

Date: 16042021

Urgent Field Safety Notice
UBC Rapid

For Attention of*:Christian Wandschneider

Contact details of local representative (name, e-mail, telephone, address etc.)*

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Urgent Field Safety Notice (FSN)

UBC Rapid 10-138

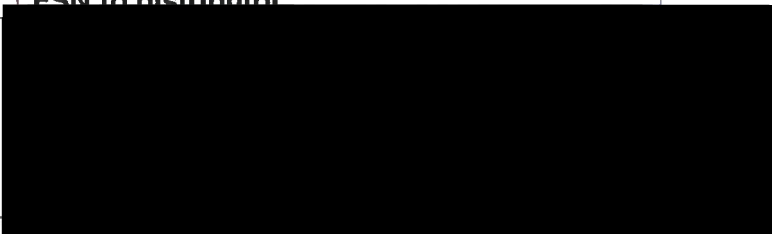
Risk addressed by FSN

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	UBC Rapid, article number 10-138
1	2. Commercial name(s)
.	UBC® Rapid
1	3. Unique Device Identifier(s) (UDI-DI)
.	(01)17350040681388(17)220630(10)3170
1	4. Primary clinical purpose of device(s)*
.	UBC® Rapid is a lateral flow immunoassay for aid in diagnosing and monitoring of bladder cancer patients in conjunction with standard diagnostic procedure. UBC® Rapid can also be used for early detection of patients with symptoms of bladder cancer and for patients at risk to develop bladder cancer. It measures soluble fragments of cytokeratin 8 and 18 in urine samples.
1	5. Device Model/Catalogue/part number(s)*
.	10-138
1	6. Software version
.	N.A
1	7. Affected serial or lot number range
.	Only affect the current batch F-3170
1	8. Associated devices
.	N.A

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	The product currently fulfils the acceptance criteria. However, an adverse trend has been observed during the ongoing stability study, posing risk for future non-fulfilment of the acceptance criteria.
2	2. Hazard giving rise to the FSCA*
.	No hazard has been identified for the use of the product so far, but there is a potential hazard of stability failure if continuously used.
2	3. Probability of problem arising
.	It is probable (level 4) that a stability failure occurs if the product is continuously used.
2	4. Predicted risk to patient/users
.	If stability failure (hazard) happens, a false negative result (hazardous situation) could occur, which may cause indirect harm to patient due to delayed treatment. However, according to Instruction for use, the result should be interpreted in conjunction with all available clinical and diagnostic data of the patient and not be interpreted as absolute evidence for the presence or absence of transitional cell carcinomas of the urinary bladder. If standardised methods indicate presence of bladder cancer the patient will be further investigated despite the negative UBC® Rapid test. Thus, this is considered a minor (2) severity. The risk RPN level is 8.
2	5. Further information to help characterise the problem
.	N.A

2	6. Background on Issue
.	The adverse trend was observed during the ongoing stability study as the concentration decision point at 700000 has increased significantly during the 8 months storage (28 µg/l) and close to the upper specification limit (30 µg/l). The lot was set on stability study due to difficulties of adjusting the process parameters during the manufacturing and therefor had a longer production time compared with other batches.
2	7. Other information relevant to FSCA
.	No other batch of UBC Rapid is affected by the problem.

3. Type of Action to mitigate the risk*	
3.	<p>1. Action To Be Taken by the User*</p> <p> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Provide further details of the action(s) identified.</p>
3.	<p>2. By when should the action be completed? As soon as possible, and no later than 2021-05-15.</p>
3.	<p>3. Particular considerations for: IVD</p> <p>Is follow-up of patients or review of patients' previous results recommended? No UBC Rapid lot F-3170 has been performed in accordance with the set specification limits, therefore all results obtained by the product so far have been valid.</p>
3.	<p>4. Is customer Reply Required? * Yes (If yes, form attached specifying deadline for return)</p>
3.	<p>5. Action Being Taken by the Manufacturer</p> <p> <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Recall UBC Rapid lot F-3170</p>
3	<p>6. By when should the action be completed? The distributor should have received all remaining unused test no later than 2021-06-15.</p>
3.	<p>7. Is the FSN required to be communicated to the patient /lay user? Yes</p>
3	<p>8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?</p> <p>Yes Not appended to this FSN</p>

4. General Information*	
4.	1. FSN Type* New
4.	2. For updated FSN, reference number and date of previous FSN Provide reference and date of previous FSN if relevant
4.	3. For Updated FSN, key new information as follows: Summarise any key difference in devices affected and/or action to be taken.
4.	4. Further advice or information already expected in follow-up FSN? * Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to: Eg patient management, device modifications etc
4	6. Anticipated timescale for follow-up FSN For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name IDL Biotech AB
	b. Address Karlsbodavägen 39, Bromma
	c. Website address www.idlbiotech.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *
4.	9. List of attachments/appendices: FSN to distributor
4.	10. Name/Signature 

Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*</p>

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.