Rev 1: September 2018
FSN Ref: FSN-2020-0009 FSCA Ref: FSN-2020-0009

Date: 10.Dec.2020

Urgent Field Safety Notice
Remel BactiDrop™ Potassium Hydroxide (10%)

For Attention of*: Lab Managers

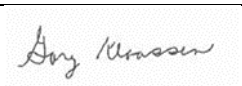
Contact details of local representative (name, e-mail, telephone, address etc.)*
Email : mbd.vigilance@thermofisher.com Telephone: +44(0) 1256 841144 Fax: +44(0) 1256 479525

Urgent Field Safety Notice (FSN)
Remel BactiDrop™ Potassium Hydroxide (10%)
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Reagent
1.	2. Commercial name(s)
	Remel BactiDrop™ Potassium Hydroxide (10%)
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	This is a reagent recommended for use in the initial preparation of clinical specimens for microscopic examination of fungal elements
1.	5. Device Model/Catalogue/part number(s)*
	R21524
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	969370
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	An internal technical investigation has confirmed that some vials from BactiDrop Potassium Hydroxide (10%) R21524 Lot 969370 expiration 2022/02/07 were labeled incorrectly as Lactophenol Aniline Blue (R21526 lot 969368, expiration 2022/3/18).
2.	2. Hazard giving rise to the FSCA*
	Incorrectly labelled product.
2.	3. Probability of problem arising
	Moderate, not all vials or boxes are impacted.
2.	4. Predicted risk to patient/users
	There are no adverse health consequences due to this labeling issue. The product in the vials is the correct product, KOH, as indicated on the box label. KOH is a clear liquid, while the Lactophenol is blue and there are no reports of the vials containing a blue liquid
2.	5. Further information to help characterise the problem
	
2.	6. Background on Issue
	An internal technical investigation has confirmed that some vials from BactiDrop Potassium Hydroxide (10%) R21524 Lot 969370 expiration 2022/02/07 were labeled incorrectly as Lactophenol Aniline Blue (R21526 lot 969368, expiration 2022/3/18). The exterior box labeling is correct. The clear reagent inside the vials is the correct product, Potassium Hydroxide (KOH 10%), and not Lactophenol, which is a blue liquid.
2.	7. Other information relevant to FSCA
	Expiry 2022-Feb-07 (2022/02/07)

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	
3.	2. By when should the action be completed?	immediately
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No The clear reagent inside the vials is the correct product, Potassium Hydroxide (KOH 10%), and not Lactophenol, which is a blue liquid. There have been no reports of vials containing blue liquid.	
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	
3	6. By when should the action be completed?	30-60 days for issuance
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	NA
4.	**3.** For Updated FSN, key new information as follows:	
	NA	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	NA	
4	6. Anticipated timescale for follow-up FSN	NA
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Remel Inc
	b. Address	12076 Santa Fe Trail Drive, Lenexa KS 66215 USA
	c. Website address	www.thermofisher.com/microbiology
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	
4.	10. Name	Gary Klaassen
	Signature	

	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) 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.*