

Date: 20/06/2024

Urgent Field Safety Notice
Proclarix® Risk Calculator (REF. PCLX RICALI)
Underestimation of Proclarix® Risk Score due to overestimated
bioMérieux VIDAS® FPSA

For attention of the Laboratory Director and/or any other personnel responsible for the release of patient results.

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1. Affected products			
Product	REF	UDI-DI	Versions
Proclarix® Risk Calculator The Proclarix® Risk Calculator is a software to integrate the results from Proclarix® Assays together with age, total and free PSA (from third party manufacturers) to calculate the Proclarix® Risk Score. The Proclarix® Risk Score can be used as an aid in discriminating between high-grade (Gleason Score ≥ 7) prostate cancer and low-grade prostate cancer or benign prostate disease. Prostate biopsy is required for diagnosis of prostate cancer. Proclarix® is indicated in men with elevated total PSA (2.0 to 10.0 ng/mL), a digital rectal examination finding consistent with elevated prostate volume (≥ 35 mL) and not suspicious for cancer. It is intended for professional use only.	PCLX RICALI	7649992696PCLXRICALIXV	2.1.1 2.2.1

2. Reason for Field Safety Corrective Action (FSCA)																																					
1. Description of the problem																																					
An overestimation of free PSA results was observed by bioMérieux (VIDAS® FPSA - Ref. 30440 - Slow Drift leading to potential Overestimated Result - FSCA - FIELD SAFETY CORRECTIVE ACTION - FA-TWD-000006). Affected bioMérieux lots: <table border="1"> <thead> <tr> <th>Lot Number/Serial Number/Product version</th><th>Product Expiration Date (if applicable)</th></tr> </thead> <tbody> <tr><td>1009453100</td><td>23-May-23</td></tr> <tr><td>1009487340</td><td>21-Jun-23</td></tr> <tr><td>1009584820</td><td>18-Aug-23</td></tr> <tr><td>1009650220</td><td>12-Sep-23</td></tr> <tr><td>1009698340</td><td>13-Oct-23</td></tr> <tr><td>1009807810</td><td>13-Dec-23</td></tr> <tr><td>1009875100</td><td>17-Jan-24</td></tr> <tr><td>1009916000</td><td>08-Feb-24</td></tr> <tr><td>1009971000</td><td>12-Mar-24</td></tr> <tr><td>1010036350</td><td>12-Apr-24</td></tr> <tr><td>1010130650</td><td>11-Jun-24</td></tr> <tr><td>1010229580</td><td>01-Aug-24</td></tr> <tr><td>1010274360</td><td>03-Sep-24</td></tr> <tr><td>1010357680</td><td>16-Oct-24</td></tr> <tr><td>1010462360</td><td>04-Dec-24</td></tr> <tr><td>1010540310</td><td>11-Jan-25</td></tr> <tr><td>1010630590</td><td>15-Mar-25</td></tr> </tbody> </table> Free PSA serves as one of the input values of the Proclarix® Risk Calculator and is combined with the results of the Proclarix® Assays, age and total PSA to generate the Proclarix® Risk Score. An overestimation of free PSA leads to an overestimation of the PSA ratio, which leads to an underestimation of the Proclarix® Risk Score. Corrected thresholds suggested by bioMérieux cannot be applied onto the results of the Proclarix® Risk Calculator.		Lot Number/Serial Number/Product version	Product Expiration Date (if applicable)	1009453100	23-May-23	1009487340	21-Jun-23	1009584820	18-Aug-23	1009650220	12-Sep-23	1009698340	13-Oct-23	1009807810	13-Dec-23	1009875100	17-Jan-24	1009916000	08-Feb-24	1009971000	12-Mar-24	1010036350	12-Apr-24	1010130650	11-Jun-24	1010229580	01-Aug-24	1010274360	03-Sep-24	1010357680	16-Oct-24	1010462360	04-Dec-24	1010540310	11-Jan-25	1010630590	15-Mar-25
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2. Hazard giving rise to the FSCA																																					
Patients whose Proclarix® Risk Score was calculated using free PSA values from one of the affected lots are at risk of having a false negative result. Their Risk Score could be below the 10%																																					

cut-off indicating a low risk for clinically significant prostate cancer (csPCa) only because of the overestimation of free PSA. Patients whose Proclarix® Risk Score was above the cut-off also received underestimated Proclarix® Risk Scores, but the clinical interpretation of the result should not be affected. It may be however, if patient and physician decided against a prostate biopsy based on the combination of a Proclarix® result just above the cut-off value and other available diagnostic results (e.g., additional biomarker tests or an MRI).

3. Action to be taken

- We advise all customers to refrain from using one of the affected VIDAS® FPSA lots in combination with Proclarix®. Corrected thresholds for the clinical interpretation of PSA ratios as suggested by bioMérieux are not applicable for Proclarix®. No corrected threshold for Proclarix® Risk Scores generated with the affected VIDAS® FPSA lots can and will be given.
- For Proclarix® Risk Scores generated since May 2023 using one of the affected VIDAS® FPSA lots, we strongly recommend informing physicians about the implications on Proclarix® Risk Scores:
 - Patients with a result below 10% (low risk for clinically significant prostate cancer) may have had a false negative result. Re-testing should be performed.
 - Patients with a result above 10% were correctly diagnosed with a high risk for clinically significant prostate cancer, but the absolute value of the Proclarix® Risk Score was underestimated. Re-testing should be considered on a case-by-case basis by the physician. If a higher Proclarix® Risk Score would have changed the physician's decision on further treatment, re-testing may be advised. If a biopsy has been performed in the meantime, re-testing may not be necessary.All re-testing should be performed using PSA values from new VIDAS® FPSA lots conform with bioMérieux' performance claims or from other PSA systems supported by Proclarix® Risk Calculator.
- Where patients need to be informed directly (e.g., self-testers), patients instead of physicians should be informed as explained above.

- The Competent Authority of your country has been informed about this communication to customers.
- This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- 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.

Please return the acknowledgement form “3039_FO_FSN Customer Reply_PCLX underestimation_006-24_v02_240620” to contact@proteomedix.com.

Change History

Version	Description of changes	Date	Author	Type
1	Initial version	240617	RHU	-
2	Extended list of affected VIDAS® FPSA lots	240619	RHU	Major
3	Adapted instructions to reflect usual information flow from lab to physician to patient	240620	RHU	Major

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	006-24
FSN Date	17/06/2024
Product/Device name	Proclarix® Risk Calculator
Product Code	PCLX RICALI
UDI-DI	7649992696PCLXRICALIXV
Version Numbers	2.1.1 2.2.1

2. Customer Details	
Organisation Name	
Organisation Address	
Contact Name	
Phone	
Email	

3. Customer action undertaken on behalf of organisation	
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.
☐	The information has been brought to the attention of all relevant users.
☐	I performed all corrective actions as requested by the FSN.
☐	I am not affected by the FSN. Please state reason(s):
Name	
Date	
Signature	

It is important that your organisation takes the actions detailed in the FSN and confirms that the FSN has been received. Please return signed form to contact@proteomedix.com.

Change History

Version	Description of changes	Date	Author	Type
1	Initial version	240617	RHU	-
2	Added "not affected by FSN" option	240620	RHU	Major