GRIFOLS

Rev 1: September 2018
FSN Ref: 800012088 FSCA Ref: 01/23

Date: 03. Aug. 2023

Urgent Field Safety Notice
Screen-Cyte 0.8%

A small subset of kits of the three-cell antibody screening product Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, contains a cell number 1 of the wrong lot (lot 600123022 instead of lot 600123024).

For Attention of: Distributors and Health Care Professionals, who received Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02.

Contact information

For additional information, please contact your local service representative at

Country	Email Contact
Belgium	virginie.behague@grifols.com
Canada	linda.boggs@grifols.com; kaikhushru.parakh@grifols.com
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Italy	walter.arcano@grifols.com
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Distributors	service.distributor@grifols.com

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1. Information on Affected Devices	
1.	1. Device Type(s)
	Screen-Cyte 0.8% is intended for the detection of irregular antibodies.
1.	2. Commercial name(s)
	Screen-Cyte 0.8%
1.	3. Unique Device Identifier(s) (UDI-DI)
	07640137340568
1.	4. Primary clinical purpose of device(s)
	Screen-Cyte 0.8% is intended fo the detection of irregular antibodies. It used by Health Care professionals.
1.	5. Device Model/Catalogue/part number(s)
	ref. 213590
1.	6. Affected serial or lot number range
	lot 600023024, exp. 2023-09-02

2 Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	During our routine vigilance process, it has been detected that a small subset of kits (13 kits in total) of the three-cell antibody screening product Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, contains a cell number 1 of the wrong lot (lot 600123022 instead of lot 600123024). The cell number 1 of the wrong lot number was introduced in this small subset of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, during production due to inappropriate line clearance. The majority of the objectionable kits have already been identified and segregated, but we cannot exclude that isolated objectionable kits are distributed to end customers and have not been identified and segregated. However, cell 2 and cell 3 of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, are not impacted by this event. Furthermore, the product Screen-Cyte 0.8%, ref. 213590, lot 600023022, exp. 2023-09-02, is not impacted by this event.
2.	2. Hazard giving rise to the FSCA
	Details of the greatest hazard to the patient/end user that the advice/action is intended to mitigate: We would like to add that Grifols has completed a risk assessment for the product Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02: The objectionable kits of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, contain cell 1 of Screen-Cyte 0.8%, ref. 213590, lot 600023022, exp. 2023-09-02. The complete and correct cell 1 lot number is printed on the kit label and thus, when verifying component lot number on the vial label vs kit label, operator will detect the mismatch and do not use the product. In the unlikely and rare event of accidental missed verification and use of the objectional kit, the following risk applies prior FSN action: The objectionable kits do not possess a Lua positive cell in their kit, Furthermore, and contrary to the correct kit composition, the objectional kits do not possess a homozygous cell for Jkb and Fyb. However, cell 2 of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, is a Fya,b

	heterozygous cell, and cell 3 of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, is Jka,Jkb heterozygous cell and thereby would continue to meet minimal requirements from internationally accepted transfusion guidelines. In case a customer would use an objectionable kit of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, a Lua antibody could be missed during antibody screening. However, in case this customer is using an Erytra or an Erytra Eflexis instrument an error message will be triggered by the instrument and the run will not be launched, which reduces the risk. In case at least one cell of the screening set is reacting, an identification panel will be used. The aim of the Antibody Identification is to identify red cell antibodies with clinical significance. Only in case the screening panel results are considered for subsequent antibody identification in combination with the identification panel result, it may lead to inconclusive results and further investigations to identify the underlying antibody are necessary. This could cause a delay in obtaining the results, which could cause a delay of transfusion. As an immediate measure: Please verify for every kit of the product Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, that it includes a cell 1 of lot 600123024. In case a kit of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, contains a cell 1 of lot 600123022, do not use this kit, segregate this kit and contact your local representative. There is no residual risk if the FSN action is taken. Please note that that cell 2 and cell 3 of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, are not impacted by this event. Therefore, Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, when no cell number 1 of the wrong lot (lot 600123022 instead of lot 600123024) is present, is not impacted by this event, and the use of it is completely the expected one. Furthermore, the product Screen-Cyte 0.8%, ref. 213590, lot 600023022, exp. 2023-09-02, is not impacted by this event.
2.	3. Probability of problem arising
	The majority of the objectionable kits have already been identified and segregated, but we cannot exclude that isolated objectionable kits are distributed to end customers and have not been identified and segregated.
2.	4. Predicted risk to patient/users
	From the output of the Health Hazard Evaluation the anticipated risk of patient harm is negligible.
2.	5. Further information to help characterise the problem
	The majority of the objectionable kits have already been identified and segregated, but we cannot exclude that isolated objectionable kits are distributed to end customers and have not been identified and segregated.
2.	6. Background on Issue
	During our routine vigilance process, it has been detected that a small subset of kits (13 kits in total) of the three-cell antibody screening product Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, contains a cell number 1 of the wrong lot (lot 600123022 instead of lot 600123024). The cell number 1 of the wrong lot number was introduced in this small subset of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, during production due to inappropriate line clearance. The majority of the objectionable kits have already been identified and segregated, but we cannot exclude that isolated objectionable kits are distributed to end customers and have not been identified and segregated. However, cell 2 and cell 3 of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, are not impacted by this event. Furthermore, the product Screen-Cyte 0.8%, ref. 213590, lot 600023022, exp. 2023-09-02, is not impacted by this event. Accordingly, an internal CAPA will be defined, to improve the line clearance.
2.	7. Other information relevant to FSCA
	Please note that that cell 2 and cell 3 of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, are not impacted by this event. Therefore, Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, when no cell number 1 of the wrong lot (lot 600123022 instead of lot 600123024) is present, is not impacted by this event, and the use of it is completely the expected one. Furthermore, the product Screen-Cyte 0.8%, ref. 213590, lot 600023022, exp. 2023-09-02, is not impacted by this event

	3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Please verify for every kit of the product Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, that it includes a cell 1 of lot 600123024. In case a kit of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, contains a cell 1 of lot 600123022, do not use this kit, segregate this kit and contact your local representative. There is no residual risk if the FSN action is taken.	
3.	2. By when should the action be completed?	The action has to be done after the receipt of the FSN and previous to the use of the affected products.
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes In case an objectionable kit of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, which contains a cell 1 of lot 600123022, was used. Review of the screening results is needed.	
3.	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None The 13 objectionable kits of Screen-Cyte 0.8%, ref. 213590, lot 600023024, exp. 2023-09-02, were replaced. The FSN goes for any potential additional objectionable kit which is still undetected by customers during incoming inspection. An internal CAPA will be defined, to improve the line clearance.	

	4. General Information	
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Medion Grifols Diagnostics AG**
	b. Address	**Bonnstrasse 9; 3186 Düdingen; Switzerland**
	c. Website address	**www.grifols.com**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. Name/Signature	[redacted]

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.