



12th July 2021

URGENT: FIELD SAFETY NOTICE – IDS-21-4201

BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate), CPU 120

&

BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate), CPU 20

REF & Lot Numbers: See Table 1

Type of Action: Product Removal

Dear Customer,

BD is conducting a Field Safety Corrective Action to remove a specific lot of **BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate), CPU 120** and **BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate), CPU 20** referenced in Table 1 below. According to our distribution records your organisation may have received the impacted product.

Description of the Problem

Based on customer feedback, customers have reported contamination (*Gemella morbillorum*) on the plates for the product listed in Table 1.

This product removal is limited to the product code / lot numbers listed in Table 1 below.

Product Name	Catalogue (REF) Number	Lot Number(s)	Expiration Date
BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate), CPU 20	254476	1104468	15 July 2021
BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate), CPU 120	257589		

Table 1: Impacted catalogue Numbers and Lot Numbers

Clinical Risk

When a specimen is contaminated, it can lead to a delay in results, as the plate will be discarded and there is a potential that the clinician will need to obtain another specimen to redo the diagnostics. Additionally, there is a low possibility that a patient will be treated with unnecessary antibiotics if the contaminated specimen is considered by the clinician as clinically relevant



Advice on actions to be taken by the Customer:

1. Inspect your inventory, locate, and quarantine any units of the impacted lot numbers. Destroy all impacted product(s).
2. If you have further distributed the product, please identify those facilities, notify them at once of this product removal and have them return the affected product to your facility.
3. BD recommends discussing the content of this letter with your laboratory director regarding the need to review previous test results associated with these impacted lots.
4. Complete the customer response form on page 3 indicating:
 - the quantities destroyed/returned **OR**
 - that your organisation does not have any impacted units left in inventory
5. Return the completed customer response form to <<insert contact details here>> for replacement **as soon as possible or no later than 10th August 2021.**

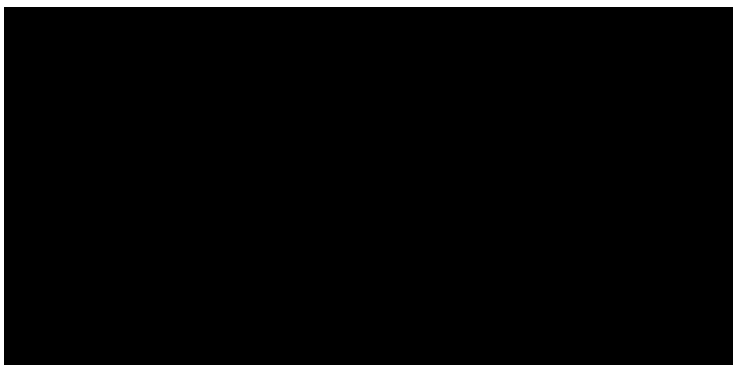
Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,





Customer Response Form – IDS-21-4201

BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate), CPU 120

&

BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate), CPU 20

Please read in conjunction with Field Safety Notice IDS-4201 and return completed and signed form as soon as possible or **no later than the 10th August 2021** to <insert fax/email address here>.

- I confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Tick the appropriate box below

☐ We do not have any of the affected product as listed in Table 1 in our possession.

OR

☐ We have the following units of the affected product as listed in Table 1 in our possession and I confirm that the units have been destroyed (*Please complete the table below with the lot number and the number of units destroyed*)

Catalogue (REF) Number	Lot Number/s:	Units destroyed (insert quantity below)
	1104468	

Account/Organisation Name:	
Department (if applicable):	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Signature:	Date:

This form must be returned to BD before this action can be considered closed for your account