

**Field Safety Notice
N. 02/2022**

Product Name	List Number REF	Lot Number	Expiration Date
Copper	17638H	00273	04/2022
		00818	04/2022
		10323	09/2023
		10656	04/2024
Copper	17106	00010	03/2022
		10033	10/2022
		10310	10/2022
		10657	05/2024
Clin Chem Control 1	16150	00234	04/2022
		00245	04/2022
		00612	04/2022
		10022	04/2022
		10406	03/2023
		11103	11/2023
Clin Chem Control 2	16250	00317	06/2022
		00843	03/2023
		10089	03/2023
		10899	11/2023
		20187	11/2023

UDI	SRN - Manufacturer
08058056680020	IT-MF-000012556
08058056680761	
08058056680099	
08058056680105	

Date: March 23, 2022

Details on affected devices:

This letter contains important information regarding the Copper assays - REF 17638H and REF 17106 - and related controls - Clin Chem Control 1 REF 16150 and Clin Chem Control 2 REF 16250, for the lots referenced above.

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

Description of the problem:

A potential inaccuracy issue using Sentinel Copper analytical system has been reported. Thorough testing was implemented to verify the issue and multiple materials and lots were tested on Clinical Chemistry analyzers to check the accuracy of the Copper assay. Investigations confirmed a 16% underestimation of patient results may be found when using the standard component contained in the Copper assay kit. The related controls are impacted too.

Patient Impact:

Even if underestimation identified is analytically detectable, no relevant clinical impact on patient management is expected. The copper measurement alone is indeed not sufficient for the diagnosis of a serious illness like the Wilson disease: measurement of ceruloplasmin will help in excluding the possibility of important patient consequences.

Actions 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 in "Receipt of the Safety Notice" and return it to your local contact.
3. Review the content of this communication with your Medical Director and retain this letter for any future reference.

Updated Standard and Control Values

STANDARD

- Inform users of the described underestimation.
- For the product lots listed below, do not consider the value of the standard reported in the Instructions for use or on the standard vial label but calibrate the assay with the new value reported in the following tables:

REF 17638H Copper (Standard included in the kit)						
Kit Lot	Component Lot	Expiration Date	New Value		Value reported in labeling	
			µg/dL	µmol/L	µg/dL	µmol/L
00273	H0427	04/2022	115	18.09	100	15.73
00818	L0989	04/2022				
10323	L1482	09/2023				
10656	M1020	04/2024				

REF 17106 Copper (Standard included in the kit)						
Kit Lot	Component Lot	Expiration Date	New Value		Value reported in labeling	
			µg/dL	µmol/L	µg/dL	µmol/L
00010	H0424	03/2022	115	18.09	100	15.73
10033	L1482	10/2022				
10310	L1482	10/2022				
10657	M1020	05/2024				

CONTROLS

- Inform users of the described underestimation.
- When using the multiparametric controls listed below with the impacted Copper lots listed in this communication, use the newly assigned values for copper analyte reported in the below tables:

REF 16150 Clin Chem Control 1						
New values to be used for Copper analyte only						
Kit Lot	Component Lot	Expiration Date	New Value		Values reported in labeling	
			µg/dL	µmol/L	µg/dL	µmol/L
00234	L0216	04/2022	96 ± 17	15.1 ± 2.7	81 ± 15	12.8 ± 2.3
00245	L0216	04/2022	96 ± 17	15.1 ± 2.7	81 ± 15	12.8 ± 2.3
00612	L0216	04/2022	96 ± 17	15.1 ± 2.7	81 ± 15	12.8 ± 2.3
10022	L0216	04/2022	96 ± 17	15.1 ± 2.7	81 ± 15	12.8 ± 2.3
10406	L1390	03/2023	83 ± 15	13.1 ± 2.3	73 ± 13	11.5 ± 2.1
11103	M1463	11/2023	99 ± 18	15.6 ± 2.8	88 ± 13	13.4 ± 2.4

REF 16250 Clin Chem Control 2						
New values to be used for Copper analyte only						
Kit Lot	Component Lot	Expiration Date	New Value		Values reported in labeling	
			µg/dL	µmol/L	µg/dL	µmol/L
00317	L0217	06/2022	221 ± 36	34.8 ± 5.7	189 ± 31	29.8 ± 4.9
00843	L1391	03/2023	220 ± 36	34.6 ± 5.6	191 ± 31	30.1 ± 4.9
10089	L1391	03/2023	220 ± 36	34.6 ± 5.6	191 ± 31	30.1 ± 4.9
10899	M1464	11/2023	215 ± 35	33.8 ± 5.5	191 ± 31	30.1 ± 4.9
20187	M1464	11/2023	215 ± 35	33.8 ± 5.5	191 ± 31	30.1 ± 4.9

Transmission of this Field Safety Notice:

This notice must 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 your local Customer Service.

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

Best Regards,

Marco Buonaguidi
Head of Marketing and Sales

Patricia Dupé
Head of Quality System