DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160	6/12/2025-6/16/2025* FEI NUMBER 3002808041

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jacinta George, Vice President & Managing Director

FIRM NAME	STREET ADDRESS
Reading Scientific Services Ltd	Reading Science Centre, The University; Pepper Lane
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Reading, WOK, RG6 6LA United Kingdom	Control Testing Laboratory

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

TM-578, titled "The Determination of (b) (4) (b) (4) by Inductively Coupled Plasma – Mass Spectroscopy (ICP-MS)," requires that internal quality control and standard performance characteristic tests (b) (4) (b) (4) criteria (b) (4) to performing ICP-MS metal analysis. Failed instrument performance checks have been documented on the "Test Batch Report Sheet for Metals" across client data packages. In response, new standard controls were prepared and failed controls re-analyzed to confirm reliable instrument operation before proceeding with the sample analysis. However, you did not initiate or complete laboratory investigations to determine the root cause of the initial instrument performance failures observed during preliminary testing for the following client batches.

A. Batch # (b) (4) – On 12/21/2023, there was a (b) (4) ICP-MS instrument (part # (b) (4)) failure for (b) (4)

B. Batch # (b) (4) - On 02/20/2024 there was a (b) (4) (b) (4) ICP-MS instrument (part # (b) (4)) failure for (b) (4)

AMENDMENT 1

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Burnell M Henry, Investigator
Gene D Arcy, Investigator

X Burnell M Henry Investigator Signed By: Burnell M. Henry -S Date Signed: 06-16-2025 08:37:29

DATE ISSUED
6/16/2025

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C.Batch # (b) (4) - On 04/03/2025 there was a (b) (4) (b) (4) ICP-MS instrument (part # (b) (4)) failure for (b) (4)

Additionally, QSOP-41, titled "Out of Specification (OOS) and Out of Trend (OOT) Result Investigation for GMP Analysis" addresses only client OOS results in accordance with applicable product specifications. The procedure lacks provisions for initiating and documenting investigations into equipment performance failures.

***DATES OF INSPECTION**
6/12/2025(Thu), 6/13/2025(Fri), 6/16/2025(Mon)

X Gene D Arcy
Investigator
Signed By: 1300159963
Date Signed: 06-16-2025 08:38:30

AMENDMENT 1

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Burnell M Henry, Investigator
Gene D Arcy, Investigator

X Burnell M Henry
Investigator
Signed By: Burnell M. Henry -S
Date Signed: 06-16-2025 08:37:29

DATE ISSUED
6/16/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."