DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S Food and Drug Administration 10903 New Hampshire Avenue Bldg 51 Room 4225 Silver Spring, MD 20993 PH: (301)796-3334 Fax (301) 847-8738 Industry Information: www.fda.gov/oc/industry	September 25,26,27, 2017
	FEI NUMBER 3004186644

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Bob Van Doorsselaere, QHSE Manager Benelux Operational Integrity

FIRM NAME	STREET ADDRESS
SGS Lab Simon	Vieux Chemin du Poete 10-B1301
CITY, STATE AND ZIP CODE Wavre, Belgium	TYPE OF ESTABLISHMENT INSPECTED Contract Testing Laboratory

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Established test procedures and laboratory control mechanisms are not followed and documented at the time of performance. Specifically,

1. Laboratory investigations issued to evaluate test results as described in approved procedure BE-LSS-WVR-MQA-SOP003, Treatment of Out of Specifications (OOS), Out of Expectation (OOE) or Out of Trend (OOT)-Rev 20, approved to describe actions to be taken on discovery of results that fall outside pre-definned acceptance criteria, are not always fully reported and documented as described in the procedure. For example, events reported by clients and tracked with investigation numbers are not recorded in applicable form (eg: 1600077), or reported description of additional measures or work done (page 4) are not fully described as required with applicable attachment form A07 (1600059; 1500004) .

2. Samples received and processed as described in approved procedure BE-LSS-WVR-QC-SOP007, Detailed Description of Laboratory Processes-Rev 04, do not include complete verification of quantities received. The actual quantity of material received per unit is not always included in containers received or verified for accuracy prior to acceptance of units (samples).

3. Approved procedure BE-LSS-WVR-CBR-GP003, Use and Preparation of Solutions in the Laboratory Rev-10, established on site to document activities for registration of reagent solutions prepared on site do not include complete instructions on how to record verification activities for solutions obtained as "ready to use" but that are referenced in the same procedure. Ready to use solutions are verified as described in the procedure, but no instructions are described in the procedure on how to log these materials or how to maintain raw data obtained after the verification of the solution (original raw data was observed stored without any control as part of the logbook used for prepared solutions).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Noreen Muniz, Consumer Safety Officer	9/27/17

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4. Weight sets used for (b) (4) verification activities on balances used in the Analytical Laboratory are not verified for accuracy or calibrated status at any regular frequency, when used as described in approved procedure BE-LSS-WVR-QC-GP017,Rev 02-Use, Maintenance and Qualification of Balances. The process to verify the frequency of this verification is to be approved as referenced on current version (Rev 02) of the procedure. Revision 01 of procedure did not require verification of the weights used (b) (4) unless a deviation was reported during (b) (4) balance verification.

OBSERVATION 2

Records are not kept for the maintenance and inspection of equipment. Specifically,

1 (b) (4) qualification of refrigerator 1178 (5C+/-3C) used to store reagents under refrigerated conditions (E.G: reagents used for Endotoxin Testing) as described in most recent qualification report # 1704B006 dated April 2017, failed to include: documented evidence of load reported during the exercise; justification for the number and clear description of location of probes used based on intended use; rationale for the completion of the exercise in (b) (4) for equipment to be used 24 hrs./7 days; documented evidence of the verification of the calibration status of the temperature sensors used during the exercise.

2. Initial qualification of stability chamber 3509 (25C/60RH) conducted in May 2017, intended for storage of stability samples on site , failed to include complete documentation of qualification activities conducted as described in applicable protocols to ensure equipment is suitable for intended use. For example:

a. Tests conducted as part of qualification exercise # 59226176070010, 2/5/17, included reference to tests reported as "fail" but that were also described as "not applicable" without written justification (section: 3.1-Chamber Configuration, 3.15-Potential fee alarm output).

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	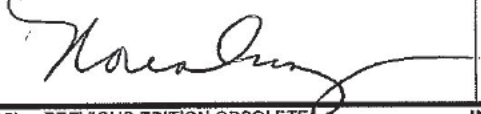	Noreen Muniz, Consumer Safety Officer	9/27/17

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b. Executed documented evidence of load reported during the final performance qualification exercise failed to include: justification for the number and clear location of temperature sensors used based on intended use; description and configuration of load used for the full (loaded) study; evidence for the verification of the calibration status of the temperature sensors used during the exercise.

NA
9/27/17

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