

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>11D0909399</p>	<p>(X3) Date Survey Completed</p> <p>02/04/2025</p>
<p>Name of Provider or Supplier</p> <p>Dawson Pediatrics Pc</p>	<p>Street Address, City, State</p> <p>300 Dawson Commons Circle Suite 320, Dawsonville, GA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>A recertification survey was performed on February 04, 2025. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director NOTE: The CMS-2567 (Statement of Deficiencies) is an official , legal document,. All information must remain unchanged except for entering the Plan Of Correction (POC), correction dates, and the signature space. Any discrepancy n the original deficiency citation(s) will be reported the the Georgia Regional Office (RO) for referral the Office of the Inspector General (OIG) for possible fraud if the information is inadvertently changed by the provide/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<p>D2003</p>	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency test (PT) records and interview with a laboratory testing personnel (TP) , the laboratory failed to enroll for PT testing for the neonatal bilirubin (NBIL). Findings: 1. Review of API PT testing records for 2023 Events 2 & 3, and 2024 Events 1, 2, & 3 revealed the laboratory was not participating in PT for NBIL performed on the UNISTAT BILIRUBINOMETER. Enrollment only for Complete Blood Count (CBC). 2. Interview with TP #1 (CMS 209) on 02/04/25 in the hallway office at 3pm confirmed the aforementioned finding.</p>
<p>D2009</p>	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p>

	<p>CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of API PT records and interview with a laboratory testing personnel (TP) , the laboratory testing personnel and lab director failed to attest that PT samples were tested in the same manner as patient specimens. Findings: 1. Review of the 2023 API PT records revealed the lack of attestation statements for events #2 & #3. 2. Interview with TP #1 (CMS 209) on 02/04/25 in the hallway office at 3pm confirmed the aforementioned finding.</p>
<p>D2015</p>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of API PT records and interview with a laboratory testing personnel (TP) , the laboratory failed to retain a copy of all records pertaining to the testing of PT samples. Findings: 1. Review of the 2023 API PT records revealed the lack of analyzer print outs for event #3. 2. Interview with TP #1 (CMS 209) on 02/04/25 in the hallway office at 3pm confirmed the aforementioned finding.</p>
<p>D5211</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of API PT records and interview with a laboratory testing personnel (TP) , the laboratory failed to document review and evaluate the results obtained on proficiency testing performed. Findings: 1. Review of the 2023 API PT records revealed the lack of result review for event #3. 2. Interview with TP #1 (CMS 209) on 02/04/25 in the hallway office at 3pm confirmed the aforementioned finding.</p>
<p>D5221</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p>

	<p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of API PT records and interview with a laboratory testing personnel (TP) , the laboratory failed to document corrective actions for an unacceptable analyte result obtained on proficiency testing performed. Findings: 1. Review of the 2023 API PT records revealed the lack of corrective action for event #3 platelet count with a score of 80%. Sample HEM-13 received an unacceptable performance. 2. Interview with TP #1 (CMS 209) on 02/04/25 in the hallway office at 3pm confirmed the aforementioned finding.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on policy and procedure (P&P) manual (SOP) review and staff interview, the laboratory failed to ensure the laboratory had written P&P for all tests performed. Findings include: 1. SOP review revealed the lab did not have P&P for NBIL performed with the UNISTAT BILIRUBINOMETER, a downtime policy for inoperable test systems, or defining critical/panic values. 2. Interview with TP #1 (CMS 209) on 02/04/25 in the hallway office at 2pm confirmed the aforementioned finding.</p>
<p>D5411</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of the UNISTAT Bilirubinometer operators manual, calibration/high level check log sheet, and staff interview, the laboratory failed to calibrate the analyzer per the manufacturer. Findings: 1. Review of the operators manual revealed the bilirubinometer is to be calibrated every 6 months or after all service procedures including a bulb change. 2. Review of the calibration/high level check log sheet revealed the calibration dates as: 4/24/18, 1/1/20, 1/12/21, 8/2/21, 2/7/22, 8/10/22, 2/28/23, 8/16/23, and 9/5/24. Date spans of: 21 months, 12 months, 7 months, 6 months, 6 months, 6 months, 6 months, and 13 months. 3. Interview with TP #1 (CMS 209) on 2/4/25 in the hallway office at 2:30 p.m confirmed the aforementioned findings.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on lack of equipment maintenance documents and subsequent staff interview, the laboratory failed to perform and document equipment maintenance. Findings include: 1. Laboratory document review revealed there were no routine maintenance documents available for the month of September 2023. 2. Interview with TP #1 (CMS 209) on 02/04/25 in the hallway office at 3:30 pm confirmed the aforementioned finding.

D5447

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(g)

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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on quality control (QC) document review, high-level check log sheet review, and staff interview, the lab failed to monitor the accuracy and precision of test performance of the bilirubinometer. Findings: 1. Review of QC sheets revealed the lack of QC documentation for the bilirubinometer. No external QC was performed. 2. Review of the high-level check log sheet revealed the calibration verification documentation (electronic QC) was: 4/24/18, 1/1/20, 1/12/21, 8/2/21, 2/7/22, 8/10/22, 2/28/23, 8/16/23, and 9/5/24. Date spans of: 21 months, 12 months, 7 months, 6 months, 6 months, 6 months, 6 months, and 13 months. Calibration and calibration verification is required every 6 months. 3. Interview with TP #1 (CMS 209) on 2/4/25 in the hallway office at 2:30 p.m confirmed the aforementioned findings.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on QC, Maintenance, patient logs document review, review of the SOP, and review of PT documents, the laboratory director failed to provide overall management and direction to the laboratory. Findings: Refer to: D2003, D2009, D2015, D5211, D5221, D5401, D5411, D5429, D5447, D6070

D6070

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on review of patient testing logs, the testing personnel (TP) job description, maintenance procedure logs, and an interview with TP #1 (CMS 209), the laboratory TP failed to follow the required job functions of the laboratory. Findings: 1. Review of the TP job description revealed the TP were to adhere to: all P&P of the laboratory, maintain all records & logs, identify problems, perform PT, maintenance, and document all corrective actions. 2. Review of the patient testing logs for March 10 - March 28, 2023 revealed 13 of 30 test results were not initialed by the TP; February 2 - February 29, 2024 revealed 2 of 55 test results were not initialed by the TP, resulting in incomplete log sheets. Review of the patient testing logs revealed 2 of 5 NBIL tests (2/2/24 - 2/29/24) did not have results entered on the log sheets, resulting in incomplete log sheets. 3. Review of Daily, Weekly, & Monthly Routine lab procedure logs for September 2023 revealed weekly and monthly maintenance/procedures were not completed. 4. Interview with TP #1 (CMS 209) on 02/04/25 in the hallway office at 3:30 pm confirmed the aforementioned findings.