DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Office of Study Integrity and Surveillance USFDA-CDER WO 21, RM4512, 10903 New Hampshire Ave, Silver Spring, MD 20993 Tel: 301-796-3865 Industry Information: www.fda.gov/oc/industry	07/14/2025-07/18/2025 and 07/21/2025 to 07/25/2025
	FEI NUMBER 3007267856

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Rajen Shah, Director

FIRM NAME	STREET ADDRESS
Raptim Research Private Limited	A-239/A-242, M.I.D.C., T.T.C. Industrial Area, Mahape
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Navi Mumbai-400710, India	Contract Research Organization

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. The firm did not follow practices and procedures established in standard operating procedures (SOPs) or standard test procedures (STPs). Specifically:

   a. eSOP/ANA/006 (version 05, Amendment 01) states that analytical runs should not be considered final until QA has reviewed and approved the status of the run. In study (b) (4), run 251024 (b) (6) was finalized as rejected by QA on 29/Oct/2024. However, samples from subject (b) (6) were reanalyzed on 28/Oct/2024 (run 281024REP01 (b) (6)), which was prior to final QA approval of run 251024 (b) (6)

   b. eSOP/ANA/001 states that biological sample disposal details should be recorded on the biological sample disposal record form, ANA-eFM-179. However, for multiple studies including (b) (4), (b) (4), (b) (4), and (b) (4), the form did not contain complete disposal details.

   c. The STP/ANA/946 for quantitation of (b) (4) and (b) (4) requires that samples should be discarded after completion of an analytical batch. However, in project (b) (4), samples from a repeat run completed on 03/Jul/2025, were retained in the autosampler until at least 14/Jul/2025, despite batch processing records indicating sample disposal on 04/July/2025.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Courtney N. Long -S Digitally signed by Courtney N. Long -S Date: 2025.07.25 10:13:01 +05'30' Melkamu Getie Kebtie -S Digitally signed by Melkamu Getie Kebtie -S Date: 2025.07.25 10:15:32 +05'30' KARA A. SCHEIBNER -S Digitally signed by KARA A. SCHEIBNER -S Date: 2025.07.25 10:14:08 +05'30' Arindam Dasgupta -S Digitally signed by Arindam Dasgupta -S Date: 2025.07.25 10:16:42 +05'30'	Kara A. Scheibner, Ph.D., Pharmacologist Melkamu Getie-Kebtie, R.Ph.,PhD., Pharmacologist Courtney N. Long, Investigator Arindam Dasgupta, Ph.D., Div. Director (Acting)	07/25/2025

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Office of Study Integrity and Surveillance USFDA-CDER WO 21, RM4512, 10903 New Hampshire Ave, Silver Spring, MD 20993 Tel: 301-796-3865 Industry Information: www.fda.gov/oc/industry	07/14/2025-07/18/2025 and 07/21/2025 to 07/25/2025
	FEI NUMBER 3007267856

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Rajen Shah, Director

FIRM NAME	STREET ADDRESS
Raptim Research Private Limited	A-239/A-242, M.I.D.C., T.T.C. Industrial Area, Mahape
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Navi Mumbai-400710, India	Contract Research Organization

d. eSOP/ANA/021 states that QC audit findings reported in the QC report will be reviewed and addressed by the respective departments, including any corrections as needed. The corrections will be subsequently verified by QC. However, QC review reports found in a binder labeled "Miscellaneous data" in instrument room 02 were incomplete because they did not contain departmental responses, required corrective actions and subsequent QC verification. Impacted projects include (b) (4) and RRL-ANA-MV-896.

e. eSOP/ANA/001 states that biological matrix (e.g., plasma) should be used within one year after collection. The firm had multiple lots of pooled plasma samples exceeding the one-year expiration date that were not discarded. Examples include plasma lots:

i. 210324 (b) (4) – stored on 21/Mar/2024; 46 mL not discarded
ii. 210324 – stored on 21/Mar/2024; 135 mL not discarded
iii. 180324 – stored on 18/Mar/2024; 144 mL not discarded
iv. 080523 – stored on 05/Aug/2023; 169 mL not discarded

2. The firm did not have adequate information in their source documents for complete reconstruction of study activities.

a. Analytical staff could not locate the current storage location of lot 012024004103 of plasma. The plasma was transferred from the clinical department to the analytical department on 8/Nov/2024 for use as blank biological matrix for method development/validation. The Biological Matrix Consumption Record documented that the plasma was stored in Freezer INS/ANA/505 on 8/Nov/2024. Freezer INS/ANA/505 is no longer present at the facility.

