URGENT: FIELD SAFETY NOTICE

Potential for Negatively Biased Troponin Results on Triage Cardiac Panel

May 25, 2023

Dear Valued Customer / Distributor,

This notification provides important information regarding the possibility of negatively biased troponin results when using the affected product, listed below.

Affected Product Name	Product Code (Unique Identifier)	Affected Lots
Quidel Triage Cardiac Panel	97000HS	See Appendix 1 List of Affected Lots
Quidel Triage Cardiac Panel (Worldwide)	97000HSEU	
Quidel Triage Cardiac Panel	97000QIL	
Quidel Triage Cardiac Panel, Troponin I	97021HS	

Intended Use:

The Quidel Triage Cardiac Panel is a fluorescence immunoassay to be used with the Quidel Triage Meters for the quantitative determination of creatine kinase MB (CK-MB), myoglobin and Troponin I in EDTA anticoagulated whole blood or plasma specimens. The test is used as an aid in the diagnosis of myocardial infarction (injury).

Reason for the notification:

Quidel Cardiovascular Inc. (QuidelOrtho) received and confirmed complaints of low recovery for troponin in proficiency samples on Quidel Triage Cardiac Panel products.

In an initial investigation using 4 patient samples, the products showed various degrees of signal reduction ranging from -8.0% to -73.5%. An additional investigation using 109 well characterized[1, 2, 3] samples representing serial draws from 34 patients showed an average 30% reduction across the measurement range (0.05 ng/mL to 30 ng/mL). Of 26 samples around the cutoff of 0.4 ng/mL (0.2 ng/mL to 0.6 ng/mL), the mean bias was -26.7% and ranged from -57.4% to 4.3%. Of three (3) samples around 0.05 ng/mL (0.05ng/mL to 0.1 ng/mL), the mean bias was -27.3% and ranged from -33.3% to -20.0%.

At present, QC testing will not detect this anomaly.

Quidel has identified the cause to be related to a raw material and is working to resolve the issue. This notice only applies to the troponin assays on the products listed in Appendix 1. CK-MB and myoglobin assays are not affected.

Immediately discontinue use of this product and use an alternate method. If an alternate method is not available, see **Required Actions** below for recommendations on how to mitigate potential patient impact when continuing use of the product.

Currently, no unaffected product is available for distribution. It is highly recommended that you stop using this product and switch to another method. However, if you are unable to switch to an alternative method and need additional products, QuidelOrtho will provide lots impacted by this issue but will communicate the list of affected lot numbers until the issue has been fully resolved.

[1]Am J Emerg Med. 2017, 35(5), 704–709. Missed Myocardial Infarctions in ED Patients Prospectively Categorized as Low Risk by Established Risk Scores.

[2] Am J Nephrol. 2017, 45, 304–309. Renal Function and Scaled Troponin in Patients Presenting to the Emergency Department with Symptoms of Myocardial Infarction.

[3] Bayl Univ Med Cent. 2017, 11–15. Interpretation of Positive Troponin Results Among Patients With and Without Myocardial Infarction.

Impact to Results:

When using the affected lots, customers may experience negatively biased troponin results due to the signal reduction. As a result, there is a potential that a troponin level close to the cut-off concentration may be affected to an extent that an elevated troponin may be indicated as normal leading to potentially missed early myocardial infarction diagnosis. In these instances, missed or delayed diagnosis of myocardial infarction could result in inappropriate/inadequate medical intervention, especially for patients with atypical signs and symptoms and unremarkable EKGs. Consult your Medical Director on the need to complete a review of previously reported results.

The impact to results may be mitigated by following the required actions summarized below.

Required Actions:

QuidelOrtho recommends the following for our customers using impacted product lots:

- If you have an alternate method, please discard all unused material.
  - QuidelOrtho will credit your account. Use the Confirmation of Receipt Form, Appendix 2, to obtain the credit.
- If you do not have an alternate method, please follow these steps, as applicable, to minimize patient risk.
  1. Flag all negative results reported to clinicians as possibly inaccurate until lots of unaffected product are used.
  2. Use results from an alternate clinical laboratory analyzer when troponin results are below or close to the cutoff and myocardial infarction is suspected.
  3. Perform serial sampling. Keep patients until at least 3 negative troponin values have been obtained.
  4. Use all Triage troponin results in conjunction with the patient's risk factors, clinical presentation, EKG, and other imaging.
  5. Consider recommendations by the ACC, ESC guidelines and the Fourth Universal Definition of Myocardial Infarction for monitoring a patient for a rise or fall pattern of troponin.[4, 5, 6]
- If you are experiencing issues with Proficiency testing, contact your local Technical Solutions Center.

