DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	2/9/2026-2/13/2026
	FEI NUMBER 3000215335

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Gil Raviv, CEO/President

FIRM NAME	STREET ADDRESS
Snap Diagnostics, LLC.	616 Atrium Dr Ste 100
CITY, STATE, ZIP CODE, COUNTRY Vernon Hills, IL 60061-1713	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:

OBSERVATION 1

Corrective action was not adequately taken to eliminate the cause of nonconformities in order to prevent recurrence.

Specifically, your firm opened a corrective action (CAPA 0072) to address a failure with the effort sensor of the Class II SAM Model 9-10000 Sleep Apnea Recorder (K240100, MNR) and did not adequately implement an action to eliminate the cause of the effort sensor failure. The SAM Model 9-10000 Sleep Apnea Recorder is intended to be used as an aid that records airflow, breathing effort, and body position for diagnostic evaluation of patients using quantitative and qualitative analysis. Your firm identified 4,079 units out of (b) (4) units since (b) (4) that had an effort sensor failure due to the durability issues of the effort sensor material, which caused the failure to record data. Your firm implemented (b) (4) component changes from (b) (4) without adequately eliminating the cause of the effort sensor failure. The corrective action record has been open since February 2025. Your firm continues to distribute the SAM Model 9-10000 Sleep Apnea Recorders with effort sensor components, despite the self-identified high failure rate and the component changes that were implemented to improve performance of the device. Currently, there are (b) (4) units with the original (b) (4) effort sensor component, (b) (4) units with the (b) (4) component change of a (b) (4) effort sensor, and (b) (4) units with the (b) (4) component change of a (b) (4) ffort sensor that are cycled for distribution. Based on your firm's current Risk Assessment and Risk Management Plan, the effort sensor failure was identified as low risk. However, based on the probability of harm and severity, the risk level should have been identified, at minimum, as a medium risk level to the end users.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Shuana H Xiong, Investigator	X Shuana H Xiong Investigator Signed By: Shuana H. Xiong -S Date Signed: 02-13-2026 16:05:35	2/13/2026

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One or more processes for risk management in product realization have not been adequately documented.

Specifically, your firm failed to adequately identify the risk and risk control measures to manage the risk of an effort sensor failure of the Class II SAM Model 9-10000 Sleep Apnea Recorder (K240100, MNR). The SAM Model 9-10000 Sleep Apnea Recorder is intended to be used as an aid that records airflow, breathing effort, and body position for diagnostic evaluation of patients using quantitative and qualitative analysis. Your firm identifies the harm of device sensor malfunction to be a delayed diagnosis with a severity level of minor, a probability of harm to be remote, and a low risk level. Your firm did not accurately identify the probability of harm based on the product life cycle, therefore inaccurately identifying a risk level. Based on your firm's current Risk Management Plan, the probability of harm based on the product life cycle should have been identified as probable with a severity level of at minimum, minor; therefore, increasing the risk level to medium. Additionally, the risk control measures identified to address the issue are not adequately identified to prevent the harm of a delay in treatment to the patient. For example, the LED indicates a device error, which does not prevent a loss of data, which then may lead to a delay of diagnosis and a harm of delay in treatment.

OBSERVATION 3

Procedures to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product were not adequately documented.

Specifically, your firm failed to adequately define the controls to document and evaluate nonconforming product. Your procedure, "Control of Nonconforming Product/Processes Procedure" (QP-009, Rev. L 03/03/2025 and Rev. J, 02/25/2022), requires that all product discovered (b) (4) s nonconforming will be documented in a nonconformance log and either on a paper record ((b) (4)) or electronically through a (b) (4) . Your firm manufactures the SAM Model 9-10000 Sleep Apnea Recorder (K240100, MNR), which is intended to be used as an aid that records airflow, breathing effort, and body position for diagnostic evaluation of patients using quantitative and qualitative analysis. Your firm identified

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(b) (4) units since (b) (4) of the Class II SAM Model 9-10000 Sleep Apnea Recorder as nonconforming product due to an effort sensor failure and documented them in the nonconformance log with no additional evaluation documented on a (b) (4) record or in the (b) (4). Additionally, your firm failed to implement controls to prevent the distribution of potentially nonconforming product and continued to distribute units containing outdated components despite identifying a high failure rate. Based on your firm's current Risk Management Plan the probability of harm based on the product life cycle should have been identified as probable with a severity level of at minimum, minor; therefore, increasing the risk level to medium. A nonconformance report was not opened until 02/07/2026, over 20 months after the issue was identified, to address all (b) (4) units of the SAM Model 9-10000 Sleep Apnea Recorder.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

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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."