

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D2283698	(X3) Date Survey Completed 05/19/2026
Name of Provider or Supplier Plaistow Freestanding Emergency Room	Street Address, City, State 26 Plaistow Rd, Plaistow, NH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, the laboratory's policy, and interviews with staff, the laboratory failed to ensure that supplies were stored according to the manufacturer's instructions for 2 of 2 areas where supplies were stored. Findings Include: a. On 5/19/2026 at 9:30 AM, an observation of patient room number 4 revealed the following items (sampling) stored in the room: 1. 15 tubes; BD Vacutainer lavender top; lot number 6005602, expiration date 04/30/2027; Store at 4C [degrees Celsius]-25C. 2. 2 bottles; BD Bactec Lytic//10 Anerobic; lot number 6022202 Expiration date 10/27/2026, Store at 2C-25C. b. During an interview on 05/19/2026 at 9:30 AM, the Manager confirmed supplies were stored in patient rooms, and the temperatures were not monitored in the rooms. c. A review of the laboratory's room temperature monitoring system revealed that room temperature was defined as 15-30C. d. On 05/19/2025 at 4:16 PM, an observation in the laboratory revealed the following items stored at room temperature (sampling): 1. 4 bags; Cardinal Health Collection and Transport Swabs; lot number 5K07A, expiration date 04/07/2027, Store at 4C-25C 2. 2.5 cases; BD Vacutainer lavender top; lot number 6005602, expiration date 04/30/2027; Store</p>

at 4C-25C. e. During an interview on 05/19/2026 at 4:25 PM, Technical Consultant #2 confirmed the laboratory's defined room temperature range exceeded the manufacturer's required storage temperature.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on direct observation, a review of the manufacturer's instructions, and an interview with Technical Consultant #2, the laboratory failed to label 3 of 4 in-use reagent cartridges with new expiration dates when removed from refrigeration. Findings Include: a. On 05/1/2025 at 11:34 AM, 3 Triage Tox D 94600 test cartridges, lot number T15920, were observed on the shelf stored at room temperature and were not labeled with dates removed from refrigeration or expiration date. b. A review of the manufacturer's instructions, "Triage Tox Drug Screen 94600" revealed "Storage and Handling Requirements ...Once removed from refrigeration, the pouched Test Device is stable for up to 14 days when stored at 18C [degrees Celsius] to 28C, but not beyond the expiration date printed on the pouch." c. During an interview on 05/19/2026 at 11:34 AM, Technical Consultant #2, as listed on the CMS 209, confirmed the findings.

D5807

TEST REPORT
CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's procedure, patient test reports, and an interview with Technical Consultant #2, the laboratory failed to ensure that the established reference range correlated with the reference ranges on the patient test reports for 3 of 3 patients reviewed. Findings Include: a. A review of the laboratory policy "Sysmex pocH-100i Hematology Analyzer" approved 01/2026, revealed "Expected Values: Established Normal Range: Test/Reference CBC [complete blood count] WBC [white blood cell count]/3.9-11.0 10^3 /uL [microliter] RBC [red blood cell count] /4.30-5.00 10^6 /uL HGB [hemoglobin]/11.0-17.0 g/dL [grams per deciliter] HCT [hematocrit] /34.0-51.0 % [percent] ..." b. A review of patient reports for CBC revealed: 1. Adult Male Patient: M63620686346 Test/Reference WBC/3.9-9.4 10^3 /uL RBC/4.14-5.52 10^6 /uL HGB/11.09-16.7 g/dL HCT 32.5-49.4% 2. Adult Female Patient: M63620706029 Test/Reference WBC/4.1-10.4 10^3 /uL RBC 3.43-5.21 10^6 /uL HGB 10.3-14.8 g/dL HCT 32.5-49.4% 3. Pediatric Male Patient: M63619568534 Test /Reference WBC/3.9-10.1 10^3 /uL RBC/3.71-5.52 10^6 /uL HGB/10.9-16.7 g/dL HCT

/32.5-49.4% c. During an interview on 05/19/2026 at 10:38, Technical Consultant #2, as listed on the CMS 209, confirmed the reference ranges listed in the procedure did match the ranges on the patient's reports.