

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0922674	(X3) Date Survey Completed 03/20/2025
Name of Provider or Supplier Piedmont Healthcare Urgent Care	Street Address, City, State 700 Sullivan Road, Statesville, NC	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2023, 2024 and 2025 Technical Consultant (TC) competency records, absence of documentation, and interviews with the Laboratory Director (LD) and TC 03/20/25, the laboratory failed ensure TC competency was assessed and documented since 12/21/21, a period of approximately 51 months. Findings: Review of 2022, 2023, 2024 and 2025 TC competency records revealed the TC competency assessment was performed on 12/21/21, there was no documentation of an assessment in 2022, 2023, 2024 or 2025. During an interview at approximately 12:15 p.m., the TC confirmed there are no additional competency records available for review. During the exit interview at approximately 2:30 p.m., the LD stated he could not recall the last time the TC's competency was evaluated.</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2023 American Proficiency Institute (API) proficiency testing (PT) records, absence of documentation and interview with TC 03/20/25, the</p>

laboratory failed to review and verify the accuracy of "not graded" PT results. Findings: Review of 2023 API PT records revealed no documentation of a review to verify the accuracy of the following "not graded" PT results: 2023 Hematology /Coagulation - 1st event: Sample DXH-04 - Lymphocytes. 2023 Chemistry - Core - 2nd event: Samples CM-06 and CM-09 - Troponin. 2023 Hematology/Coagulation - 3rd event: Samples DXH-11 and DXH-14 - Lymphocytes. Interview with TC at approximately 11:10 a.m. confirmed the laboratory failed to review and verify the accuracy of the "not graded" PT results. They stated they were unaware they should be reviewed if they were not graded.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) 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 review of operators manual for the DXH 520 hematology analyzer, review of 2023, 2024 and 2025 hematology maintenance logs, lack of documentation and interview with TC 03/20/25, the laboratory failed to perform yearly maintenance, "Lubricating Pistons", since time of last survey, 02/25/22, a period of approximately 25 months. Findings: Review of operators manual for the DXH 520 hematology analyzer revealed "Table 12.1 Matrix of Frequency for Cleaning Procedures". The table lists "Lubricating Pistons" and a frequency of "Yearly". Review of 2023, 2024 and 2025 hematology maintenance logs for the DXH 520 hematology analyzer revealed no documentation the yearly maintenance, "Lubricating Pistons", was performed since time of last survey, 02/25/22. Interview with TC at approximately 12:00 p.m. confirmed the laboratory failed to perform the yearly maintenance as required in the operators manual.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(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.

This STANDARD is not met as evidenced by:
Based on review of laboratory procedure, 2024 temperature and humidity logs, and interview with TC 03/20/25, the laboratory failed to document corrective action when temperatures and humidity readings were not documented. Findings: Review of "General Laboratory Conditions Standard Operating Procedure", revealed "Each day of operation the temperature will be read and recorded for all refrigerators, freezers, humidity, and room temperature. If any readings are not within acceptable limits, appropriate remedial action will be taken and documented.". Review of the 2024"

