**INFORMATION : CBC-3D**

**Lot :** **B1122 – Normal Level**

**Expiration :** **2023-02-05**

Noyal-Chatillon-Sur-Seiche, November 8th, 2022

Dear CBC-3D user,

Our records indicate that you recently purchased **R&D CBC-3D Hematology Control lot number B1122.**

**Please be aware of the following information :**

The purpose of this communication is to advise you that the manufacturer R&D Systems is alerting you regarding the above-mentioned product. For the most recent lot of **CBC-3D** Hematology Control you received, **Lot B1122, the Normal Level** may exhibit hemolysis or deterioration due to mibrobial contamination.

We request that you perform the following tasks :

* File this letter as documentation regarding the product
* Inspect the Normal Level control for signs of hemolysis or deterioration :
* Signs of hemolysis or deterioration include observing an unclear separation between the blood cells and the supernatant, a very dark red supernatant or obtaining unacceptable results when the control is run on the hematology analyzer.
* If signs of hemolysis or deterioration are noted, discard the tube per the instructions for use. Do not use the product if hemolysis or deterioration is suspected.
* Sign the acknowledgement and Receipt form on page 2 of this letter and return to diagnostics.emea@bio-techne.com **by November 18, 2022.**

A new lot of CBC-3D Normal Level Hematology Control will be available January 16, 2023.

The Low and High Levels Hematology Controls do not show signs of contamination. Your site is encouraged to follow CLIA requirements for running a minimum of two levels of quality control material.

If you have any questions or concerns, please contact us.

Please accept our apology for any inconvenience you may have experienced.

**Mrs BETHUEL Corinne**

**Bio-Techne France Director**

 

**MEDICAL DEVICE IMPORTANT PRODUCT NOTICE RETURN RESPONSE**

**Acknowledgement and Receipt Form**

**Response is required by November 18, 2022**

**Customer Information :**

Customer code \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Customer name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Town, State, Zip Code\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**R&D CBC-3D Hematology Control**

**Lot B1122N**

I have read and understand the instructions provided in the Important Product Notice Letter of November 08, 2022.

Yes \_ No\_ (check one)

Have there been any adverse events associated with product? Yes \_ No \_ (check one)

If yes, please explain:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Affected Product Information:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Product description** | **Catalog number received** | **Quantity used** | **Quantity destroyed** |
| CBC-3D Normal Level (Hematology Control) |  |  |  |

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| Name |  |
| Telephone |  |
| Email Address  |  |

Return completed form by email to : diagnostics.emea@bio-techne.com