BIO-RAD

Bio-Rad Laboratories

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Marnes-la-Coquette, November 27, 2023

Ref. Letter Field Safety Corrective Action ID 2023-001

Field Safety Notice

This information is intended for the end user of this product
If you are not the end user, please forward this information to
the appropriate laboratory personnel

Dear Valued Customer,

This letter is to inform you of a Field Safety Notice for the following product from Bio-Rad (SRN FR-MF-000006261):

Monolisa HCV Ag-Ab ULTRA V2

Code Number 72561 (1 plate - 96 tests) - UDI (01)03610520013762
Code Number 72562 (5 plates - 480 tests) - UDI (01)03610520013779

Current batches on the market:

Code article	Batch	Expiration date
72561 96 tests	2J0063	2024-01-28
	2L0064	2024-03-24
	3A0065	2024-06-09
	3B0066	2024-07-14
	3B1066	2024-07-14
	3C0067	2024-08-11
	3H0068	2024-12-22
	3K0069	2025-02-25
72562 480 tests	2J0579	2024-01-28
	2L0580	2024-03-24
	3A0581	2024-06-09
	3B0582	2024-07-14
	3D0583	2024-09-01
	3F0584	2024-10-13
	3H0585	2024-12-22
	3K0586	2025-02-25

We have observed a decrease of HCV antigen sensitivity for specimens that are near the limit of detection. Due to this decrease in HCV antigen sensitivity, a recent HCV infection may not be detected in patient samples as early as prior batches of the **Monolisa HCV Ag-Ab ULTRA V2** assay. There is no impact to seroconversion observed for these batches through HCV antibody detection.

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All batches of **Monolisa HCV Ag-Ab ULTRA V2** assay currently on the market have been tested on 12 HCV seroconversion panels. A few additional days of delay (≤ 7 days on average) for HCV Antigen positivity are observed in seroconversion sample testing when compared to HCV NAT testing and predicate combined Ag-Ab HCV assay testing results in the original performance studies provided in the IFU. Early HCV infections are still detectable with positive HCV Antigen prior to HCV antibody assays (>12 days on average).

The **Monolisa HCV Ag-Ab ULTRA V2** assay batches currently on the market can continue to be used as intended for detection of infection by HCV based on the detection of anti-HCV antibodies and capsid antigen in serum or human plasma. In case of suspected early HCV infection, we recommend performing HCV NAT testing in addition to testing on the **Monolisa HCV Ag-Ab ULTRA V2** assay.

We would like to inform you that our Notified Body and our European Competent Authority (ANSM) have been informed about this field safety notice.

We apologize for the inconvenience and your local customer technical support remains available for any further information. We are currently actively working to resolve this matter.

Please forward this letter to whomever it may concern.

Sincerely,

[redacted]

Sylvie Fernez
Associate Director Regulatory Affairs
Bio-Rad
France

GLOBAL FIELD ACTION FORMS	
Global Process Owner:	**RAQA**

CUSTOMER FIELD ACTION RESPONSE FORM

Field Action Reference Number: ID 2023-001
Bio-Rad Product Segment: Infectious Disease
Single Registration Number (SRN): FR-MF-000006261

PRODUCT

Product UDI	Product Name	Catalog No	Serial/ Lot No	Expiry Date	Software Version
03610520013762	Monolisa HCV Ag/Ab ULTRA V2	72561			
03610520013779	Monolisa HCV Ag/Ab ULTRA V2	72562			

CUSTOMER INFORMATION

Account Name:	
Undersigning Manager Name:	
Address:	
Telephone Number / Fax:	
Customer Account Number:	

STATEMENT:

- ☐ No affected product received
- ☐ I am aware of the information about the field action concerning the above reference product(s) and have proceeded according to the instructions issued by Bio-Rad.

Number of affected products received:		Number of affected products corrected/ destroyed/ returned (as applicable to the Field Action instructions):	
If number of products corrected/ destroyed/ returned is different to the number received, please account for the difference:			

Date: Customer Signature (and Stamp if applicable)

PLEASE RETURN THIS FORM TO: [ENTER LOCAL DETAILS]