



IMPORTANT: FIELD CORRECTIVE ACTION

January 27, 2023

Product: MicroVue™ C1-Inhibitor Plus EIA
Catalog Number: A037
Lot Number: 213783
Manufacturing/Distribution Dates: 2022-08-30
Expiration Date: 2024-01-31

Dear Valued Customer/Distributor,

Quidel is performing a voluntary Field Corrective Action for the **A037, MicroVue C1-Inhibitor Plus EIA**. Internal investigations at Quidel have confirmed that plates with ID numbers above 2200 received non-uniform plate coating.

As a result of this investigation, Quidel is issuing this communication and requesting that you identify, account for, and remove any kit containing Coated Strips, REF: 4634, with identification (ID) number 2200 and above.

This Field Corrective Action is intended to provide guidance on the next actions for replacement of the affected kits you currently have in stock, as well as information for replacement of used kits which contained plates that failed to produce valid results.

Reason for the notification:

Our records indicate that you have recently received the MicroVue C1-Inhibitor Plus EIA. We are investigating a potential failure of kits that contain Coated Strips with ID numbers 2200 and above. Those kits with affected microtiter plates have the potential to produce low OD values, causing the run to fail, per the Validation requirements of the Package Insert.

Risk to Health:

MicroVue C1-Inhibitor Plus EIA patient results should not be impacted as the reduced OD values for the Controls and/or Standard would have caused the plate to fail, per the Validation requirements of the Package Insert. As a result of this failure, patient results would be invalidated.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Immediately quarantine any remaining inventory of MicroVue C1-Inhibitor, lot 213783.
2. Identify if these materials contain the affected Coated Strips, REF: 4634, with an ID number of 2200 or above.

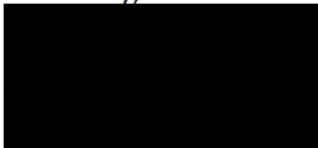
- a. The ID number is printed on both the frame of the microtiter plate as well as on the external plate pouch label. Please refer to images below.



3. Affected Coated Strips will bear an ID number of 2200 or higher. For example, if the ID number found on the external plate pouch is 2350, then the plate is affected, and the entire kit contents should be permanently removed from inventory.
4. Report to Quidel the final count of kits removed from useable inventory using either the attached **Confirmation of Action for End-Users (Attachment 1)** or the **Confirmation of Action for Distributors (Attachment 2)** form.
5. Report to Quidel the number of used kits which produced failing results related to low OD values using the attached form.
6. Return the completed form to Quidel via fax at 740.592.9820 or email at customernotifications@quidel.com.
7. Upon completion and return of the Confirmation of Action form, Quidel will provide the requested replacement materials.

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,



Sr. Manager, Technical Support



Attachment 1

IMPORTANT: FIELD CORRECTIVE ACTION

Confirmation of Action for End-Users: E-Mail / Fax-Back Form

End-User instructions:

Please confirm that actions prescribed for the product shown below has been completed, sign and date below, then **return completed form** to Technical Support at:

E-mail: customernotifications@quidel.com

Fax: 740.592.9820

Product Information/Description:

Catalog Number: **A037**

Product Description: **MicroVue™ C1-Inhibitor Plus EIA**

Lot Number: **213783**

Manufacturing/Distribution Dates: **2022-08-30**

Expiration Date: **2024-01-31**

Customer Confirmation Information:

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

Affected Product Information:

Product Names (UDI number)	Catalog Number	Lot No.	Quantity of Affected Kits Removed from Inventory	Quantity of Previously Failed Kits	On-hand Quantity Destroyed
MicroVue C1-Inhibitor Plus EIA (3001461333558 0)	A037	213783			

Replacements are available from the same lot with these kits containing the unaffected plate ID numbers (Lot 213783) or kits from a new lot (Lot 229556). Please indicate which lot you prefer to receive:

Subject: **IMPORTANT: Field Corrective Action**
A037, MicroVue C1- Inhibitor Plus EIA, lot 213783



Customer Actions, Response and Signature:

	Yes	No
I have read and understand the Advisory instructions provided in the letter dated January 26, 2023.	<input type="checkbox"/>	<input type="checkbox"/>
Any adverse events associated with affected product?	<input type="checkbox"/>	<input type="checkbox"/>

If yes, please explain:

Please have Technical Support contact me.

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

Signature

Title

Date



Attachment 2

IMPORTANT: FIELD CORRECTIVE ACTION

Confirmation of Action for Distributors: E-Mail / Fax-Back Form

Distributor instructions:

Please provide a copy of this communication to your affected customers and provide Quidel with their contact information in the space provided below. In addition, confirm that actions prescribed for the product shown below which remains in your possession has been completed, sign and date below, then **return completed form** to Technical Support at:

E-mail: customernotifications@quidel.com

Fax: 740.592.9820

Product Information/Description:

Catalog Number: **A037**

Product Description: **MicroVue™ C1-Inhibitor Plus EIA**

Lot Number: **213783**

Manufacturing/Distribution Dates: **2022-08-30**

Expiration Date: **2024-01-31**

Affected Customer Information:

Company Name	Contact Name	Contact E-mail	Contact Phone	Company Address	Country

Distributor Confirmation Information:

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



Affected Product Information:

Product Names (UDI number)	Catalog Number	Lot No.	Quantity of Affected Kits Removed from Inventory	On-hand Quantity Destroyed
MicroVue C1-Inhibitor Plus EIA (3001461333558 0)	A037	213783		

Replacements are available from the same lot with these kits containing the unaffected plate ID numbers (Lot 213783) or kits from a new lot (Lot 229556). Please indicate which lot you prefer to receive:

Distributor Actions, Response and Signature:

I have read and understand the Advisory instructions provided in the letter dated January 26, 2023.

Yes

No

I have notified all end-users who received this product.

Any adverse events with affected product?

If yes, please explain:

Please have Technical Support contact me.

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

Signature

Title

Date