

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.

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.

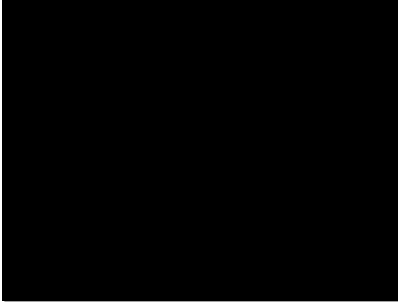
Transmission of this Field Safety Notice:

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.

Reference person:

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

Best regards



Urgent Field Safety Notice
N. 02/2020

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
Plasmaproteins Cal	11200D	80377	G0430	2020/05
		90362	H0420	2021/04
Immuno Control Set	11211A	80412	G0551	2021/06
			G0552	
		90125	G0551	2021/06
			G0552	
		90308	G0551	2021/06
			G0552	
		90598	H0813	2022/07
			H0814	
		90679	H0813	2022/07
			H0814	

Date: February 14th, 2020

Details on affected 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, REF 11200D Plasmaproteins Cal and REF 11211A Immuno Control Set. Please review the information carefully and follow the actions reported.

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.

Actions to be taken:

Haptoglobin

- If the concerned REF 11206D Plasmaproteins Cal 3X, REF 11200D Plasmaproteins Cal and REF 11211A Immuno Control Set 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

Plasmaproteins Cal REF 11200D				
Haptoglobin				
Lot	Component Lot	Exp Date	New Value [mg/dL]	Previous Value [mg/dL]
80377	G0430	2020/05	154	112
90362	H0420	2021/04	148	107

SENTINEL DIAGNOSTICS

Immuno Control Set REF 11211A				
Haptoglobine				
Lot	Component Lot	Exp Date	New Value [mg/dL]	Previous Value [mg/dL]
90679	H0813	2022/07	71±18	52±13
	H0814		220±55	159±40
90598	H0813	2022/07	71±18	52±13
	H0814		220±55	159±40
90308	G0551	2021/06	56±14	42±10
	G0552		159±40	120±30
90125	G0551	2021/06	56±14	37±9
	G0552		159±40	114±29
80412	G0551	2021/06	56±14	37±9
	G0552		159±40	114±29

- 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, REF 11200D Plasmaproteins Cal and REF 11211A Immuno Control Set 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

Plasmaproteins Cal REF 11200D				
Alpha 1-Acid Glycoprotein				
Lot	Component lot	Exp Date	New Value [mg/dL]	Previous Value [mg/dL]
80377	G0430	2020/05	91*	91
90362	H0420	2021/04	85	88

*Not modified from the previously assigned value.

SENTINEL DIAGNOSTICS

Immuno Control Set REF 11211A				
Alpha 1-Acid Glycoprotein				
Lot	Component lot	Exp Date	New Value [mg/dL]	Previous Value [mg/dL]
80412	G0551	2021/06	41±10	37±9
	G0552		126±32	114±29
90125	G0551	2021/06	41±10	37±9
	G0552		126±32	114±29
90308	G0551	2021/06	41±10	37±9
	G0552		126±32	114±29
90598	H0813	2022/07	42±11	37±9
	H0814		131±33	119±30
90679	H0813	2022/07	42±11	37±9
	H0814		131±33	119±30

- 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.

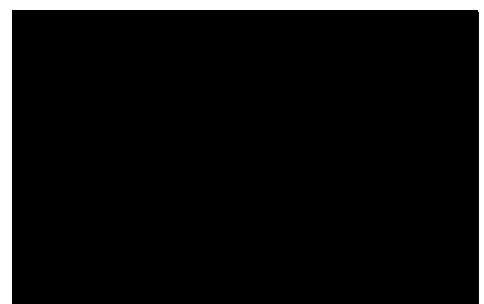
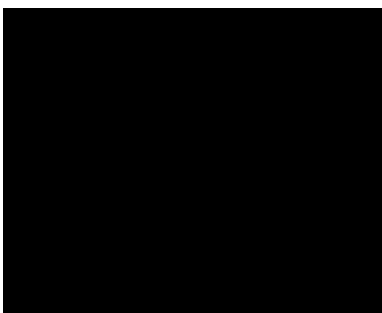
Transmission of this Field Safety Notice:

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.

