

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2135624	(X3) Date Survey Completed 10/03/2024
Name of Provider or Supplier Valley Health Urgent Care - Rutherford Crossing	Street Address, City, State 160 Merchant Street, Ste 200, Winchester, VA	
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	An announced CLIA validation survey was conducted at Valley Health Urgent Care - Rutherford Crossing on October 3, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the Conditions under 42 CFR part 493 CLIA Regulation: D5400 - 42 CFR. 493.1250 Analytic Systems D6000 - 42 CFR. 493.1403 Laboratory Director.
D2093	<p>ROUTINE CHEMISTRY CFR(s): 493.841(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) documentation, and an interview, the laboratory failed to ensure Chemistry Module PT test results for Sodium (Na), Potassium (K), Chloride (Cl), Glucose (Gluc), Urea Nitrogen (BUN), and Creatinine (Creat) were returned to American Association of Bioanalysts/Medical Laboratory Evaluation (AAB/MLE) within the program's deadline for one (1) of three (3) events in calendar year 2023. The findings include: 1. Review of the laboratory's 2023 AAB/MLE Chemistry PT documentation (Events 1-3) revealed that the laboratory failed to submit PT results and received failure to participate scores for the following modules/analytes: 2023 Chemistry-Event 2: five of five samples received zero percent (0%) scores for Na, K, Cl, Gluc, BUN, and Creat for samples CHM 06-10. 2. In an interview with the Laboratory Director (LD) on October 3, 2024 at 10:00 AM, the LD stated "The testing was performed but we did not submit the results in time."</p>
D2123	HEMATOLOGY

CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's proficiency testing (PT) documentation, and an interview, the laboratory failed to ensure Non-Chemistry Module PT test results for Erythrocyte Count (RBC), Hematocrit (HCT), Hemoglobin (HGB), Leukocyte Count (WBC), Platelets (PLT) and WBC Differential (Diff) were returned to American Association of Bioanalysts/Medical Laboratory Evaluation (AAB/MLE) within the program's deadline for one (1) of three (3) events in calendar year 2023. The findings include: 1. Review of the laboratory's 2023 AAB/MLE Non-Chemistry PT documentation (Events 1-3) revealed that the laboratory failed to submit results and received failure to participate scores for the following modules/analytes: 2023 Non-Chemistry-Event 2: five of five samples received zero percent (0%) scores for RBC, HCT, HGB, WBC, Diff for samples NCH 06-10. 2. In an interview with the Laboratory Director (LD) on October 3, 2024 at 10:00 AM, the LD stated "The testing was performed but we did not submit the results in time."

D3031

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policy and procedures, temperature log sheets, lack of documentation and interview, the laboratory failed to follow their established policy and retain documentation of the monitoring and recording of daily refrigerator, freezer, room temperature and humidity from January 1, 2023 until December 31, 2023 (12 Months). The findings include: 1. Review of the laboratory's "Rutherford Urgent Care Daily Maintenance Log" revealed a statement in the header, "All staff are responsible for completing every task on the log, initial in the box that it has been performed." Further review of the "AM Maintenance" section listed a task "Record Temp/Humidity". Review of the maintenance logs sheets revealed staff initials in the boxes indicating staff completion of the tasks from July 2002 until July 2024. 2. Review of the available laboratory temperature log sheets from July 2022 until July 2024 revealed a lack of temperature log sheets from January 1, 2023 until December 31, 2023 (12 Months). The surveyor requested to review the temperature logs from January 1, 2023 until December 31, 2023. The laboratory provided no documentation to review. 3. Review of the laboratory's policy and procedures revealed a policy, "Lab Monitors", revealed a statement "All forms are kept for 2 years per COLA

requirements." 4. In an exit interview with the Laboratory Director (LD) on October 3, 2024 at 12:15 PM, the findings were confirmed.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on a review of the laboratory's policies and procedures, manufacturer's instrument instruction manuals, maintenance records, Quality Control records (QC), calibration records, Quality Assessment (QA) records, lack of documentation, and interviews, the laboratory failed to: 1. document performance of the required monthly maintenance for the Medonic M Series Hematology analyzer (see D5429A). 2. document performance of the required six-month cleaning procedures for the Medonic M Series Hematology analyzer (see D5429B). 3. document calibration procedures every six (6) months for Complete Blood Count (CBC) testing on the Medonic M Series Hematology analyzer (see D5437). 4. perform Levy-Jennings (LJ) chart evaluations for QC shifts and trends for Hematology CBC testing(see D5791A). 5. follow their established QA plan to identify and address analytic issues with the specialty of Hematology (see D5791B). 6. follow their established QA plan to identify and correct issues with Hematology QC and calibration (see D5793).

