Field Safety Notice

SBN-CPS-2018-006

CPS / Hematology
Version 1
21-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	**cobas m** 511 integrated hematology analyzer
GMMI / Part No **Device Identifier**	07261691190
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

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

Description of Situation

During the technical evaluation of the cobas m 511, discrepant results have been reported 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 and observed on sites where the incidence of hemoglobinopathies are common.

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For global epidemiology of haemoglobin disorders and derived service indicators please refer to the table below:

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

	Demography2003				% of the populationcarrying			Affected conceptions(per 1000)			Affected births (% of under-5 mortality)
WHO region	Population (millions)	CrudeBirthrate	Annual births (1000s)	Under-5 mortality rate	Significant varianta	α+thalassaemiab	Any variantc	Sickle-cell disordersd	Thalassaemiase	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
South-east Asian	1 564	24.4	38 139	83	6.6	44.6	45.5	0.68	0.66	1.34	1.6
Western Pacific	1 761	13.6	23 914	38	3.2	10.3	13.2	0.00	0.76	0.76	2.0
World	6 217	20.7	128 814	81	5.2	20.7	24.0	2.28	0.46	2.73	3.4

a Significant variants include Hb S, Hb C, Hb E, Hb D etc. β thalassaemia, α0 thalassaemia.b α+ thalassaemia includes heterozygous and homozygous α+ thalassaemia.c Allows for (1) coincidence of α and β variants, and (2) harmless combinations of β variants.d Sickle-cell disorders include SS, SC, S/β thalassaemia.e Thalassaemias include homozygous β thalassaemia, haemoglobin E/β thalassaemia, homozygous α0 thalassaemia, α0/ α+ thalassaemia (haemoglobin H disease).

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

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”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

This notice must be passed on to all those who need to be aware within your organization. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA.

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

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

Sincerely,

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