



## Urgent Field Safety Notice

**Incorrect Reference Value for Trace Elements NR Serum Control,**  
**Product# 66816, Lot# C2540**



Dear Customer,

UTAK has initiated a Field Safety Corrective Action for the affected Trace Elements, Product# 66816, Lot# C2540. The situation for the device in question was evaluated as low risk and no health hazard was identified.

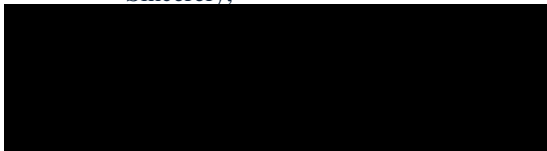
An investigation into an internal Nonconformance Report identified that the product in question has an incorrect Reference Value for the analyte Cadmium on the product IFU. The value on the IFU is “8.6 ng/mL” with an expected range of “7.31 – 9.89 ng/mL” however results for the product have been reported and confirmed to be on average “<.5 ng/mL” and expected range of “0.0 - .5 ng/mL”:

| Product Number | Lot Number | Description       | Correct Reference Value |
|----------------|------------|-------------------|-------------------------|
| 66816          | C2540      | Trace Elements NR | <0.5 ng/mL              |

We advise you take the following steps:

1. Destroy IFU with incorrect values.
2. Replace IFU with revised IFU with corrected values (see attached).
3. Review and acknowledge UTAK’s recall advisory form (2020-01). Return the completed form to our Customer Service Team

Sincerely,



The Undersign confirms that the appropriate authorities have been notified.

If you have any questions about this Field Safety Corrective Action and its instructions, please contact our Customer Service team at [welovecontrol@utak.com](mailto:welovecontrol@utak.com) or 1.800.235-3442. We appreciate your understanding and apologize for any inconvenience may have caused your testing laboratory.

