



Abbott Diagnostics Technologies AS
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Enterprise No. NO 981 363 019 MVA

May 22, 2024

Dear Distributor,

This letter is to inform you that Abbott Diagnostics Technologies AS, manufacturer of the Afinion™ products, is performing a product field safety notice (FSN) relating to the Afinion™ 2 analysers. Please refer to the enclosed customer field safety notification (FSN) letter for details of the actions required.

The following products are in scope:

Product Description	Part Number(s)	UDI	Serial number(s)
Afinion™ 2 , IN	1116772	7070060014432	Series AF20052000 to AF20060000
Afinion™ 2 , JP	1116774	7070060014456	
Afinion™ 2 , NOR	1116777	7070060014487	
Afinion™ 2 , NOR	1116778	7070060014494	
Afinion™ 2	1116770	7070060014418	
Afinion™ 2	1116771	7070060014425	
Afinion™ 2 , IN	1117030	7070060015118	

Actions to be taken:

1. Run a traceability report of Afinion 2 to identify all end customers with name, address, contact information that have received the product within the serial range identified above.
2. Acknowledge the receipt of this letter within 5 business days after receipt using the enclosed FSN distributor acknowledgement form, indicating instrument inventory on-hand, as applicable.
3. Send the enclosed customer letter to the end users (customers) within 5 business days after receipt of this letter.
 - a. Reconcile and document receipt of the customer reply form.
 - b. At minimum, 3 documented attempts need to be made to request receipt of the customer reply.
4. Upon completion of the receipt of customer reply forms, provide a list customer acknowledgement to CMIFIELDACTION@abbott.com.

Enclosed document for reference:

- Distributor reply form and the Customer Letter/Customer Reply form

Sincerely,

David Gillooly
Director Quality & Compliance
Abbott Diagnostics Technologies AS

Field Safety Notice - Distributor acknowledgment form

Afinion™ 2

This response form is to confirm the receipt of this notification.

1. Distributor Details

Account/Customer Number	
Distributor name Name*	
Contact name*	
Title or function	
Telephone number*	
E-mail*	
Organisation Address*	
Quantity on Hand – if applicable	

2. Distributor action undertaken

<input type="checkbox"/>	I confirm that we, the Distributor, have received this Notification Letter.*
<input type="checkbox"/>	If I encounter any questions regarding this product correction, I will direct inquiries to Abbott Technical Service.
<input type="checkbox"/>	I confirm that we, the Distributor, will be sending the Customer Notification Letter to all customers impacted by the scope of this Product Correction.

Mandatory fields are marked with *

3. Return acknowledgement to sender

Email	CMIFIELDACTION@abbott.com
Deadline for returning the distributor reply form*	Please complete and return this form within 5 business days of receipt