



FIELD SAFETY NOTIFICATION

Product Name	Part Number	Lot Number	Expiration Date	UDI
Aptiva CTD Essential Controls	723102	100475	1/31/2027	84307930401983

March 11, 2026

Dear Valued Werfen Customer,

Werfen is issuing this Field Safety Notification as part of a Field Safety Corrective Action regarding Aptiva CTD Essential Controls (P/N 723102), Lot Number 100475.

Description of the issue:

The barcode label for Control 1 of the Aptiva CTD Essential Controls (P/N 723102, L/N 100475) encodes an incorrect standard deviation value of 140 IU/mL (20 FLU) rather than the intended value of 1.4 IU/mL (0.2 FLU) for dsDNA. This error widens the acceptable range applied to dsDNA Control 1 when the barcode is scanned by the Aptiva instrument software.

All other barcode information, including the control target mean, expiration date, and the control values and standard deviations for the remaining analytes, was encoded correctly.

This action is being taken to correct the barcode parameter so that the instrument software evaluates dsDNA Control 1 using the intended standard deviation value.

Actions to be taken by the Customer:

1. Adjust the target standard deviation for Control 1 in the Aptiva instrument software to the correct value. Follow the instructions below in accordance with the Aptiva Instrument Operators Manual:

- a) Login to the Aptiva software as a *manger* level access.
- b) Select **Config** from the menu on the left side of the screen.
- c) Select the **QC Materials** card.
- d) Select the CTD Essential Control **CTDE1**, L/N 100475.
- e) Adjust the **Target SD**
 - i. If units are in IU/mL, set it to **1.4**.
 - ii. If the units are in FLU, set it to **0.2**.
- f) Select the **Save** button in the lower right corner of the window.



2. If the control has already been used, review the obtained Control 1 dsDNA values and verify that the results fall within the expected range of **6.51–14.91 IU/mL (0.93–2.13 FLU)**, as specified in the Certificate of Analysis (CoA).

Distribution of this notice:

Please share this notification with all personnel who use the Aptiva CTD Essential Controls or who need to be aware of this correction.

We appreciate your understanding regarding this matter. Werfen is committed to providing quality products and superior customer service. Should you require further assistance, please contact your local Werfen representative.

Sincerely,

Rashid Abdulle
Post Market Compliance
Autoimmunity Headquarters and Technology Center