DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	2/20/2018-3/2/2018* FEI NUMBER 1219913

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Frank G. Fives, VP Manufacturing & Walpole Site Manager

FIRM NAME	STREET ADDRESS
Siemens Healthcare Diagnostics, Inc	333 Coney St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
East Walpole, MA 02032-1516	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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically, the firm failed to adequately verify the effectiveness of the corrective and preventive actions taken related to CAPA 6726; CAPA 6420; and CAPA 6533.

OBSERVATION 2

Procedures for acceptance activities have not been adequately established.

Specifically,

a) The investigations of the deviations and/or out of specification results observed during quality control acceptance activities, such as, qualification of a new antibody pool and batch/ lot quality control in-process and final testing are not adequately documented.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Maryam Tabatabaie, Investigator	X Maryam Tabatabaie Investigator Signed By: Maryam Tabatabaie -S Date Signed: 03-02-2018 10:51:26	3/2/2018

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b) The accuracy of the data contents of the linear bar codes on the (b) (4) (b) (4)) are not verified by Quality Control, prior to release to the production Print Room. The(b) (4) s are enclosed with subsequent assay kit builds/ package.

OBSERVATION 3
Software used as part of production has not been adequately validated for its intended use according to an established protocol.

Specifically, the verification of the accuracy of the reagent expiration dates calculated and generated by the (b) (4) software was not performed and included as part of the software validation functional performance testing.

OBSERVATION 4
Schedules for the adjustment, cleaning, and other maintenance of equipment have not been adequately established.

Specifically, The (b) (4) and (b) (4) preventive maintenance activities performed in the Controlled Temperature Rooms, including (b) (4) coolers and freezers, used for storage, handling and processing of products are not documented.

Annotations to Observations

Observation 1:	Promised to correct
Observation 2:	Promised to correct
Observation 3:	Promised to correct
Observation 4:	Promised to correct

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*DATES OF INSPECTION

2/20/2018(Tue), 2/21/2018(Wed), 2/22/2018(Thu), 2/26/2018(Mon), 2/27/2018(Tue), 2/28/2018(Wed), 3/02/2018(Fri)

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