



Product Correction

Immediate Action Required

Date Issued

June 29, 2017

Product

Product Name	List Number (LN)	Lot Number	UDI Number
MULTIGENT Quinidine	6L31-20	All	N/A

Explanation

Abbott received the attached letter from Microgenics Corporation, part of Thermo Fisher Scientific and the manufacturer of the MULTIGENT Quinidine reagent, to state that they are conducting a field correction for this assay. Interference from triglycerides occurs at a level lower than what is stated in the package insert. The labeling indicates that interference occurs at 1,127 mg/dL of triglycerides and current data shows interference at 461 mg/dL.

Patient Impact

Please refer to the attached letter from Microgenics Corporation.

Necessary Actions

- Please review the attached letter from Microgenics Corporation and follow the instructions.
- Complete and return the Customer Reply Form.
- Contact Abbott Customer Service for assistance if needed.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
- Please retain this letter for your laboratory records.

Contact Information

We sincerely regret any inconvenience this issue may cause your laboratory. If you or any of the health care providers you serve have any questions regarding this information, U.S. Customers, please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.

URGENT MEDICAL DEVICE FIELD CORRECTION
Thermo Scientific™ Quinidine Assay

Catalog Numbers

6L31-20

June 21, 2017

Dear Lab Manager

The purpose of this letter is to advise you that Microgenics Corporation, part of Thermo Fisher Scientific, is conducting a field correction for the Quinidine Assay. The Quinidine Assay is intended for the quantitative determination of quinidine in human serum or plasma on automated clinical chemistry analyzers. The results obtained are used in the diagnosis and treatment of quinidine overdose and in monitoring levels of quinidine to help ensure appropriate therapy.

REASON FOR FIELD CORRECTION:

Interference from triglycerides occurs at a level lower than what is stated in the package insert. The labeling indicates that interference occurs at 1,127 mg/dL of triglycerides and current data shows interference at 461 mg/dL. Therefore, the package insert is being revised to update the interference limit and the percent recovery.

PRODUCT INFORMATION:

This field correction affects all lots of the Quinidine Assay. The following part numbers are associated with this assay. Our records indicate that you have purchased one or more of these products.

Table 1

Product Name	Catalog Number	Lot Number
Quinidine Assay	6L31-20	All lots under this Catalog Number are affected

RISK TO HEALTH:

If triglyceride interference occurs, it can cause the reported Quinidine value to be lower than expected. The corrected concentration at which triglyceride interference occurs is still well above the normal level found in normal patient samples. Therefore, lower level of triglyceride interference is unlikely to present a risk to patient health.

Triglyceride interference at the corrected level will only have a potential impact on those patients with significantly elevated triglyceride levels. Severe hypertriglyceridemia (500 to 2,000 mg/dL) is rare in the general population, with an estimated prevalence of 1.5%.^{1,3} Among persons with underlying cardiac disease, the prevalence of severe hypertriglyceridemia is estimated to be < 1.0%.^{1,2} Thus, the vast majority of patients undergoing therapeutic drug monitoring of quinidine with the product will be unaffected by the triglyceride interference issue.

ACTIONS TO BE TAKEN BY THE CUSTOMER / USER:

1. Determine if you are using or have inventory of any of the affected lots of Quinidine Assay.
2. Follow your lab QC procedure and Sample Handling instructions provided in the Package Insert.
3. Take note of the corrected triglyceride interference concentration and percent recovery. The Updated Value is in the table below.

References

¹Christian JB, et al. *Prevalence of severe (500 to 2,000 mg/dL) hypertriglyceridemia in the United States adults.* *Am J Cardiol.* 2011 Mar 15;107(6):891-7.
²Klempfner R, et al. *Elevated Triglyceride Level is Independently Associated With Increased All-Cause Mortality in Patients with Established Coronary Heart Disease. Twenty-Two Year Follow-up of the Bezafibrate Infarction Prevention Study and Registry.* *Circ Cardiovasc Qual Outcomes.* 2016;9:100-108.
³Miller M, et al. *Triglycerides and Cardiovascular Disease. A Scientific Statement from the American Heart Association.* *Circulation.* 2011;123:2292-2333.

Table 2

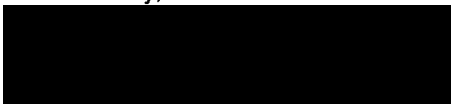
	Triglyceride Concentration	% Quinidine Recovery (6.0 µg/mL)
Product Insert Value	1,127 mg/dL	92.18%
Updated Value	461 mg/dL	90.00%

Please Note: The root cause of the change to the concentration at which Triglyceride interference occurs is still under investigation. The updated value, reported in Table 2 above, has been validated following appropriate clinical laboratory guidelines using kits from four separate lots of the Quinidine Assay.

4. Retain a copy of this letter for your laboratory records.
5. If you have forwarded kits of the affected lots of Quinidine Assay to another laboratory, please provide a copy of this letter to them.
6. Please see attached Abbott's cover letter for further instructions and contact information.

We appreciate your immediate attention to this field correction. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

Sincerely,



David Schultenover, CQE, CPGP
 Sr. Director, Regulatory, Quality and Compliance
 Clinical Diagnostics – Niche Products
 Thermo Fisher Scientific