DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	3/9/2026-4/9/2026* FEI NUMBER 1216602

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Richard P. Pampuro, Senior Director, Site Lead for Internal Manufacturing Billerica

FIRM NAME	STREET ADDRESS
Lantheus Medical Imaging, Inc.	331 Treble Cove Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
North Billerica, MA 01862-2849	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 WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, your firm released (b) (4) lot (b) (4), in which visual inspection defect rates exceeded action level specification in all defect categories (critical, major, and minor). Your firm works with a contract manufacturing organization (CMO) that produces approximately (b) (4) of (b) (4) lots. (b) (4) lot (b) (4) was manufactured by the CMO. The lot was visually inspected (b) (4) by the CMO and (b) (4) at Lantheus prior to release. The following visual inspection results were obtained for lot (b) (4)

1. CMO initial inspection:
   Critical rejects 1.9%, (action level (b) (4) %)
   Overall rejects 2.9%, (action level (b) (4) %). Most critical defects were for vial overseal crimp defects (e.g., loose crimp).

2. CMO reinspection:
   Critical rejects 0.8%
   Overall rejects 6%.

   Because the alert and action levels for reinspection differ from those for initial inspection, the lot was deemed passing per the CMO's procedures and released to your firm. The root cause of the

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defect rate exceeding action limits was not definitively identified by the CMO, but the CMO's investigation cited nine work orders related to mitigating/investigating seal quality issues on the oversealer in July 2025, when lot (b) (4) was capped.

3. Lantheus inspection:
   Critical defect rejects: 165 vials (action limit: (b) (4))
   Major defect rejects: 995 vials (action limit: (b) (4))
   Minor defect rejects: 5176 vials (action limit (b) (4))

Your firm released lot (b) (4) on the rationale that all defective units were (b) (4) during visual inspection and that the lot passed tightened AQL. Your firm's investigation of the high defect rates (DIRC 629191) states that the root cause is "Material" and that since the lot passed tightened AQL, no further investigation by your firm was required. There was no additional investigation of the vial supplier, analysis of why defects were repeatedly found and (b) (4) during re-inspections, or assessment of other lots with high reject rates that may have been released to the market. (b) (4) Lot (b) (4) was manufactured on (b) (4) and expires (b) (4).

In addition, your firm opened six deviations between 11/24/2024 and 11/24/2025 for visual inspection results exceeding action limits in lots produced by the CMO. Five were for minor defects, and one was for critical defects. Each of these six deviations states that no additional containment was required due to all rejects being removed during the inspection process.

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

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Specifically,

a. Your firm failed to evaluate the quality impact of your contract manufacturing organization (CMO) (b) (4) visual inspection rejects that, if not removed, would exceed your firm's action limits during your firm's subsequent visual inspection. Specifically, approximately (b) (4) of your firm's (b) (4) drug product lots are manufactured at your CMO, which conducts 100% visual inspection of filled vials against your CMO's specifications before shipping the unlabeled vials to your facility. Your CMO counts and (b) (4) visual inspection rejects prior to shipment. Upon receipt, your firm conducts a second 100% visual inspection against your own specifications, which are significantly tighter than your CMO's specifications.

Your firm does not separately evaluate whether the number of rejects (b) (4) by your CMO would have exceeded your alert/action limits. As a result, your CMO may deliver lots that meet the CMO's specifications but would have failed your firm's visual inspection criteria had all originally filled units been evaluated against your standards.

The following are batches reflecting the number of critical and minor rejects noted by your CMO and the number of critical and minor rejects noted during your firm's visual inspection of the lot upon receipt. Note that all lots listed met the CMO's visual inspection limits. However, these lots would have resulted in exceeding your firm's alert/action limits if the CMO's reject quantities were evaluated as part of the overall reject rate (bolded).

Batch Number and Expiry		Critical	Major	Minor
(b) (4)	CMO	50	16	172
	Lantheus	0	26	2485

