

Field Safety Notice

**IDL Biotech's UBC Rapid
(UDI: (01)17350040681388(17)220630(10)3170,
Manufacturer's SRN: SE-MF-000014846)
Batch F-3280 not stable after 20 months of storage**

Dear Customer,

In an in-house stability study of UBC Rapid batch F-3280 it was discovered that after 20 months of storage the signal loss was outside the specification limit. This means that if UBC Rapid batch F-3280 is still used for testing samples with cytokeratin concentration lower and slightly above 30 µg/l:

- 1) False negative result can be obtained for patients having cytokeratin concentration slightly above 10 µg/l, where the correct result should be slightly elevated (inconclusive).
- 2) Inconclusive result can be obtained for patients having cytokeratin concentration slightly above 30 µg/l, where the correct result would be positive (elevated).

All acceptance criteria were met for UBC Rapid batch F-3280 at product release. UBC Rapid lot F-3280 was performing according to the set specification limits.

Our risk assessment indicates that this error does not lead to a serious risk to the patient.


In relation to this notice, we would like to ask you to perform the following actions:

- 1) Stop using UBC Rapid batch F-3280 and destroy it or send it back to the distributor together with the attached Customer Reply Form as soon as possible but no later than 2023-05-31. The destroyed kits will be replaced free of charge.
- 2) We advise the clinicians to follow up the results of patients tested **only** with UBC Rapid batch F-3280 in the last four months.

For any questions or considerations, please contact our local representative: Christian Wandschneider, cwandschneider@concile.de, +49(0)76115 14 7410, Kronenmattenstrasse 6, 791 00 FREIBURG, Germany

We strive to provide high quality products that are clinically useful, match customer expectations and fulfill the regulatory requirements. We apologize for the inconvenience this has caused you. Thank you for your understanding and support.

Best regards,


Quality Assurance Officer

Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN UBCR F-3280
FSN Date*	2023-04-20
Product name*	UBC Rapid
Product Code(s)	10-138
Batch/Serial Number (s)	F-3280

2. Customer action undertaken on behalf of Healthcare Organisation			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.		
<input type="checkbox"/>	I performed all actions requested by the FSN.		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.		
<input type="checkbox"/>	<table border="0" style="width: 100%;"> <tr> <td style="width: 35%;">I have affected products stock</td> <td>If yes, please indicate how many test cassettes you have in stock: Customer to complete</td> </tr> </table>	I have affected products stock	If yes, please indicate how many test cassettes you have in stock: Customer to complete
I have affected products stock	If yes, please indicate how many test cassettes you have in stock: Customer to complete		
<input type="checkbox"/>	<table border="0" style="width: 100%;"> <tr> <td style="width: 35%;">I have returned affected products - enter number of products returned and date complete.</td> <td>Qty (test cassettes):</td> </tr> </table>	I have returned affected products - enter number of products returned and date complete.	Qty (test cassettes):
I have returned affected products - enter number of products returned and date complete.	Qty (test cassettes):		
<input type="checkbox"/>	<table border="0" style="width: 100%;"> <tr> <td style="width: 35%;">I have destroyed affected products – enter number destroyed and date complete.</td> <td>Qty (test cassettes):</td> </tr> </table>	I have destroyed affected products – enter number destroyed and date complete.	Qty (test cassettes):
I have destroyed affected products – enter number destroyed and date complete.	Qty (test cassettes):		
<input type="checkbox"/>	I do not have any affected products.		
Print Name and address*	Customer print name and address or stamp here		
Signature*	Customer signature here		
Date*			

3. Return acknowledgement to sender	
Email	cwandschneider@concile.de
Customer Helpline	+49(0)76115 14 7410
Postal Address	Kronenmattenstrasse 6, 791 00 FREIBURG, Germany
Web Portal	https://www.concile.de/

Fax	+49 761 1514 7419
Deadline for returning the customer reply form*	2023-05-31

Mandatory fields are marked with *

The destroyed kits will be replaced free of charge.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.