



## Field Safety Notice

N°01/2023

Date 31.05.23

CATALOGUE/PART NUMBER/REF	PRODUCT NOME	LOT NUMBER	EXPIRATION DATE
LC77016	Calibrator for Biogenes Amines in urine	007	2026-03
LC77019	Control for Biogenes Amines in urine	007	2026-03

REF	UDI-DI	SRN
LC77016	803367312LIO7015T	IT-MF-000034499
LC77019	803367312LIO7025V	IT-MF-000034499

### Details on Affected Devices

This letter contains important information regarding:

- LC77016 Calibrator for Biogenes Amines in urine
- LC77019 Control for Biogenes Amines in urine

Please review the below information carefully and follow the necessary actions.

### Description of the problem

A thorough examination at customer site of the calibrator performance showed that the Noradrenaline values were overestimated. The cause was found to be a human error in reporting the Noradrenaline calibrator value in the technical sheets.

### Patient Impact

The accuracy of patient results is not affected. However the use of LC77016 calibrator for Biogenes Amines in urine and LC77019 Control for Biogenes Amines in urine may cause a delay in patient result reporting.

A delay in obtaining the test results would not represent an immediate risk for the patient as Noradrenaline is not a unique marker for catecholamine-secreting tumors and a clinical decision is not based only on the Noradrenaline result. Impact on patient management can be considered low.

### Action to be taken

- 1- In order to use the product properly, please follow the instructions described here below
- 2- Fill in all the required fields of the "receipt of the Safety Notice" and return it to your local representative
- 3- Review the content of this communication with your Medical Director, and retain this letter for any future reference.



If the following lots of LC77016 Calibrator for Biogenes Amines in urine and LC77019 Control for Biogenes Amines in urine have been distributed inside or outside your company, please consider the new following values

LC77016 Calibrator for Biogenes Amines in urine lot 007									
	Analyte	Measurement unit	C0	C1	C2	C3	C4	C5	C6
NEW TARGET VALUES	Noradrenaline	µl/l	15,7	22,6	56,3	80,5	147,3	202,6	271,1
OLD TARGET VALUES	Noradrenaline	µl/l	30,4	45,7	145,7	225,1	442,0	818,8	1066,0

LC77019 Control for Biogenes Amines in urine lot 007								
	Analyte	Measurement unit	MEDIUM VALUE L1	RANGE L1	MEDIUM VALUE L2	RANGE L2	MEDIUM VALUE L3	RANGE L3
NEW TARGET VALUES	Noradrenaline	µl/l	67,2	47,0-87,3	176,7	123,7-229,7	225,4	157,7-293,0
OLD TARGET VALUES	Noradrenaline	µl/l	265,9	186,1-345,7	739,7	517,8-961,6	944,6	661,2-1227,9

#### Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organization or to any organization/individuals where the potentially affected devices have been transferred.

#### Reference person

If you or any of your customers have any questions regarding this information, please contact Eureka Customer Service at [info@eurekaone.com](mailto:info@eurekaone.com)

We apologize for any inconvenience this may cause and thank you for your collaboration.

Best regards

AQ/RA  
Dr.ssa Miranda Moroni