DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	3/5/2026-3/9/2026* FEI NUMBER 3010484784

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tyler G. Hill, VP of Operations

FIRM NAME	STREET ADDRESS
Advanced Breath Diagnostics LLC	318 Seaboard Ln Ste 310
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Franklin, TN 37067-2880	Manufacturing / Spec Developer

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

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

Specifically,

Your firm created a Risk Analysis (PFMEA) for Crackers (labeled PFMEA-Cracker Subassembly), however the document did not include the "Process Failure Mode (HAZARD)" with a category labeled "Contamination." It also does not contain risk control measure(s) to control the hazard or the effects of the hazard on patient(s) using your Class III GEBT kits. The current and potential hazards found at your firm are listed below:

1. Your Director of Manufacturing expressed that their current manufacturing practices do not require employees to change gloves when directly handling and repackaging crackers. However, the risks that can occur if your patient ingests a contaminated cracker is not listed in the PFMEA.

2. A potential future hazard is that your current manufacturing area lies (b) (4) away from a (b) (4) door used for the delivery of raw ingredients. However, if you are manufacturing cracker pouches when the (b) (4) door is open you are not able to stop the outside air from entering the space where the open cracker sleeves are located. Any potential airborne contaminants can land onto the crackers and contaminate the crackers, which is not addressed on your current version of your PFMEA.

Your firm manufactures a Class III GEBT kit, which is used in the "measurement of the rate of gastric emptying of solids" and diagnosing of gastroparesis in patients.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Nikki S Bryant, Investigator X Nikki S Bryant Investigator Signed By: NIKKI S. BRYANT -S Date Signed: 03-09-2026 15:18:22	3/9/2026

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*DATES OF INSPECTION

3/05/2026(Thu), 3/06/2026(Fri), 3/09/2026(Mon)

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Annotations to Observations

Observation 1: 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."