DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of Generic Drug Study Integrity Office of Study Integrity and Surveillance USFDA-CDER 10903 New Hampshire Ave, Silver Spring, MD 20993 Tel:301-796-1327 Industry Information: www.fda.gov/oc/industry	05/05/2025 - 05/09/2025
	FEI NUMBER 3036040213

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Hans Bernd Kucher, Study Director

FIRM NAME	STREET ADDRESS
Labor Augsburg MVZ GmbH	August-Wessels-Straße 5
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
86154 Augsburg, Bavaria, Germany	Biopharmaceutical Analytical 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:

The following pertains to clinical trial [redacted] (b) (4) (study # [redacted] (b) (4) for measurement of C-telopeptide cross-link of type 1 collagen [sCTx]).

1. The firm did not adhere to their established acceptance criterion for individual quality control samples in evaluating method performance prior to starting study subject sample analysis for the day. Specifically, the firm analyzed samples on March 17, 2021, August 24, 2022, September 8, 2022, and September 21, 2022, despite the method performance assessment prior to sample analysis not meeting acceptance criterion (i.e., % bias for the high QC was greater than 20%).

2. The firm did not retain the electronic source data (i.e., Cobas 6000 instrument generated readings [electrochemiluminescence values] from which concentration data were derived) for sample analysis.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Melkamu Getie Kebtie -S Digitally signed by Melkamu Getie Kebtie -S Date: 2025.05.09 04:45:45 -04'00'	Melkamu Getie-Kebtie, Ph.D., R.Ph., Pharmacologist	5/9/2025

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."