DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Headquarters - White Oak - CDER/OTS/OSIS/DGDSI 10903 New Hampshire Ave White Oak, Building 51 Industry Information: www.fda.gov/oc/industry	06/09/2025 to 06/13/2025
	FEI NUMBER 3020784373

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dave Masters-Moore, Senior Director/ Site Head

FIRM NAME	STREET ADDRESS
ICON PLC	10836 Strang Line Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Lenexa, KS	Bioanalytical Facility

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 (I) (WE) OBSERVED:

1-In study (b) (4) for the (b) (4) the firm used calibration standards and QC samples outside the established stability time period of 35 days. Specifically, ISR run 16 was performed on 01/26/2024 with calibration standards and QCs prepared on 12/07/2023. ISR run 16 was accepted. The calibration standards and QCs were used after being stored for 50 days at -70◦C when only 35 days of long-term stability for (b) (4) in plasma at -70◦C was established.

2-In study (b) (4) for the (b) (4) a run was stopped due to instrument related errors and samples already injected were reinjected, but samples reinjection was not included in the study report. Specifically, run 1 was stopped and subsequently reinjected.

3- In study (b) (4) for the (b) (4), samples for subject (b) (6) were reprocessed but not reported. Specifically, subject samples in a plate for run 7 did not meet plate acceptance criteria and were subsequently reprocessed in run 15.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Sylvestre K. Dossou -S Digitally signed by Sylvestre K. Dossou -S Date: 2025.06.13 11:40:45 -04'00'	Sylvestre K Dossou, Ph.D., Biologist	06/13/2025

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 judgement, 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."