

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D2308580	(X3) Date Survey Completed 01/15/2025
Name of Provider or Supplier Dhart - Manchester	Street Address, City, State 202 Perimeter Rd, Hangar 3, Manchester, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to enroll in an approved proficiency testing (PT) program in 2024 or 2025 for regulated routine chemistry and hematology analytes. Findings include: 1. Review on 1/15/25 of the lab's enrollment for PT for 2025 revealed the laboratory ordered PT samples through another laboratory's CLIA number. The PT order included the following analytes: hematocrit, ionized calcium, potassium, sodium, hydrogen concentration (pH), partial pressure of oxygen, and partial pressure of carbon dioxide. 2. Interview on 1/15/25 at 9:20 a.m. with the Technical Consultant (TC) revealed the lab was testing patients in August of 2024 and did not enroll in proficiency testing in 2024. The TC confirmed the lab had ordered samples under another lab's CLIA number and not their own CLIA number. The TC revealed that they had performed no proficiency testing to date.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test</p>

procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory's (lab) procedure manual for hematology and routine chemistry testing failed to include instruction for entering results in the patient record and reporting patient results. Findings include: 1. Review on 1/15/25 of the laboratory procedure titled "iStat Analyzer Procedure - Point of Care", approved 10/24/2024, section X. Reporting of Results, revealed the following: " Results will transmit directly into eDH [electronic Dartmouth Health] after the analyzer is docked as long as the patient's CSN [Client Serial Number] was entered as the patient ID [identification]. Dock analyzer at minimum once per week to transmit results. If a results need to be charted right away dock the iSTAT immediately after testing." There was no instruction in the procedure on how to enter and report results in the lab's "Triangle Report" and "DHART Patient Care Report." 2. Interview on 1/15 /25 at 10:15 a.m. with the Technical Consultant (TC) revealed the lab performed EG7 testing (analytes: hematocrit, ionized calcium, potassium, sodium, hydrogen concentration (pH), partial pressure of oxygen, and partial pressure of carbon dioxide) on the i-STAT while transporting patients to a hospital. The lab test results were hand written on a "triangle report" and handed off with the patient at the receiving hospital. The lab results were also hand recorded on the "DHART Patient Care Report" which is uploaded into the hospital electronic medical record (EMR). The lab results were also uploaded from the i-STAT into the lab information system and then the EMR. Interview revealed that patients and providers can review the "DHART Patient Care Report" and the EMR report. Interview also revealed that testing personnel do not enter the patient's CSN as the patient ID.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this

section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory (lab) failed to perform quality control (QC) testing at least once each day patient specimen are assayed for hematology and routine chemistry testing. Findings include: 1. Review on 1/15/25 of the lab's QC records for August 2024-present revealed the laboratory performed QC testing on the i-STAT EG7 test cartridges monthly (12/24, 11/24, 10/24, 9/24, and 8/24). EG7 test cartridges measure the following analytes: hematocrit, ionized calcium, potassium, sodium, hydrogen concentration (pH), partial pressure of oxygen, and partial pressure of carbon dioxide. 2. Review on 1/15/25 of the lab's Individualized Quality Control Plan (IQCP), signed 2/19/2016, revealed that the plan was not signed by the lab director and did not have a risk assessment or documentation of potential failures and errors in the testing process and environment for this lab. 3. Interview on 1/15/25 at 9:45 a.m. with the Technical Consultant (TC) confirmed that the IQCP was not performed specifically for this laboratory or signed by this lab director.

D5805

TEST REPORT

CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory (lab) failed to have a test reports that indicates the name and address of the lab performing hematology and routine chemistry testing, specimen source, and the units of measure. Findings include: 1. Interview on 1/15/25 at 10:15 a.m. with the Technical Consultant (TC) revealed the lab performed EG7 testing (analytes: hematocrit, ionized calcium, potassium, sodium, hydrogen concentration (pH), partial pressure of oxygen, and partial pressure of carbon dioxide) on the i-STAT while transporting patients to a hospital. The lab test results were hand written on a "triangle report" and handed off with the patient at the receiving hospital. The lab results were also hand recorded on the "DHART Patient Care Report" which is uploaded into the hospital electronic medical record (EMR). The lab results were also uploaded from the i-STAT into the lab information system and then the EMR. Interview revealed that patients and providers can review the "DHART Patient Care Report" and the EMR report. 2. Review on 1/15/25 of 3 of 3 "triangle" reports (Patient 1, Patient 2, and Patient 3), revealed that the lab reports did not include units of measure or where the test was performed. 3. Review on 1/15/25 of 5 of 6 "DHART Patient Care Reports" (Patient 1, Patient 2, Patient 3, Patient 4, and Patient 5) revealed that the lab reports did not include the units of measure or where the test was performed. 4. Review on 1/15/25 of 5 of 6 EMR reports (Patient 1, Patient 2, Patient 4, Patient 5, and Patient 6) revealed lab reports did not include the specimen source or where the test was performed.

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 record review and staff interview, the laboratory (lab) failed to provide reference intervals (normal reference ranges) for hematology and routine chemistry tests to authorized persons using the test results while treating patients in 2024 and 2025. Findings include: 1. Review on 1/15/25 of 6 of 6 test reports for testing performed using the i-STAT EG7 test cartridge (analytes: hematocrit, ionized calcium, potassium, sodium, hydrogen concentration (pH), partial pressure of oxygen, and partial pressure of carbon dioxide) revealed no reference intervals were provided on the "Triangle Report" used during transport and treatment and provided to the receiving hospital and there were no reference intervals on the "DHART Patient Care Report" provided to the receiving hospital without 24 hours of the patient transfer. 2. Interview on 1/15/25 with Staff A (flight nurse and testing personnel) confirmed the above finding. Staff A revealed the reference intervals were on a reference card but could not locate the reference card at the time of survey.