Reference person:

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

Best regards



Urgent Field Safety Notice N. 03/2020

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
Immuno Control Set	11211A	80412	G0551	2021/06
			G0552	
		90125	G0551	2021/06
			G0552	
		90308	G0551	2021/06
			G0552	
		90598	H0813	2022/07
			H0814	
		90679	H0813	2022/07
			H0814	

Date: February 15th, 2020

Details on affected devices:

The purpose of this communication is to inform you that new AAt (Alpha 1-Antitrypsin) and AGP (Alpha 1-Acid Glycoprotein) values have been assigned to the listed lots of REF 11206D Plasmaproteins Cal 3X and REF 11211A Immuno Control Set. Please review the information carefully and follow the actions reported.

Description of the problem:

Alpha 1-Antitrypsin

Using the listed items for Alpha 1-Antitrypsin determination (REF 11012N) the analysis of results indicates a drift up vs primary standard for Alpha 1-Antitrypsin (ERM-DA470K/IFCC), resulting in an overestimation up to approximately 16% 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:

Alpha 1-Antitrypsin

Alpha 1-antitrypsin (AAt) deficit causes important pulmonary and liver damages and has low intra- and inter-individual biological variation with a CV and Bias analytical quality specification of 3.0% and 4.3% respectively.

An overestimation in a patient affected by congenital deficit of the protein may mask the insufficiency and delay the diagnosis. However, these patients usually have very low AAt plasma concentration. In conclusion, an overestimation of 16% is not so relevant from the clinical point of view.

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.

Actions to be taken:

Alpha 1-Antitrypsin

- If the concerned REF 11206D Plasmaproteins Cal 3X and REF 11211A Immuno Control Set kits have been distributed inside or outside the company, inform users of the updated Alpha 1- Antitrypsin values:

Plasmaproteins Cal 3X Ref 11206D				
Alpha 1- Antitrypsin				
Lot	Component Lot	Exp Date	New Value [mg/dL]	Previous Value [mg/dL]
80440	G0420	2020/05	337	417
90372	H0400	2021/04	350	394
90620	H0845	2021/08	340	403

Immuno Control Set REF 11211A				
Alpha 1- Antitrypsin				
Lot	Component lot	Exp Date	New Value [mg/dL]	Previous Value [mg/dL]
80412	G0551	2021/06	65±16	85±21
	G0552		200±50	219±55
90125	G0551	2021/06	65±16	85±21
	G0552		200±50	219±55
90308	G0551	2021/06	65±16	85±21
	G0552		200±50	219±55
90598	H0813	2022/07	64±16	78±19
	H0814		212±53	239±60
90679	H0813	2022/07	64±16	78±19
	H0814		212±53	239±60

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

SENTINEL DIAGNOSTICS

Alpha 1-Acid Glycoprotein

- If the concerned REF 11206D Plasmaproteins Cal 3X and REF 11211A Immuno Control Set 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

Immuno Control Set REF 11211A				
Alpha 1-Acid Glycoprotein				
Lot	Component lot	Exp Date	New Value [mg/dL]	Previous Value [mg/dL]
80412	G0551	2021/06	41±10	37±9
	G0552		126±32	114±29
90125	G0551	2021/06	41±10	37±9
	G0552		126±32	114±29
90308	G0551	2021/06	41±10	37±9
	G0552		126±32	114±29
90598	H0813	2022/07	42±11	37±9
	H0814		131±33	119±30
90679	H0813	2022/07	42±11	37±9
	H0814		131±33	119±30

- 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.

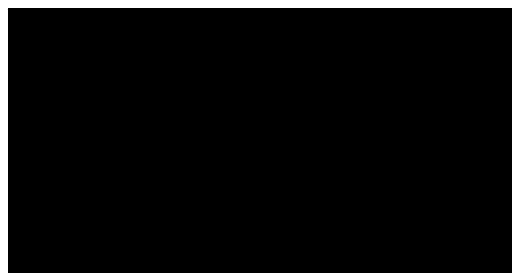
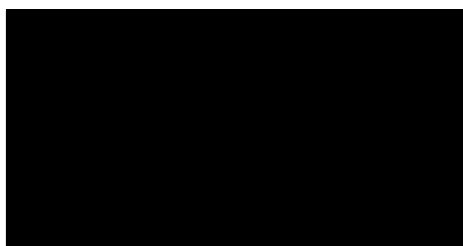
Transmission of this Field Safety Notice:

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Reference person:

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Best regards



Urgent Field Safety Notice N. 04/2020

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
Plasmaproteins Cal	11200D	80377	G0430	2020/05
		90362	H0420	2021/04

Date: February 14th, 2020

Details on affected devices:

The purpose of this communication is to inform you that new HPT (Haptoglobin), AAt (Alpha 1-Antitrypsin) and AGP (Alpha 1-Acid Glycoprotein) values have been assigned to the listed lots of REF 11206D Plasmaproteins Cal 3X and REF 11200D Plasmaproteins Cal. Please review the information carefully and follow the actions reported.

