



Quality Letter

October 4, 2023

To Whom It May Concern:

This letter is to share information regarding UTAK's Validity Control 3, Part# 17012, Lot D1821.

While doing containment for a related issue, it was discovered by UTAK that particulate matter may be present in the product.

We kindly request that you take the following actions:

1. Discontinue the use of this specific lot and gather any remaining vials of this product.
2. Contact UTAK customer service at welovecontrol@utak.com or 1-888-882-5522 to arrange for replacements or credits for any remaining inventory from this lot.

In response to these complaints, we initiated an investigation and conducted independent third-party testing to identify the particulate matter. The results of the Microbial Analysis are summarized as follows:

- | | |
|-------------|--|
| 1. Test: | Bacterial Culture – Counts with Identification |
| 2. Results: | Total Bacterial Count < 10 CFU/mL No growth |

Our team is actively looking into the root cause of this matter. It is important to note that our investigation has determined that this incident does not pose a health risk and does not warrant mandatory device reporting.

We appreciate your understanding and apologize for any inconvenience this may have caused your testing laboratory. Should you have any questions or require further assistance, please do not hesitate to contact our Customer Service Team at welovecontrol@utak.com or by phone at 1-888-882-5522.

Sincerely,