- Complete the Appendix 2, Confirmation of Receipt Form within ten business (10) days from receipt of this notification.

  Note: Please complete the form even if you no longer have inventory of affected product.

- Please forward this notification if the product was distributed outside of your facility.

[4] *Fourth Universal Definition of Myocardial Infarction (2018)*

[5] *Jean-Philippe Collet et al. 2020 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: The Task Force for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation of the European Society of Cardiology (ESC). Heart Journal, Volume 42, Issue 14, 7 April 2021, Pages 1289–1367.*

[6] *Martha Gulati et al., 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Volume 144, Issue 22, 30 November 2021; Pages e336-e367*

Contact Information:

We apologize for the inconvenience this will cause your facility. If you have further questions, please contact us at one of the numbers below or contact your local Technical Solutions Center.

- For North America, Canada, Asia-Pacific, and Latin America, please call 858.552.1100
- For Europe, Middle East, and Africa, please call +353 (91) 412 474
- For China, please call 0400 920 9366 or +86 021 3217 8300

EU authorized representative: MDSS GmbH, Tel.: +49-511-62628630, vigilance@mdss.com

To report adverse events, contact your local Technical Solutions Center.

URGENT PRODUCT CORRECTION NOTIFICATION

Appendix 1 – List of Affected Lots **Revision 1**

Item Number	Description	Lot Number	EXP
97000HS	Quidel Triage Cardiac Panel	T13666N	2023-06-26
		T13667N	2023-07-03
		T13669N	2023-07-08
		T13706N	2023-07-21
		T13826N	2023-09-03
		T13944N	2023-10-14
		T13948N	2023-10-20
		T13949N	2023-10-22
		T14019N	2023-11-05
		T14020N	2023-11-05
		T14023N	2023-11-11
97000HSEU	Quidel Triage Cardiac Panel (Worldwide)	T13668RBN	2023-07-05
		T13705RN	2023-07-14
		T13765RBN	2023-08-26
		T13825RBN	2023-08-27
		T13828RBN	2023-09-18
		T13946RBN	2023-10-16
97000QIL	Quidel Triage Cardiac Panel	T13825RNQ	2023-08-27
97021HS	Quidel Triage Cardiac Panel, Troponin I	T13665RN	2023-06-25
		T13707RN	2023-06-28
		T13709RN	2023-08-11
		T13827RN	2023-09-04
		T13829RN	2023-09-18
		T13942RN	2023-10-09
		T13950RN	2023-10-23
97000HS Or 97000HSEU Or 97000QIL Or 97021HS	Quidel Triage Cardiac Panel Or Quidel Triage Cardiac Panel (Worldwide) Or Quidel Triage Cardiac Panel Or Quidel Triage Cardiac Panel, Troponin I *Note- Any of the lots listed may be assigned to any of the item numbers listed	T13831N T13831RBN T13831RN T13831NQ T13831RBNQ T13831RNQ	2023-09-26
		T14021N T14021RBN T14021RN T14021NQ T14021RBNQ T14021RNQ	2023-11-06

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Appendix 1 – List of Affected Lots **Revision 1**

Item Number	Description	Lot Number	EXP
97000HS Or 97000HSEU Or 97000QIL Or 97021HS	Quidel Triage Cardiac Panel Or Quidel Triage Cardiac Panel (Worldwide) Or Quidel Triage Cardiac Panel Or Quidel Triage Cardiac Panel, Troponin I *Note- Any of the lots listed may be assigned to any of the item numbers listed	T14022N T14022RBN T14022RN T14022NQ T14022RBNQ T14022RNQ	2023-11-10
		T14024N T14024RNB T14024RN T14024NQ T14024RNBQ T14024RNQ	2023-11-15
		T14025N T14025RBN T14025RN T14025NQ T14025RBNQ T14025RNQ	2023-11-19
		T14041N T14041RBN T14041RN T14041NQ T14041RBNQ T14041RNQ	2023-12-13
		T14042N T14042RBN T14042RN T14042NQ T14042RBNQ T14042RNQ	2023-12-18
		T14043N T14043RBN T14043RN T14043NQ T14043RBNQ T14043RNQ	2023-12-19
		T14044N T14044RBN T14044RN T14044NQ T14044RBNQ T14044RNQ	2023-12-20
		T14045N T14045RBN T14045RN T14045NQ T14045RBNQ T14045RNQ	2023-12-24

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Appendix 2 – Confirmation of Receipt Form

Confirmation of Receipt Form – Response Required

Date of Issue: May 25, 2023

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Please complete and return this form, even if you do not have impacted product within 10 business days of receipt of this notification.

