



April 30, 2019

URGENT: FIELD SAFETY NOTICE

Product: **MicroVue™ C4d Fragment EIA**
Catalog Number: **A008**
Lot Number: **134472**
Manufacturing/Distribution Dates: **2019JAN18 through 2019MAR01**
Expiration Date: **09/30/2019**



Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Quidel Corporation is voluntarily recalling the **MicroVue C4d Fragment EIA**, an enzyme immunoassay for the quantitation of the C4d-containing fragments of activated C4 of the Classical and Lectin Complement Pathways.

Quidel has identified that the material labels of the High Control (Part #A9573) and Low Controls (Part #A9572) as well as the Certificate of Analysis (CoA) for the MicroVue Cd4 Fragment EIA, Item #A008, Lot 134472, contains a typographical error on the acceptable reference ranges.

This product communication is to provide and certify the correct High and Low Control ranges. The corrected CoA is attached to this communication.

Reason for the Voluntary Recall: Quidel has identified that the material labels of the High Control (Part #A9573) and Low Controls (Part #A9572) as well as the Certificate of Analysis (CoA) for the MicroVue Cd4 Fragment EIA, Item #A008, Lot 134472, contains a typographical error on the acceptable reference ranges.

The current range is approximately 20% higher than the true range, which may cause the end user to repeat testing due to High or Low Control values falling outside of the printed range.

Risk to Health:

- MicroVue Cd4 Fragment EIA patient results and High and Low Control results are based on the data generated using the assay Standards, which are unaffected by this Recall.
- To assess if the device has failed, the value of the High or Low Control will be outside of the currently printed range. If this is to occur, the patient data should not be reported, and the test should be repeated. Any data which has been previously generated should be re-evaluated against the corrected High and Low Controls labeling and CoA. Assays with values outside this corrected range should be repeated.



Quidel requests that you take the following actions:

1. Immediately review your inventory and determine if you have any of the affected product remaining. If so, please remove it from inventory and complete the following steps.
2. Please refer to the corrected CoA when utilizing this lot of MicroVue C4d Fragment EIA. Test values generated in this range ensures the product has met performance specifications.
3. It is recommended that any data which has been previously generated be re-evaluated against the corrected High and Low Controls labeling and CoA. Assays with values outside this corrected range should be repeated.
4. The Certificate of Analysis document in any remaining recalled product inventory should be removed, destroyed, and replaced with the corrected Certificate of Analysis.
5. The High and Low Control products must be removed from remaining inventory and disposed of according to local guidelines.
6. Replacement High and Low Control products have been provided. Please replace the recalled controls with the High and Low Controls bearing the correct reference ranges.
7. Please disseminate this notification letter along with the re-labeled replacement High and Low Control products to any customer that may have received the recalled product.
8. Complete the attached **Confirmation of Action** form and return to Quidel via fax number 740.592.9820 or via email to technicalsupport@quidel.com.

Please feel free to contact Technical Support at technicalsupport@quidel.com or by calling 800.874.1517 (in the U.S.) or 858.552.1100 (outside the U.S.) with any questions or concerns that you may have regarding this issue.

Sincerely,

A handwritten signature in blue ink that reads "Lauren Grippa".

Lauren Grippa
Manager, Technical Support

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Confirmation of Action: Customer E-Mail / Fax-Back Form

Customer Instructions: Please confirm that actions prescribed for the product shown below have been completed, sign and date below, then return completed form to Technical Support at:
 e-mail: technicalsupport@quidel.com fax: 740.592.9820.

Product Information/Description:

Catalog Number: **A008**
 Product Description: **MicroVue™ C4d Fragment EIA**
 Lot Number: **134472**
 Manufacturing/Distribution Dates: **2019JAN18 through 2019MAR01**
 Expiration Date: **09/30/2019**

Customer/Distributor Confirmation Information:

Contact Person:	
Company Name:	
City, State, Zip Code:	
Country:	
Telephone Number:	
Fax Number:	
E-mail:	

Affected Product Information:						
Product Names (UDI number)	Manuf. Catalog Number	Lot No. shipped	Quantity in inventory	Quantity re-labeled	Quantity quarantined / destroyed / returned	
MicroVue C4d Fragment EIA (3001461333xxxx)	A008	134472			quarantined	
					destroyed	
					returned	

Customer/Distributor Actions, Response and Signature:

I have read and understand the recall instructions provided in the letter dated April 30, 2019.	Yes	No
	<input type="checkbox"/>	<input type="checkbox"/>
Have there been any adverse events associated with this recalled product?	<input type="checkbox"/>	<input type="checkbox"/>

If yes, please explain:

Please have Customer Support contact me.

Distributors: Check your stock and quarantine recalled product inventory (please indicate number of remaining inventory in the table above); identify and notify your customers that were shipped or may have been shipped recalled product by **specify date and method of notification**.

The information in this document is accurate to the best of my knowledge.

Signature	Title	Date
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