Ö	**Immediate Action Required**
	Action Required
	Information Only

URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Field Safety Notice Ref No: BFSN_02_16 cobas b221<6>: Potentially incorrect Urea results SB-CPS-2016-20
Document Date: 19/10/2016
Type of Action: Field Corrective Action

Product Affected:	GLU/LAC/UREA(BUN) Cassette
System Affected:	**cobas b** 221 <6>
Summary of Issue:	Potentially incorrect Urea Results

Details of Affected Devices:	**cobas b** 221 <6>
Material No:	03261085184
Lot: No:	All

Reason for Notice:	We have become aware of an issue that may lead to erroneous Urea results. The issue occurs sporadically and can lead to an under- or over-recovery of the Urea sample result and/or QC result. The issue was discovered internally and no cases have been reported from the global market thus far. We have identified temporary measures that reduce the occurrence and ensure the detectability of the issue until a final solution will be provided with the next SW Version in January 2017. Internal studies revealed a software issue which affects the Urea sample measurement results. The Urea recovery for samples and QC measurement results can be both, too low or too high. All customers using any lot of MSS Cassettes GLU/LAC/UREA(BUN) to test for Urea on the cobas b 221 <6> instrument are affected. To avoid any risk of reporting wrong patient sample results for the Urea parameter, sample measurements have to be measured two times until this issue is fixed in an upcoming software version, planned for January 2017. Glucose and Lactate measurement results are not affected. The medical risk for patients with falsely lowered urea values

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can be considered remote since no medical consequence will arise from lowered urea values alone except in children. Beside the patients most at risk, the risk for the overall patient population, with falsely low or high values, is considered remote. No severe adverse health effects are to be expected within that deviation, but further unnecessary diagnostic measures may be initiated.

Falsely normal results may cause, that further necessary examination is not carried out, with the possibility of a delay in the diagnosis and treatment. A medical risk cannot entirely be entirely excluded therefore the workaround described in the next section has been developed until the issue is fixed in the upcoming software version.

Action Required:

The operator is advised to determine the Urea sample concentration by measuring in duplicate in case the Urea measurement result will be used for further medical decisions.

If at least one of the two measurement results is greater or equal to 2 mmol/L and the bias between the two results differ by more than 15 %, a third measurement of the sample is required in order to determine the correct sample concentration. If both of the results are below 2 mmol/L, a third measurement is needed when the difference is more than 0.3 mmol/L.

The repeated measurements from the same sample should be done on the same device immediately (no longer than 30 minutes after the initial measurement) as stated in the Instruction For Use for the cobas b 221 system (V14.1, chapter 6: Measurement / Preanalytics / Sample handling).

Either of the matching results from the repeated measurements can be reported if the measurement bias is within the limits described above.

Multiple measurements for the Urea parameter need to be performed until the issue has been fixed in the updated software version.

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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

Kindly complete the attached Fax Back form and return by no later than 11th November 2016

Actions taken by Roche Diagnostics

Software Version where the issue is solved will be made available January 2017.

Attachments: BFSN_02_16 cobas b221<6>: Potentially incorrect Urea results SB-CPS-2016-20 Fax back

This action is being conducted with the knowledge of the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Products Regulatory Authority (HPRA), and other International Regulatory Agencies.

** Please bring this notice to the attention of all personnel in your hospital/ Health Care facility who need to be aware of this safety issue. If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this letter to them. **

If you require any further information please contact our Professional Services Department / Technical Support Hotline on:
UK: 0808 100 19 20
Ireland：1800 40 9 564

A copy of this notice can also be found on www.cobas-roche.co.uk

To enable Roche Diagnostics to fulfil its vigilance duties in entirety with respect to the IVD Directive 98/79 EC, please complete and return the fax-back form which accompanies this Field Safety Notice.

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