b. Disposal of samples from study (b) (4) (Analytical aliquot) was documented on 07/Aug/2023 in the sample disposal record. However, the samples were documented as disposed on 17/Oct/2024 in CREDBio.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Kara A. Scheibner, Ph.D., Pharmacologist Melkamu Getie-Kebtie, R.Ph.,PhD., Pharmacologist Courtney N. Long, Investigator Arindam Dasgupta, Ph.D., Div. Director (Acting)	07/25/2025

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Office of Study Integrity and Surveillance USFDA-CDER WO 21, RM4512, 10903 New Hampshire Ave, Silver Spring, MD 20993 Tel: 301-796-3865 Industry Information: www.fda.gov/oc/industry	07/14/2025-07/18/2025 and 07/21/2025 to 07/25/2025
	FEI NUMBER 3007267856

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Rajen Shah, Director

FIRM NAME	STREET ADDRESS
Raptim Research Private Limited	A-239/A-242, M.I.D.C., T.T.C. Industrial Area, Mahape
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Navi Mumbai-400710, India	Contract Research Organization

c. The unique identifier of a lot of whole blood used as blank biological matrix for method development RRL-ANA-MD-1336 was documented incorrectly. Lot No. 012025000575 of whole blood (300 ml) was transferred from the clinical department to the analytical department on 2/Mar/2025. The volunteer consent form for blank biological matrix donation lists the unique identifier as 012025000575. However, the Biological Matrix Consumption Record and the documentation for RRL-ANA-MD-1336 document the lot No. as 012025000515.

d. CredBio and the logbook for freezer INS/ANA/507 documented that period 1, period 2, and period 3 samples from study (b) (4) were stored on shelf A4 of the freezer. However, when sample custodians attempted to retrieve the samples, period 2 samples were not located on shelf A4, but were instead on shelf A5.

e. The Sample Disposal Records from in vitro study (b) (4) contained multiple discrepancies.

i. Samples from Donor (b) (6) cell 10, aliquot 1 were documented as disposed of on a Biological Sample Disposal Record dated 14/May/2025. However, an additional form for in vitro sample disposal dated 18/Jun/2025 documents the disposal of samples from Donors (b) (6), aliquot 1, including Donor (b) (6) cell 10, aliquot 1. The freezer logbook for INS/ANA/259 also documented disposal of samples from Donor (b) (6) cells 1-22, aliquot 1 on 18/Jun/2025.

ii. The in vitro sample disposal record dated 14/May/2025 documents that the samples were retrieved for disposal from freezer number INS/ANA/269. The samples are also documented as being retrieved and discarded of from freezer INS/ANA/259 on 14/May/2025. INS/ANA/269 is not a valid Raptim Research freezer identification number.

iii. There were 308 samples collected per donor (14 samples per cell, 22 cells) in study (b) (4). The Biological Sample Disposal Record dated 14/May/2025 documents that 14 samples were discarded for Donor (b) (6) cell 10, aliquot 1. The INS/ANA/259 freezer log documents that the total number of samples discarded for Donor (b) (6) is 292 which indicates that 16 samples were previously discarded instead of 14 samples.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Kara A. Scheibner, Ph.D., Pharmacologist Melkamu Getie-Kebtie, R.Ph.,PhD., Pharmacologist Courtney N. Long, Investigator Arindam Dasgupta, Ph.D., Div. Director (Acting)	07/25/2025

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Office of Study Integrity and Surveillance USFDA-CDER WO 21, RM4512, 10903 New Hampshire Ave, Silver Spring, MD 20993 Tel: 301-796-3865 Industry Information: www.fda.gov/oc/industry	07/14/2025-07/18/2025 and 07/21/2025 to 07/25/2025
	FEI NUMBER 3007267856

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Rajen Shah, Director

FIRM NAME	STREET ADDRESS
Raptim Research Private Limited	A-239/A-242, M.I.D.C., T.T.C. Industrial Area, Mahape
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Navi Mumbai-400710, India	Contract Research Organization

iv. The In vitro Sample Disposal Record dated 17/Jun/2025 documents that 2380 samples were discarded for Donors (b) (6), aliquot 1. The logbook for freezer INS/ANA/259 documents that 2378 samples were discarded for Donors (b) (6), aliquot 1.

