

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D2308580	(X3) Date Survey Completed 08/07/2026
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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) (a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on review of Certification and Survey Provider Enhanced Reporting (CASPER) 0096D report, College of American Pathologists (CAP) proficiency testing (PT) records, and interview with the Technical Consultant (TC1), the laboratory (lab) failed to authorize CAP to release routine chemistry and hematology PT results for 4 of 4 PT events reviewed from 2025 and 2026 to Centers for Medicare and Medicaid Services (CMS) and New Hampshire Department of Health and Human Services (NH DHHS). Findings include: 1. Review on 8/7/2026 of CASPER 0096D report revealed no PT results for the following regulated analytes tested by the lab: hydrogen concentration (pH), partial pressure of oxygen (pO2), partial pressure of carbon dioxide (pCO2), sodium (Na), potassium (K), and hematocrit (Hct). 2. Review on 8/7/2026 of CAP PT evaluation reports from 2025 (3 events) and 2026 (1 event) revealed the lab was enrolled in PT for pH, pO2, pCO2, Na, K, Hct, and ionized calcium (iCa). The evaluation reports failed to include CMS and NH DHHS in the "Copied To" section on page 1 of the reports. 3. Interview on 8/7/2026 at 10:15 a.m. with TC1 confirmed the lab's PT results for pH, pO2, pCO2, Na, K, Hct, and iCa were not copied to CMS and NH DHHS.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by

the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on observation of laboratory's (lab) test equipment and supplies, review of quality control (QC) procedures and records, and interview with the Technical Consultant (TC1), lab personnel failed to follow procedures to perform chemistry and hematology control testing for i-STAT EG7+ test cartridges available for use in 2026. Findings include: 1. Observation on 8/7/2026 at 10:45 a.m. of the storage bag containing the i-STAT testing device and EG7+ test cartridges revealed 3 EG7+ test cartridges available for use with a lot number of N26074. No other EG7+ test cartridges from this lot could be found in the lab. EG7+ test cartridges include the following analytes: hydrogen concentration (pH), partial pressure of oxygen (pO₂), partial pressure of carbon dioxide (pCO₂), sodium (Na), potassium (K), ionized calcium (iCa), and hematocrit (Hct). 2. Review on 8/7/2026 of the lab's individualized quality control plan (IQCP) signed by the Lab Director (LD) on 4/4/2025 revealed on page 1 in "Monthly" and "Periodic" sections, instruction to perform testing using 3 levels of QC for each new lot and shipment and monthly thereafter. 3. Review on 8/7/2026 of QC records for EG7+ lot number N26074 revealed no QC testing was performed by the lab for any of the analytes listed above. 4. Interview on 8/7/2026 at 10:45 a.m. with TC1 confirmed the above findings. TC1 revealed each new box of EG7+ test cartridges includes 25 test cartridges.