

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0187192	(X3) Date Survey Completed 06/11/2026
Name of Provider or Supplier Dallastown Medical Associates	Street Address, City, State 1010 Blymire Rd, Dallastown, PA	
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
D0000	A recertification survey was conducted by the Pennsylvania State Agency at Dallastown Medical Associates on 06/11/2026. The laboratory was found out of compliance with the following condition: 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's humidity log records and interview with Technical Consultant (TC) #1, the laboratory failed to document corrective actions taken when room humidity (RH) exceeded the laboratory's acceptable range of 20 to 50% for 4 of 92 days from March 2026 to May 2026. Findings include: 1. On the day of the survey, 06/11/2026 at 11:50 am, review of the laboratory's Daily Ambient Lab Temperature/Humidity Log revealed the RH documentation exceeded the laboratory's acceptable range of 20% to 50% for the following 4 of 92 days from March 2026 to May 2026: - 03/02/2026: 50.3% RH - 05/27/2026: 63% RH - 05/28/2026: 57% RH - 05/29/2026: 57% RH 2. The laboratory failed to provide documentation for the</p>

corrective actions taken when RH exceeded the laboratory's acceptable range from March 2026 to May 2026. 3. TC #1 confirmed the finding above on 06/11/2026 at 12:15 pm.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on review of the CLIA's Laboratory Personnel Report (Form CMS-209), lack of Personnel Qualification records, and interview with Technical Consultant (TC) #1, the laboratory failed to ensure 1 of 33 TP (CMS 209, personnel #29, dated 5/12/2026) met the minimum educational requirements under 493.1423 to perform moderate complexity testing from 10/01/2025 to 06/11/2026. Refer to D6065

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on review of the CLIA Laboratory Personnel Report (Form CMS-209), lack of Personnel Qualification records, and interview with Technical Consultant (TC) #1, the laboratory failed to ensure that 1 of 33 testing personnel (TP) met the minimum educational requirements to perform moderate complexity testing from 10/01/2025 to 06/11/2026. Findings Include: 1. On the day of survey, 06/11/2026 at 09:15 am, the laboratory failed to provide education credentials for 1 of 33 TP (CMS 209 personnel #29, dated 05/12/2026) who performed moderate complexity hematology and chemistry examinations from 10/01/2025 to 06/11/2026. 2. The laboratory performed 139,031 Chemistry tests and 45,270 Hematology tests in 2025 (CMS 116 estimated annual test volume, dated 05/12/2026). 3. TC #1 confirmed the findings above on 06/11/2026 at 09:45 am.