f. There was a discrepancy in the biological matrix consumption record for the pooled plasma from study (b) (4) (lot 120324 (b) (4)). Pooled plasma was prepared on 12/Mar/2024, but the lot ID, matrix type, anticoagulant, number of containers, and freezer ID for that lot were documented on 12/Mar/2023.

g. The biological matrix consumption record and CREDBio entry for pooled plasma lot 120324 (b) (4) from study (b) (4) documented the presence of 3 vials (vial 01 containing 100 mL; vial 02, containing 35 mL; and vial 03 containing 35 mL) in freezer INS/ANA/835 on shelf A3. However, vial 01 could not be located in the freezer.

h. There was a discrepancy in the pooled plasma lot 100124 (b) (4) retrieval information between the biological matrix consumption record and CREDBio . Consumption records document storage of 6 pooled plasma containers in freezer ANA/INS/506, and retrieval of 3 containers on 22/Jan/2024. However, CREDBio documents transfer of the containers to freezer ANA/INS/512 on 20/Jan/2024. This information was never updated in the biological matrix consumption record.

i. Sample discard records were not stored or archived adequately. For example, for multiple studies conducted in 2022, 2023 and 2024, sample discard records were not archived in the respective archive binder for that year. Instead, they were found in a binder with records for 2025.

3. The firm did not demonstrate consistent practices and procedures. Specifically:
   a. In study (b) (4), segregation activity for ISR experiment 02 (samples from subjects (b) (6) and (b) (6)) was documented in CREDBio. However, this was not done for ISR experiment 01 (samples from subjects (b) (6)).

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Kara A. Scheibner, Ph.D., Pharmacologist Melkamu Getie-Kebtie, R.Ph.,PhD., Pharmacologist Courtney N. Long, Investigator Arindam Dasgupta, Ph.D., Div. Director (Acting)	07/25/2025

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Office of Study Integrity and Surveillance USFDA-CDER WO 21, RM4512, 10903 New Hampshire Ave, Silver Spring, MD 20993 Tel: 301-796-3865 Industry Information: www.fda.gov/oc/industry	07/14/2025-07/18/2025 and 07/21/2025 to 07/25/2025
	FEI NUMBER 3007267856

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Rajen Shah, Director

FIRM NAME	STREET ADDRESS
Raptim Research Private Limited	A-239/A-242, M.I.D.C., T.T.C. Industrial Area, Mahape
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Navi Mumbai-400710, India	Contract Research Organization

b. Replicate aliquot samples were not consistently documented in CREDBio for all studies. For example, in study (b) (4), information from replicate aliquot samples was entered in CREDBio on the date the samples were received (24/Feb/2024). However, in study (b) (4), samples were received on 27/Sep/2024, but sample information was not entered in CREDBio until 13/Apr/2025. Similarly, in study (b) (4) samples were received on 03/Apr/2024, but sample information was not entered in CREDBio until 26/Feb/2025.

c. Sample transfer records were not consistently uploaded into CREDBio. For example, for studies (b) (4) and (b) (4), sample transfer records for both analytical and replicate aliquots were uploaded into CREDBio. However, for studies (b) (4) and (b) (4), only the analytical sample transfer records were uploaded to CREDBio.

4. The firm did not consistently follow good documentation practices in their raw data management during conduct of method validation of (b) (4) (RRL-ANA-MVR1409). For example, in raw data forms (17242, 7215, 0597) several corrections were made to address QC findings. However, the changes were made without documenting when the change was made and who made the change.

5. The firm did not consistently follow the standard operating procedure eSOP/IT/006 v 01 for back up for computer system. For example, for a 90-day period (22/April-20/July/2025) that was reviewed for instrument ID API2000-01, the backup plan failed on July 14, June 27, June 26, June 16, June 03, June 1, May 1, and April 30, 2025. The eSOP/IT/006 v 01 required a full and incremental back up of the computer systems. Although the backup activity failed, backup activity was indicated to have been verified by the IT administrator and QA in verification of backup logbook (RRL-IT-LG-007-001/25).

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Kara A. Scheibner, Ph.D., Pharmacologist Melkamu Getie-Kebtie, R.Ph.,PhD., Pharmacologist Courtney N. Long, Investigator Arindam Dasgupta, Ph.D., Div. Director (Acting)	07/25/2025

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."