Proteomedix

Date: 17/09/2024

Urgent Field Safety Notice
Proclarix® Risk Calculator (REF. PCLX RICALI)
PSA quality control and the effects of incorrect total and free PSA input values on the Proclarix® Risk Score

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

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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	07649992696025	All

2. Reason for Field Safety Corrective Action (FSCA)

1. Description of the problem

Total and free PSA serve as input values of the Proclarix® Risk Calculator and are combined with the results of the Proclarix® Assays and age to generate the Proclarix® Risk Score. It is crucial that quality control is not only performed for the Proclarix® Assays, but also for PSA tests from third party manufacturers that are used to generate input values for the Proclarix® Risk Calculator. To emphasise the importance of internal and external quality control for PSA and to clarify how "wrong" input values affect the Proclarix® Risk Score, the following information was added to revision **PCLX-IFU-240916-16** of the PCLX ASSAYS & PCLX RICALI IFU and revision **RICALI-IFU-240916-08** of the PCLX RICALI IFU:

> **INTERNAL AND EXTERNAL QUALITY CONTROL OF PSA TESTS**
>
> As the Proclarix® Risk Calculator is a software to integrate not only results of the Proclarix® Assays, but also PSA values from third party manufacturers, those values must be accurate, i.e., inside the claimed specifications as stated on their QC Certificate. PSA tests are typically standardized through calibration to International Standards. This is to assure that differences between PSA test manufacturers and lot-to-lot variations as accounted for by the software do not have an impact on the calculation of the Proclarix® Risk Score. Shifted, changed or otherwise adjusted PSA values (even if suggested by the PSA manufacturer) that result in adapted clinical decision thresholds shall not be used to calculate Proclarix® Risk Scores under any circumstances.
>
> The impact could be as follows:
>
> - An overestimated total PSA value leads to a higher Proclarix® Risk Score and thus a potential false positive result, while an underestimated total PSA value leads to a lower Proclarix® Risk Score and thus a potential false negative result. In regard to free PSA, the behaviour is the opposite: an overestimated free PSA value results in a lower Proclarix® Risk Score and thus a potential false negative result, while an underestimated free PSA value leads to a higher Proclarix® Risk Score and thus a potential false positive result.
> - An overestimated total PSA value combined with an underestimated free PSA value leads to a cumulatively higher Proclarix® Risk Score, further increasing the possibility of a false positive result. Consequently, an underestimated total PSA value combined with an overestimated free PSA value leads to a cumulatively lower Proclarix® Risk Score, further increasing the possibility of a false negative result.
> - If total and free PSA values are both either overestimated or underestimated (both in the same direction), the effect on the Proclarix® Risk Score varies depending on the absolute magnitude of the errors and the relative difference between the incorrectly estimated values.
>
> Medical laboratories are recommended to follow ISO 15189 or similar national accreditation standards, establish their own internal controls and their own reference ranges and participate in External Quality Assessment (EQA) programs to verify by objective controls their laboratory's performance and produced results.

Please also note that, as a consequence of bioMérieux FSCA FA-TWD-000006, you will no longer be able to use bioMérieux PSA values until further notice. This option is no longer supported in the currently active Proclarix® Risk Calculator version 2.2.1, configuration version 4.

2. Hazard giving rise to the FSCA

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). Proclarix® Risk Scores generated with FPSA values from one of the affected lots were underestimated, as was communicated before in urgent field safety notice PMX_FSN_006-24_PCLX-RICALI by Proteomedix.

3. Action to be taken

- We advise all customers to follow the recommendations related to internal and external quality control of PSA tests as stated above and in IFU revisions **PCLX-IFU-240916-16** and **RICALI-IFU-240916-08**.
- We advise all customers to refrain from using total and free PSA values to calculate Proclarix® Risk Scores if the correctness of those PSA values is not ensured by quality control measures.
- Please discard or delete any copy of older IFU revisions. Distribute the new IFU revisions **PCLX-IFU-240916-16** and **RICALI-IFU-240916-08** as required to ensure that PSA quality control recommendations are perceived by all responsible staff.

- 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_PSA Quality Control for PCLX_006-24_v01_240917" to contact@proteomedix.com.

Change History

Version	Description of changes	Date	Author	Type
1	Initial version	240917	RHU	-

FSN Customer Reply

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSCA reference number	006-24
FSN reference	PMX_FSN2_006-24_PCLX-RICALI
FSN Date	17/09/2024
Product/Device name	Proclarix® Risk Calculator
Product Code	PCLX RICALI
UDI-DI	07649992696025
Version Numbers	All

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 acknowledge that it is my organization's responsibility to ensure the correctness of PSA values used as input for the Proclarix® Risk Calculator, e.g., by performing internal and external quality control for PSA tests of third party manufacturers.
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

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1	Initial version	240917	RHU	-