

Urgent Field Safety Notice

SBN-CPS-2018-023

CPS / Point of Care
Version 1
Dec-2018

Accutrend BM-Lactate: altitude claim change

Product Name	BM-Lactate
System	LACT Accutrend® Plus system
GMMI / Part No	GMMI 03012654370
Device Identifier	GMMI 03012654016
Production Identifier (Lot No/Serial No)	All
SW Version	N/A
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

This FSN is limited to Health Care Professionals, using the affected product in altitudes above 2000 m sea level.

Description of Situation

It has come to our attention that in the method sheet it is claimed that the BM Lactate test can be carried out at altitudes up to 3000 meters (m). Current measurements performed in pressure chambers showed that deviations of measured values at 3000 m are higher than specified.

The criterion to be met is that 95.5 % of all values are within $\pm 23\%$ from 3 to 15 mmol/L. Below this region ± 0.7 mmol/L apply.

Current measurements were carried out with samples between 0.9 mmol and 4.9 mmol. At 2000 m all values are within the allowed total error range. At 3000 m product performance was out of specification. Please find in the table below the allowed error and deviations based on concentration and percentage.

Concentration mmol/L	Allowed error mmol/L	Deviations from target value				
		Ø Result mmol/L	Maximum result mmol/L	Difference Ø mmol/L	Maximum difference mmol/L	Maximum difference %
4,9	1,13	0,83	1,23	-0,29	0,10	25%
3,4	0,78	0,88	1,12	0,10	0,34	33%
<3	0,70		0,90		0,20	40-60%

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For erroneous results a medical risk cannot entirely be excluded.

Above an altitude of more than 2000 m above sea level a medical risk for the patient population at greatest risk cannot entirely be excluded, if lactate is used in a clinical situation (hospital settings) (e.g. ICU, critically ill patients) to diagnose ischemic conditions like mesenteric infarction. In the worst case unnecessary diagnostics (e.g. intra-arterial DSA) would be initiated.

Note: Therefore, this FSN is limited to Health Care Professionals, using the affected product in altitudes above 2000 m sea level.

Actions taken by Roche Diagnostics

For selected lots already manufactured or currently in production: An Important Notice will be added in the BM-Lactate package.

- ❖ *Starting with lot 34933001, the Instructions for Use will be updated in all packages/ language versions.*

Actions to be taken by the customer/user

In order to prevent any risk to your and our valued patients we ask you for the following actions:

- ❖ *Ensure that all measurements with BM-Lactate tests are performed up to max. 2000 m above sea level. **Do not use** the product for measurements above 2000 m sea level for the described patient population*

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization where the devices have been distributed/supplied. (If appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Accutrend BM-Lactate: altitude claim change



Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com