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TYPE ESTABLISHMENT INSPECTED
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	Total	**50**	42	2657
	Lantheus **Alert**/Action	(b) (4)	(b) (4)	(b) (4)
(b) (4)	CMO	148	3	176
	Lantheus	0	20	2673
	Total	**148**	23	**2821**
	Lantheus **Alert/Action**	(b) (4)	(b) (4)	(b) (4)
(b) (4)	CMO	133	4	6
	Lantheus	2	39	3458
	Total	**135**	43	**3591**
	Alert/**Action**	(b) (4)	(b) (4)	(b) (4)
(b) (4)	CMO	77	11	353
	Lantheus	0	863	2559
	Total	**77**	894	**2912**
	Lantheus **Alert/Action**	(b) (4)	(b) (4)	(b) (4)
(b) (4)	CMO	40	18	400
	Lantheus	**1**	144	3330
	Total	**41**	162	**3730**
	Lantheus **Alert/Action**	(b) (4)	(b) (4)	(b) (4)
(b) (4)	CMO	300	14	403
	Lantheus	0	6	1271
	Total	**300**	20	1674
	Lantheus Alert/**Action**	(b) (4)	(b) (4)	(b) (4)
(b) (4)	CMO	27	16	556
	Lantheus	0	103	1941
	Total	**27**	119	**2497**
	Lantheus **Alert/Action**	(b) (4)	(b) (4)	(b) (4)
(b) (4)	CMO	3	3	682

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Investigator
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(b) (4)	Lantheus	0	5	2228
	Total	**3**	8	**2910**
	Lantheus **Alert**/Action	(b) (4)	(b) (4)	(b) (4)
(b) (4)	CMO	1	40	143
	Lantheus	0	813	1501
	Total	**1**	853	1644
	Lantheus **Alert**/Action	(b) (4)	(b) (4)	(b) (4)

In all cases above, vial lots were released by the CMO and finished product lots were released by your firm's quality unit for commercial distribution in the United States.

b. Your firm did not reliably train visual inspectors on detection of minor defects until late 2024. In 09/2025, you opened Investigation 85564 for an increased rate of minor defects detected in the (b) (4) visual inspection program from 09/2024-09/2025. Your firm attributed the increased defect rate to enhanced training on minor defect detection by a new training provider. However, as of March 2026, the challenge (b) (4) used to qualify visual inspectors for inspection of (b) (4) lots still does not include vials with minor defects, and only (b) (4) of vials with minor defects (no physical exemplars) are provided for training and testing of inspectors. In addition, your firm has opened at least 4 deviations documenting operators failing visual inspection requalification between 3/27/2025-5/9/2025 without a singular, clear root cause identified.

c. Your firm does not have documentation of periodic CGMP training/refresher training of certain employees. The training files from 2023-2025 for Associate Director, Manufacturing MS, and Engineering and Maintenance Technician III (b) (6), (b) were found to contain gaps in GMP training. Specifically, (b) (6), (b) lacks a CGMP training record for 2023, and MS lacks a CGMP training record

for 2024. (b) (6), (b) (7) job description includes performing preventative maintenance on production equipment, troubleshooting maintenance, calibration, and alarm issues, and providing support in root-cause analysis investigations. MS's job description includes ensuring that personnel, facilities, and manufacturing documentation are always in a compliant state; that data are collected and maintained in accordance with CGMPs; and that inspections, deviations, change controls, CAPAs and regulatory commitments are met with the highest quality standards. Additionally, your firm's SOP 005084 "Qualification and Training Program" does not specify a time interval for GxP refresher training.

OBSERVATION 3

Component testing is deficient in that each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

A. Your firm lacks scientific justification for your sampling specification for release testing of incoming raw material (b) (4). Your firm samples in accordance with the (b) (4) raw material specification, which requires Identification (b) (4) content) and Assay testing to be performed on (b) (4) of each received lot regardless of the size of the received lot. Your firm lacks data to demonstrate that (b) (4) would be representative of a lot, and your (b) (4) raw material specification fails to meet your procedural requirement on the number of containers necessary to be representative of a lot. Your firm uses (b) (4) as an excipient for production of all lots of drug product (b) (4). For example, for (b) (4) lot (b) (4), your firm received (b) (4) bottles of (b) (4) and sampled (b) (4) to perform Identification (b) (4) and Assay testing. Your firm used (b) (4) lot (b) (4) to manufacture (b) (4) lot (b) (4), expiry (b) (4), which your quality unit released for distribution on 12/17/2025. Your firm received approximately (b) (4) lots of (b) (4) in 2024-2025.

B. Your firm uses (b) (4) sampling for release testing of incoming raw material (b) (4) without adequate scientific justification. Your firm lacks historical data to demonstrate that (b) (4) samples will not dilute or mask potential container-specific quality issues, such as contamination by (b) (4). Your firm uses (b) (4) as an excipient for production of all lots of drug product (b) (4). For example, for (b) (4) lot (b) (4), your firm received (b) (4) bottles of (b) (4) and (b) (4) a total of (b) (4) from (b) (4) bottles to perform (b) (4), Assay, Microbial Limits, and Endotoxin testing. Your firm used (b) (4) lo(b) (4) to manufacture (b) (4) lot (b) (4), expiry (b) (4), which your quality unit released for distribution on (b) (4). Your firm received approximately (b) (4) lots of (b) (4) in 2024-2025.

