SENTINEL
DIAGNOSTICS

Urgent Field Safety Notice
N. 01/2020

Product Name	List Number (LN)	Lot Number	Component Lot	Expiration Date
Plasmaproteins Cal 3X	**11206D**	**80440**	G0420	2020/05
		90372	H0400	2021/04
		90620	H0845	2021/08

Date: February 6th, 2020

Details on effected devices:

The purpose of this communication is to inform you that new HPT (Haptoglobin) and AGP (Alpha 1-Acid Glycoprotein) values have been assigned to the listed lots of REF 11206D Plasmaproteins Cal 3X.
Please review the information carefully and follow the reported actions.

Description of the problem:

Haptoglobin
Using the listed items for haptoglobin determination (REF 11050D) the analysis of results indicates a drift down vs primary standard for haptoglobin (ERM-DA470K/IFCC), resulting in an underestimation up to approximately 37% of the test results.

Alpha 1-Acid Glycoprotein
Using the listed items for Alpha 1-Acid Glycoprotein determination (REF 11135D) the analysis of results indicates a drift down vs primary standard for Alpha 1-Acid Glycoprotein (ERM-DA470K/IFCC), resulting in an underestimation up to approximately 12% of the test results.

Patient Impact:

Haptoglobin
The analysis of the data available for haptoglobin concluded that the use of the affected lots could generate falsely low haptoglobin results in patient samples that can incorrectly lead to a suspect of intravascular hemolysis. However, the assay results are not the sole basis for the physician medical decision, but require the evaluation of other parameters such as LDH, bilirubin and free Hb. Considering that the intra- and inter-individual variability is very wide (7.4% and 38% respectively) and the reference range is very large (30 - 200 mg/dL), only variations higher than 50% and haptoglobin results <30 mg/dL may have clinical significance. It must be noted also that any decision made by the physician will be done after evaluating the complete biochemical profile of the patient and according to the clinical history of the patient and other clinical findings.

Alpha 1-Acid Glycoprotein
The analysis of the data available for Alpha 1-Acid Glycoprotein concluded that the use of the affected lots could generate falsely low Alpha 1-Acid Glycoprotein results. Despite the bias introduced by the calibrator (12%) is almost the double of the desirable one (6,8%), Alpha 1-Acid Glycoprotein does play only an ancillary role in driving medical decisions and it is usually assessed together with CRP.

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Actions to be taken:

Haptoglobin

- If the concerned REF 11206D Plasmaproteins Cal 3X kits have been distributed inside or outside the company, inform users of the updated haptoglobin values:

Plasmaproteins Cal 3X Ref 11206D				
Haptoglobin				
Lot	**Component Lot**	**Exp Date**	**New Value [mg/dL]**	**Previous Value [mg/dL]**
80440	G0420	2020/05	**322**	224
90372	H0400	2021/04	**298**	213
90620	H0845	2021/08	**304**	225

- Inform users to perform a new calibration with the new haptoglobin assigned values.
- Since haptoglobin is present in the plasma in the acute phase of inflammatory processes, we suggest to evaluate with patient physician to contact only the patients reported with a value close to the low reference limit (30 mg/dL) and recently obtained without any other hemolysis marker available to support the haptoglobin result.
- Review the content of this communication with your Medical Director and retain this letter for your laboratory records.

Alpha 1-Acid Glycoprotein

- If the concerned REF 11206D Plasmaproteins Cal 3X kits have been distributed inside or outside the company, inform users of the updated Alpha 1-Acid Glycoprotein values:

Plasmaproteins Cal 3X Ref 11206D				
Alpha 1-Acid Glycoprotein				
Lot	**Component Lot**	**Exp Date**	**New Value [mg/dL]**	**Previous Value [mg/dL]**
80440	G0420	2020/05	**198**	182
90372	H0400	2021/04	**201**	176
90620	H0845	2021/08	**203**	176

- Inform users to perform a new calibration with the new Alpha 1-Acid Glycoprotein assigned values.
- Review the content of this communication with your Medical Director and retain this letter for your laboratory records.

Transmission of this Field Safety Notice:

This notice needs to 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.

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Reference person:

If you or any of your customers have any questions regarding this information, please contact your local area Customer Service.

Best regards

Mario Fangareggi
Head of Marketing

Patricia Dupé
Head of Quality System