Daily Lab Temperatures and Cleaning" logs revealed the refrigerator, freezer, room temperature, and humidity were not documented on 6/14/24, 6/17/24, and 7/24/24. The TC signed the logs as reviewed on 7/24/24 and 8/14/24. There was no corrective action indicated on the logs. During interview at approximately 1:30 p.m., the TC confirmed that issues with the temperature and humidity logs are communicated to the nurse lead. She also confirmed that corrective actions are not documented in the form of notes or quality assessment monitors.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on review of TC competency records, TP training and competency records, Triage meter Individual Quality Control Program (IQCP), laboratory quality assessment (QA) records, absence of documentation and interview with TC 03/20/25, the LD failed to ensure QA programs were established and/or maintained to identify the failure of performance of TC competency assessments, the failure of TC to perform TP competency assessments and training as required, and the failure of the laboratory to perform QA monitors for the triage meter IQCP. 1. The LD failed to ensure QA programs were established and/or maintained to identify the failure of the performance of TC competency assessments for a period of approximately 51 months. Findings: See 6030. 2. The LD failed to ensure QA programs were established and/or maintained to identify the failure of TC to perform TP competency and training as required. Findings: See D6045 and D6046. 3. The LD failed to ensure the QA monitors for the IQCP established for the Triage meter testing were performed. Findings: Review of laboratory Triage meter IQCP revealed "QA Activity to Monitor...Lab Consultant reviews and signs instrument print-out and QC log - Monthly...Competency assessments - Initially, at 6 months, and then annually....Lab director reviews and signs lab manuals - Annually and at their discretion...". Review of laboratory QA records revealed no documentation of QA monitoring activities for the triage meter IQCP. Interview with TC at approximately 10:30 a.m. confirmed the QA monitors for the IQCP had not been performed.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on review of 2023, 2024 and 2025 TC competency records, absence of

documentation, and interviews with the LD and TC 03/20/25, the LD failed to ensure TC competency was assessed and documented since 12/21/21, a period of approximately 51 months. Findings: See D5209.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of laboratory procedure, 2023, 2024 and 2025 TP training and competency records, absence of documentation, and interviews with TC 03/20/25, and review of previously submitted Allegation of Compliance 03/27/25, the TC failed to provide the technical oversight to ensure training and competency assessments of laboratory TP was performed as required and as stated in the Allegation of Compliance submitted for deficiency D6046 cited 02/25/22. 1. The TC failed to perform and/or document Triage meter training for 1 out of 9 TP prior to patient testing. Findings: See D6045. 2. The TC failed to perform and document semi-annual and/or annual competency for 3 out of 9 TP. Findings: See D6046. 3. The TC failed to "review TP files monthly and perform any needed training or competencies." Findings: Review of Allegation of Compliance, signed 03/30/22, revealed the TC was previously cited for D6046 at last survey, 02/25/22. Review of Allegation of Compliance responses for D6046 revealed "C. What changes have been made to ensure that the deficiency does not recur? The Technical Consultant will review monthly and perform any needed competencies. D. How will this corrective action be monitored? The Technical Consultant will review employee files monthly and perform any needed training or competencies.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(7)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:
Based on review of TP training records, absence of documentation, and interview with TC 03/20/25, the TC failed to perform and/or document Triage meter training for 1 out of 9 TP prior to performing patient testing. Findings: Review of TP #7 training records revealed a checklist labeled "Test: Piccolo"; there was no documentation of training for TP #7 for the performance of testing on the Triage meter. During interview at approximately 12:45 p.m., the TC confirmed no other training documentation was available and TP #7 was performing testing on the Triage meter and the Piccolo analyzer.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff

maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on review of laboratory procedure, 2023, 2024 and 2025 TP competency and training records, absence of documentation and interview with the TC 03/20/25, the TC failed to perform and document semi-annual and/or annual competency for 3 out of 9 TP. Findings: The laboratory's "Competency Evaluations and Assessments" procedure states, "Personnel evaluations are performed annually by the Lab Consultant. Competency assessments are performed semi-annually the first year and annually thereafter and should be observed in intervals throughout each year by the Laboratory Consultant." Review of 2023, 2024 and 2025 TP competency and training records revealed the following: 1. Annual competency was documented for TP #5 on 4/22/22. There were no competency assessments for TP #5 in 2023, 2024 or 2025, a period of approximately 35 months in which competency was not accessed. 2. TP training records revealed TP #1 and TP #4 were trained for the DXH 520 hematology analyzer and the Triage meter in August 2023. TP competency records for TP #1 and TP #4 revealed no documentation of semi-annual or annual competency in 2024 and 2025, a period of approximately 19 months in which competency was not accessed. During interview at approximately 12:15 p.m., the TC confirmed there were no other competency documents available for review. This deficiency was previously cited 02/25/22.