Send to: **QuidelOrtho Technical Support** e-Mail Address: Customernotifications@quidelortho.com Fax: 858.203.9297

Verification Request

Institution: _____

Contact: _____

Address: _____

City: _____ State/Prov: _____

Country: _____

Zip/Postal Code: _____ Phone: _____

e-Mail: _____ Fax: _____

Please Confirm I received the Urgent: Field Safety Notice regarding Quidel Triage Cardiac Panel

Please choose from the following:

- ☐ My facility has not received Quidel Triage Cardiac Panels and therefore is not affected by this issue.
- ☐ My facility uses Quidel Triage Cardiac Panels but does not have the affected lots remaining in inventory.
- ☐ My facility will continue to use affected Quidel Triage Cardiac Panels following the instructions provided in this communication.
  - ☐ Check this box if you do not have an alternate troponin method.
- ☐ My facility has Quidel Triage Cardiac Panels and has discontinued use and discarded remaining affected product.

If your facility has discontinued using affected lots, please indicate the quantity below to be credited. The credit will be issued to the original invoice for unused product.

Product Name	Product Code	Lot Number	Quantity to be Credited	Unit of Measure
				☐ Each ☐ Box
				☐ Each ☐ Box
				☐ Each ☐ Box
				☐ Each ☐ Box

Print Name: _____

Title: _____

Department: _____

Phone Number: _____ Date: _____

Signature Required: Your signature confirms that you have received and understand this communication

Your Comments: _____

If you are responding for more than one location, please list below all locations that your signature represents:

Locations you Represent: _____

For Customers Who Order from a Distributor	Distributor Name
If you order from a Distributor, please provide the name of your distributor	

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Appendix 2 Confirmation of Receipt Form: Distributor Reply Form

URGENT:
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Please confirm that the actions prescribed for the products shown below has been completed, sign and date below, then **return the completed form** to Quidel Technical Support at Fax Number 858.203.9297, or e-mail to customernotifications@quidelortho.com.

Part A: To be completed and returned within Three (3) business days upon receipt of the notification:
We acknowledge receipt of the QuidelOrtho Corporation URGENT: FIELD SAFETY NOTICE dated, May 25, 2023, for the following products:

Quidel Triage Cardiac Panel (See the Urgent Field Safety Notice, Appendix 1 for affected lots)

Signature: _____Date: _____

Part B: To be completed and returned within 10 working days:

- We confirm that all areas where the product could be located have been checked.
- We have notified customers that were shipped or may have been shipped this product. We will provide QuidelOrtho with evidence of notification and acknowledgement for all customers that were shipped or may have been shipped affected product.
- Evidence of notification and acknowledgement must include at minimum:
  - Customer information for all customers that are notified – Including facility name, address, contact name, e-mail, phone number and quantity received.
  - Customers may be notified by mail, e-mail, or phone and details of each contact and formal customer acknowledgement will be made available to QuidelOrtho, upon request. Evidence of acknowledgement is defined as hard copies of customer acknowledgement forms or a report of customer contact attempts including details of each attempt. A minimum of three attempts must be made to notify customers of the Field Safety Notice and confirm receipt of the letter.
- Please indicate below the quantity and amount to be credited. You will be contacted to arrange the corresponding credit.

Product Name	Product Code	Lot Number	Quantity to be Credited	Unit of Measure
				☐ Each ☐ Box
				☐ Each ☐ Box
				☐ Each ☐ Box
				☐ Each ☐ Box

4. I confirm that all customers and distributors who were shipped affected product have been notified of this issue and all required actions have been completed

Print Name: _____
Title: _____
Department: _____
Phone Number: _____ Date: _____

Signature Required: Your signature confirms that you have received and understand this communication

Your Comments: