DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	3/24/2026-4/8/2026* FEI NUMBER 3017609580

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul E. Behrends, Quality Manager

FIRM NAME	STREET ADDRESS
Amnion LLC	14 Pidgeon Hill Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sterling, VA 20165-6155	Human Tissue Processor

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

The quality program has not established and maintained appropriate monitoring systems.

Specifically,

Review of the environmental monitoring records dated September 2025 through April 2026 revealed your firm has failed to ensure that test results were received in a timely manner.

Examples include the following:

A. (b) (4) air environmental monitoring samples were collected during the processing of the following batches of amniotic membrane and amnion-chorion membrane: AM-25-(b) (4), (b) (6), (b) (7)(C) (sample collected on (b) (4), (b) (6), (b) (7) (C)), AM-25-(b) (4), (b) (6), (b) (7)(C) (sample collected on (b) (4), (b) (6), (b) (7) (C)), AM-25-(b) (4), (b) (6), (b) (7)(C) (sample collected on (b) (4), (b) (6), (b) (7) (C)), AM-25-(b) (4), (b) (6), (b) (7)(C) (sample collected on (b) (4), (b) (6), (b) (7) (C)), and AM-25-(b) (4), (b) (6), (b) (7)(C) (sample collected on (b) (4), (b) (6), (b) (7) (C)). The test results were not reported to your firm until 4/3/26. The time from the date the samples were collected to the date the test results were received was approximately (b) (4)

B. (b) (4) environmental monitoring samples were collected in the processing room for testing on (b) (4) The test results dated (b) (6), (b) (7)(C) revealed (b) (4) surface (b) (4) samples and (b) (4) surface samples exceeded the defined action levels. Your firm requested (b) (4) identification of the test results on 1/23/26. The (b) (4) identification results were not reported to your firm until 3/31/26 and 4/3/26. The time from the date the samples were collected to the date the final results were received was approximately (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	La-Tasha M Gunter, Investigator X La-Tasha M Gunter Investigator Signed By: LATASHA GUNTER - S Date Signed: 04-08-2026 09:02:28	4/8/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	3/24/2026-4/8/2026* FEI NUMBER 3017609580

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul E. Behrends, Quality Manager

FIRM NAME	STREET ADDRESS
Amnion LLC	14 Pidgeon Hill Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sterling, VA 20165-6155	Human Tissue Processor

C. (b) (4) air and (b) (4) surface environmental monitoring samples were collected in the processing room for testing on (b) (4) The test results were not reported to your firm until 12/31/25. The time from the dates the samples were collected to the date the test results were received was approximately (b) (4)

OBSERVATION 2

Documentation of the verification of supplies did not include a certificate of analysis from the vendor.

Specifically,

Review of the "Incoming Material Inspection and Release/Incoming Inspection" records, for incoming supplies dated January 2025 through March 2026, revealed that your firm failed to maintain a certificate of analysis from the vendor, as required by Document #QC004.A01, "Material Specification Matrix". Examples include but are not limited to the following:

A. The records for environmental monitoring contact plates identified by Lot # (b) (4) , received on 3/17/26, did not include a certificate of analysis. Additionally, the records indicated that a certificate of analysis was not required.

B. The records for environmental monitoring air plates identified by Lot #(b) (4), received on 7/11/25, did not include a certificate of analysis. Additionally, the records indicated that a certificate of analysis was not required.

C. The records for (b) (4) identified by Lot # (b) (4) , received on 6/4/25, did not include a certificate of analysis. Additionally, the records indicated that a certificate of analysis was not required.

D. The records for environmental monitoring air plates identified by Lot #(b) (4), received on 1/31/25, did

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	3/24/2026-4/8/2026*
	FEI NUMBER 3017609580

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul E. Behrends, Quality Manager

FIRM NAME	STREET ADDRESS
Amnion LLC	14 Pidgeon Hill Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sterling, VA 20165-6155	Human Tissue Processor

not include a certificate of analysis.

E. The records for environmental monitoring air plates identified by Lot #(b) (4), received on 1/9/25, did not include a certificate of analysis.

OBSERVATION 3
Documentation of facility cleaning and sanitation activities was not maintained.

Specifically,

Cleaning records dated January 2025 through March 2026, revealed that your firm did not document any (b) (4) cleaning and sanitation activities. Additionally, SOP #(b) (4) 002, "Cleaning Procedure," did not require the documentation of (b) (4) cleaning and sanitation activities.

OBSERVATION 4
Records were not maintained concurrently with the performance of each step.

Specifically,

Approximately (b) (4) out of (b) (4) batch records reviewed for amniotic membrane and amnion-chorion membrane, processed from (b) (4) through (b) (4), did not identify the date that each processing step was performed.

***DATES OF INSPECTION**
3/24/2026(Tue), 3/25/2026(Wed), 3/26/2026(Thu), 3/27/2026(Fri), 3/31/2026(Tue), 4/01/2026(Wed), 4/02/2026(Thu), 4/08/2026(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	La-Tasha M Gunter, Investigator	X La-Tasha M Gunter Investigator Signed By: LATASHA GUNTER - S Date Signed: 04-08-2026 09:02:28	4/8/2026

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."