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans and test procedures designed to assure that components and drug product containers conform to appropriate standards of identity, strength, quality and purity.

Specifically,

a. For (b) (4)) to which (b) (4) are attached for transfer of (b) (4) during production operations, (b) (4) is sampled for QC testing directly from the (b) (4) sample port instead of from the (b) (4) Your firm utilizes a (b) (4) system to produce (b) (4) that feeds the (b) (4) system. The (b) (4) is used for manufacturing and cleaning. (b) (4) points of use have a (b) (4) attached for transfer of (b) (4) during operations: (b) (4), and (b) (4). "BLDG. 110 Utilities Sampling Instructions" SOP 005552 does not require attachment of the (b) (4) during QC sampling and instead specifies drawing the sample directly from the sample port of the (b) (4).

b. Your firm uses a (b) (4) to (b) (4) the API for the

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(b) (4) product (b) (4) . (b) (4)) of the (b) (4) is performed on one of (b) (4) test units. The (b) (4) (b) (4) used in (b) (4) lot (b) (4) failed (b) (4) testing (b) (4) before passing on the (b) (4) attempt on the (b) (4) test unit. The procedure for testing the (b) (4) , SOP 018436 "Operating Instructions for the (b) (4) ", fails to specify what actions to take if the (b) (4) fails certain methods of (b) (4) testing. Additionally, the (b) (4) lacks a serial number on the (b) (4) to identify it, and neither the (b) (4) test reports nor the electronic data from the (b) (4) are populated with a serial number or code to identify the (b) (4) that was tested. For example, serial number fields on the (b) (4) test reports from (b) (4) lot (b) (4) state "N/A". The electronic data reviewed on the (b) (4) do not contain a field for a (b) (4) serial number or (b) (4) identifier. (b) (4) are used to (b) (4) the API for each lot of (b) (4); for example, lot (b) (4) (MFG (b) (4)).

OBSERVATION 5

Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically,

A. Cartons bearing lot numbers and expiry dates for drug product (b) (4) are staged in cages without locks in an unsecured area of the controlled room temperature (CRT) warehouse, designated Room (b) (4), for extended periods during the packaging process. For example, on 3/18/2026, I observed cartons bearing lot number (b) (4) in an unlocked cage in an unsecured area of Room (b) (4). Status documentation on the cage indicated that cartons had been moved to that location on 2/27/2026. Personnel from your operations, manufacturing, (b) (4) packaging, supply chain, facilities, engineering, validation, quality control, and metrology departments have access to warehouse (b) (4).

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B. The firm lacks processes and procedures for verifying the count of vial labels for drug product Definity that are returned to inventory after a labeling run concludes.

OBSERVATION 6

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically, manufacturing operators have access to administrator privileges, including data deletion and date/time modification, on your firm's (b) (4) particulate counters. Your firm uses the particulate counters to perform nonviable particulate sampling in your environmental monitoring program.

OBSERVATION 7

Access to the storage area for labels and labeling materials is not limited to authorized personnel.

Specifically,

A. Your firm stores vial labels for drug product (b) (4) in a badge-access cage, designated Room (b) (4), located in the rear of the controlled room temperature (CRT) warehouse. Personnel from your operations, manufacturing, kit packaging, supply chain, facilities, engineering, validation, quality control, and metrology departments have access to this label cage.

B. Your firm stores product package inserts for drug product (b) (4) in the (b) (4) CRT warehouse, designated Room (b) (4) and (b) (4), outside of the label cage. Personnel from your operations, manufacturing, kit packaging, supply chain, facilities, engineering, validation, quality control, and metrology departments have access to this warehouse.

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C. Your firm stores cartons for drug product (b) (4) in the bulk warehouse, designated Room (b) (4). Personnel from your operations, manufacturing, (b) (4) packaging, supply chain, facilities, engineering, validation, quality control, and metrology departments have access to the bulk warehouse.

***DATES OF INSPECTION**

3/09/2026(Mon), 3/10/2026(Tue), 3/11/2026(Wed), 3/12/2026(Thu), 3/13/2026(Fri), 3/16/2026(Mon), 3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri), 4/09/2026(Thu)

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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."