DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71-5128 Silver Spring, MD 20993-0002 240-402-8906 orabioinspectionalcorrespondence@fda.hhs.gov	2/20/2020-2/27/2020* FEI NUMBER 3002638287

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Adrian Birkett, Head of Operations	
FIRM NAME Millipore (U.K.) Ltd.	STREET ADDRESS 2 Fleming Road, Kirkton Campus
CITY, STATE, ZIP CODE, COUNTRY Livingston, West Lothian, EH54 7BN United Kingdom	TYPE ESTABLISHMENT INSPECTED Licensed Bulk (FFMU) Blood Grouping Reagent Manufacturer

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

Lots of licensed products were released by the manufacturer prior to completion of tests for conformity with standards applicable to such product.

Specifically,

Complaint 2292851, received on 17Jan2020, Lot KNI1903, Anti-c FFMU, documented that the customer reported a sodium azide content of 0.03 % when the product labeling and Certificate of Analysis (CoA) states "Sodium Azide Content 0.1% w/v". Primary Production Investigation KNI1903 (RCA Task #2310298, closed on 20Feb2020, reported that investigative testing as per (b) (4) task #'s 2297056 and 2306958 confirmed the customer's measurement of sodium azide solution concentration was correct. Document No. 00007239FM, Product Field Corrective Action (FCA) Assessment Form, dated 06Feb2020, reported:

a. Sodium Azide content was not verified as part of lot release testing.

b. QC testing confirmed the low sodium azide content was 0.01% w/v.

c. The Product Evaluation Summary stated a product recall was required as the long term impact on performance of Anti-c FFMU, Lot No. KNI1903 was unknown.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Prabhu P Raju, Investigator - Team Biologics Nimmy Mathews, Investigator	X Prabhu P Raju Investigator - Team Biologics Signed By: 2000095678 Date Signed: 02-27-2020 03:29:33	2/27/2020

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OBSERVATION 2

Records are not maintained in a manner which allows steps in the manufacture of product to be traced.

Specifically,

a. The time FFMU Lot (b) (4) (Anti-A) was removed from the 2-8 °C Cold Room (b) (4) on July 30, 2019 was not documented on the transfer log sheet. FFMU Lot (b)(4) (Anti-A) was filled on July 30, 2019 from 10:30 am to 11:40 am. at ambient temperature and subsequently labeled. The time FFMU Lot (b) (4) (Anti-A) was placed in the final 2-8 °C Cold Store (b)(4), on July 30, 2019 was not recorded. Document 20452181, dated 24Feb2020, titled: (b)(4) states product (FFMU) can be held at (b)(4).

b. Complex calculations and (b)(4) testing results are not reviewed by a second individual or included in the batch record for all licensed FFMUs (For Further Manufacturing Use). A review of the batch record, (b)(4) (an Anti Cw FFMU), revealed that the (b)(4) used in the production of the FFMU were tested for (b)(4) To determine acceptability of these (b)(4) for use in production, the technician must perform complex calculations and assess (b)(4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Prabhu P Raju, Investigator - Team Biologics Nimmy Mathews, Investigator X Prabhu P Raju Investigator - Team Biologics Signed By: 2000060678 Date Signed: 02-27-2020 03:29:33	2/27/2020

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However, these calculations and assessments are not reviewed by a second individual. Furthermore, the calculation or assessment of the (b)(4) is not documented in the batch record of the FFMU to be reviewed by quality prior to batch release.

***DATES OF INSPECTION**

2/20/2020(Thu), 2/21/2020(Fri), 2/24/2020(Mon), 2/25/2020(Tue), 2/26/2020(Wed), 2/27/2020(Thu)

X Nimmy Mathews
Investigator
Signed By: 2000790204
Date Signed: 02-27-2020 03:30:15

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Prabhu P Raju, Investigator - Team Biologics Nimmy Mathews, Investigator	X Prabhu P Raju Investigator - Team Biologics Signed By: 2000086476 Date Signed: 02-27-2020 03:29:33	2/27/2020

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."