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.

Alpha 1-Antitrypsin

Using the listed items for Alpha 1-Antitrypsin determination (REF 11012N) the analysis of results indicates a drift up vs primary standard for Alpha 1-Antitrypsin (ERM-DA470K/IFCC), resulting in an overestimation up to approximately 16% 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.

SENTINEL DIAGNOSTICS

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.

Alpha 1- Antitrypsin

Alpha 1-Antitrypsin (AAt) deficit causes important pulmonary and liver damages and has low intra- and inter-individual biological variation with a CV and Bias analytical quality specification of 3.0% and 4.3% respectively.

An overestimation in a patient affected by congenital deficit of the protein may mask the insufficiency and delay the diagnosis. However, these patients usually have very low AAT plasma concentration. In conclusion, an overestimation of 16% is not so relevant from the clinical point of view.

Actions to be taken:

Haptoglobin

- If the concerned REF 11206D Plasmaproteins Cal 3X and REF 11200D Plasmaproteins Cal 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

Plasmaproteins Cal REF 11200D				
Haptoglobin				
Lot	Component Lot	Exp Date	New Value [mg/dL]	Previous Value [mg/dL]
80377	G0430	2020/05	154	112
90362	H0420	2021/04	148	107

- 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.

SENTINEL DIAGNOSTICS

Alpha 1-Acid Glycoprotein

- If the concerned REF 11206D Plasmaproteins Cal 3X and REF 11200D Plasmaproteins Cal 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

Plasmaproteins Cal REF 11200D				
Alpha 1-Acid Glycoprotein				
Lot	Component lot	Exp Date	New Value [mg/dL]	Previous Value [mg/dL]
80377	G0430	2020/05	91*	91
90362	H0420	2021/04	85	88

*Not modified from the previous assigned value.

- 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.

Alpha 1- Antitrypsin

- If the concerned REF 11206D Plasmaproteins Cal 3X and REF 11200D Plasmaproteins Cal kits have been distributed inside or outside the company, inform users of the updated Alpha 1- Antitrypsin values:

Plasmaproteins Cal 3X Ref 11206D				
Alpha 1- Antitrypsin				
Lot	Component Lot	Exp Date	New Value [mg/dL]	Previous Value [mg/dL]
80440	G0420	2020/05	337	417
90372	H0400	2021/04	350	394
90620	H0845	2021/08	340	403

Plasmaproteins Cal REF 11200D				
Alpha 1- Antitrypsin				
Lot	Component lot	Exp Date	New Value [mg/dL]	Previous Value [mg/dL]
80377	G0430	2020/05	163	208
90362	H0420	2021/04	157	197

SENTINEL

DIAGNOSTICS

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

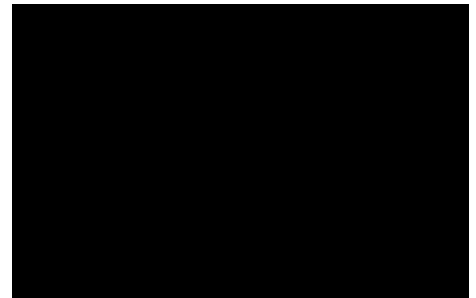
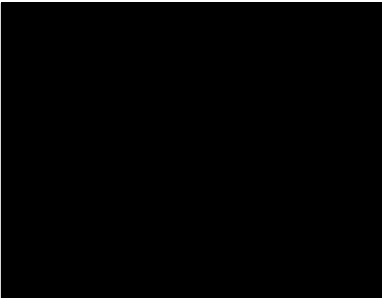
Transmission of this Field Safety Notice:

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.

Reference person:

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

Best regards



Please kindly fill in the attached form and send it back to us as soon as possible via fax (n. +39 02 34551464) or e-mail (customerservice@sentinel.it).