

Urgent Field Safety Notice

SBN-CPS-2018-006

CPS / Hematology

Version 1

xx-May-2018

cobas m 511 integrated hematology analyzer: Potential for discrepant RBC, HGB, MCH, HCT, MCV results in patients with severe microcytic anemia and thalassemia

Product Name/Description	cobas m 511 integrated hematology analyzer
GMMI / Part No	07261691190
Device Identifier	
Production Identifier (Lot No./Serial No.)	All
SW Version	Version 1.0
Type of Action	Field Safety Notification

Dear Valued Customer,

Roche Diagnostics regrets to inform you of reported cases affecting the **cobas m 511** integrated hematology analyzer.

Description of Situation

Discrepant results have been reported from Pakistan and Singapore in patients with severe microcytic anemia (e.g. iron deficiency, thalassemia) and the following parameters are affected: RBC (red blood cell count), HGB (hemoglobin concentration), MCH (mean corpuscular hemoglobin), HCT (hematocrit), and MCV (mean corpuscular volume).

This issue is preliminarily linked to the **cobas m 511** software version 1.0.

For global epidemiology of haemoglobin disorders and derived service indicators refer to the attachment.

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Potential medical impacts and risks

Of particular clinical concern are the HGB differences observed within the transfusion decision limits, which might lead to an incorrect transfusion decision.

Root cause analysis

In some cases, with extreme hypochromia the RBC count may be low. When there is severe anisocytosis, there is a bias toward measuring smaller cells, thereby underestimating MCV and MCH. The calculated values HGB and HCT will also be lower.

Actions taken by Roche Diagnostics

In all reported cases, the **cobas m 511** integrated hematology analyzer displayed messages, including "Anemia", "Anisocytosis", "Hypochromia", "Microcytosis", "RBC fragments", and "RBC interference". These messages prevent the results from being automatically released to the Laboratory Information System (LIS), thus triggering a laboratory review.

In addition, Roche will implement an additional message, "**RBC discrepancies?**" triggered by a rule. As soon as the rule is finally validated and released, it will be configured for you by your Roche Application Specialist. Roche anticipates the rule will be available by end of Q2, 2018.

Roche will provide an update of the **cobas m 511** software and the corresponding user documentation which will be rolled-out in Q4, 2018.

Actions to be taken by the customer/user

Until this rule is implemented, when **cobas m 511** integrated hematology analyzer displays a HGB value of less than or equal to 9g/dL, Roche advises the user to not report results for the RBC, HGB, MCH, HCT, and MCV parameters. Roche advises the user to perform laboratory confirmatory testing before making transfusion decisions. Delta check against previous results might additionally be used to evaluate the results.

For customer evaluating the instrument Roche kindly advises to not report values for diagnostic use until the rule is configured by your Roche Application Specialist.

Communication of this Field Safety Notice (if appropriate)

<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:

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

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

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

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the corrective action. (If appropriate).>

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

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com

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Supporting Information

Global epidemiology of haemoglobin disorders and derived service indicators

Bernadette Modell, Matthew Darlison

Volume 86, Number 6, June 2008, 480-487

Table 1. Estimated prevalences of carriers of haemoglobin gene variants and affected conceptions

WHO region	Demography2003				% of the populationcarrying			Affected conceptions(per 1000)			Affected births (% of under-5 mortality)
	Population (millions)	CrudeBirthrate	Annual births (1000s)	Under-5 mortality rate	Significant variant ^a	α -thalassaemia ^b	Any variant ^c	Sickle-cell disorders ^d	Thalassaemias ^e	Total	
African	586	39.0	22 895	168	18.2	41.2	44.4	10.68	0.07	10.74	6.4
American	853	19.5	16 609	27	3.0	4.8	7.5	0.49	0.06	0.54	2.0
Eastern Mediterranean	573	29.3	16 798	108	4.4	19.0	21.7	0.84	0.70	1.54	1.4
European	879	11.9	10 459	25	1.1	2.3	3.3	0.07	0.13	0.20	0.8