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	4/14/2026-4/17/2026
	FEI NUMBER 3010163994

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ryan Dorfman, Ph.D., Chief Operating Officer

FIRM NAME	STREET ADDRESS
Haematologic Technologies, LLC	57 River Rd Unit 1010
CITY, STATE, ZIP CODE, COUNTRY Essex Junction, VT 05452-3842	TYPE ESTABLISHMENT INSPECTED Contract Testing Laboratory

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

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

Specifically analytical sequence [redacted], titled, "[redacted] Activity in [redacted] Assay: [redacted]" potency method requires [redacted] on the [redacted] instrument. Additionally, SOP 10044, titled, "Repeat Analysis Procedure" requires an investigation of an initial OOS before retesting can occur. However, these written procedures are not always followed. For example,

Deviation 2025-005 was initiated on December 12, 2024, due to [redacted] failures obtained when testing client number [redacted] and Batch # [redacted] according to [redacted]. The potency analytical sequence runs yielded results below the client's specification of 450-575 IU/vial. The [redacted] produced [redacted] and the [redacted] failing to meet requirements. At that time, Quality Assurance decided to make this a planned deviation and discontinue the testing. The client was notified and instructed the contract laboratory to perform a retest, which met the potency specifications. There is no documentation demonstrating that a thorough investigation was conducted to determine the root cause of the initial OOS results prior to retesting, nor is there evidence that predefined laboratory retesting procedures were followed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Burnell M Henry, Investigator X Burnell M Henry Investigator Signed By: Burnell M Henry -S Date Signed: 04-17-2026 14:22:56	4/17/2026

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Essex Junction, VT 05452-3842	Contract Testing Laboratory

***DATES OF INSPECTION**
4/14/2026(Tue), 4/15/2026(Wed), 4/16/2026(Thu), 4/17/2026(Fri)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Burnell M Henry, Investigator

X Burnell M Henry
Investigator
Signed By: Burnell M. Henry -S
Date Signed: 04-17-2026
14:22:56

DATE ISSUED
4/17/2026

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."