility, we request that you please provide a copy of this letter to them.

ADDITIONAL INFORMATION

i-STAT hs-TnI cartridge lots beginning with A26 will be available for distribution starting in mid-October. Please work with your local Abbott representative for transition support as the updated inventory becomes available. These new lots and all future lots (e.g. L26XXX, L27XXX) incorporate updates intended to improve assay robustness with respect to certain forms of analytical interference described in this notification. To support implementation of these updated lots, please download and use the most current value assignment sheets (PDF or electronic version) associated with the cartridge lots.

If you have any questions regarding this information, please contact your local Abbott Point of Care Technical Support by phone or via email at oustechsvc@apoc.abbott.com or contact your local Abbott Point of Care Representative.

Abbott understands the inconvenience this may cause and is committed to supporting your facility. We appreciate and thank you for your continued support of Abbott and Abbott products.

i-STAT is a trademark of Abbott