D5429

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

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:
A. Based on a review of the laboratory's policies and procedures, Medonic M Series Hematology analyzer's maintenance instructions and records, lack of documentation, and an interview, the laboratory failed to document performance of required monthly instrument preventative maintenance for six (6) of twenty-four (24) months reviewed from July 2022 until July 2024. The findings include: 1. Review of the laboratory's "Medonic M Series Maintenance" instructions (pages 1-2) revealed instructions for performing "Monthly Cleaning Procedure", utilizing the Boule Cleaning Kit's hypochlorite and enzymatic cleaners. 2. Review of the laboratory's "Medonic M-Series Hematology Analyzer" log sheets from July 2022 until July 2024 revealed a lack of documentation of the required "Monthly Maintenance" during the following months: August 2022, July 2023, August 2023, September 2023, February 2024 and July 2024. The surveyor requested to review documentation of the monthly cleaning maintenance for the six months listed above. The laboratory provided no documentation to review. 3. In an exit interview with the Laboratory Director (LD) on October 3, 2024 at 12:15 PM, the findings were confirmed. B. Based on a review of

the laboratory's policies and procedures, Medonic M Series Hematology analyzer's maintenance instructions and records, lack of documentation, and an interview, the laboratory failed to document performance of two (2) of four (4) required six-month cleaning procedures as required in calendar year 2023 until July 2024. The findings include: 1. Review of the "Medonic M Series Maintenance" instructions (page 2) revealed instructions for performing the six month cleaning procedures utilizing the Boule Cleaning Kit's enzymatic, hypochlorite and detergent cleaners. 2. Review of the laboratory's "Medonic M-Series Hematology Analyzer" log sheets from July 2022 to July 2024 revealed documentation of the required "Six Month maintenance" utilizing the Boule Cleaning Kit during the following months: December 2022, July 2023, and January 2024. The surveyor requested to review documentation of the six-month cleaning maintenance for June 2023 and July 2024. The laboratory provided no documentation to review. 3. In an exit interview with the Laboratory Director (LD) on October 3, 2024 at 12:15 PM, the findings were confirmed.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's policies and procedures, Hematology calibration records, lack of documentation, and an interview, the laboratory failed to document calibration procedures every six (6) months for Complete Blood Count (CBC) testing according to the manufacturer's instructions for two (2) of four (4) calibrations during the twenty-four months reviewed from July 2022 until July 2024. The findings include: 1. Review of the laboratory's procedures revealed a procedure "Medonic M Series hematology analyzer" procedure (page 7), "CALIBRATION-Calibration must be performed upon setup of the instrument and then at a minimum of every 6 months." 2. Review of the laboratory's Medonic instrument's CBC calibration records from July 2022 until July 2024, revealed calibration documentation on 12/20/2022, and 7/7/2023. The surveyor noted that a 6 month calibration would have been due in June 2023, and January 2024. The surveyor requested to review the calibration documents for the months listed above. The laboratory provided no additional records to review. 3. An exit interview with the Laboratory Director (LD) on October 3, 2024 at 12:15 PM confirmed the findings.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The

laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

A. Based on a review of the laboratory's daily maintenance log, Hematology Quality Control (QC) records, lack of documentation, and interview, the laboratory failed to follow their established policy and document Levy-Jennings (LJ) chart evaluations for Hematology QC shifts and trends for twenty-four (24) of 24 months reviewed from July 2022 until July 2024. The findings include: 1. Review of the laboratory's "Daily Maintenance Log" included a statement in the header, "All staff are responsible for completing every task on the log. Initial in the box that it has been performed." Further review of the "Weekly Maintenance" listed a section "Medonic Weekly LJ review". Review of the July 2022 to July 2024 logs revealed no initials in the "Medonic Weekly IJ review" boxes from July 2022 until July 2024. 2. The surveyor requested to review documentation of the weekly LJ review. The laboratory provided no documentation for review. 3. In an exit interview with the Laboratory Director on October 3, 2024 at 12:15 PM, the findings were confirmed. B. Based on the review of the laboratory's policies and procedures, instrument maintenance records, calibration verification records, quality control (QC) records, lack of documentation and interviews, the laboratory failed to follow their established Quality Assessment (QA) plan to identify and address analytic issues within the specialties of Hematology (See D 5429, 5437 and 5793) from July 2022 until July 2024 (24 months). The findings include: 1. Review of the laboratory's Quality Assessment (QA) policies and procedures, instrument maintenance, calibration verification and quality control revealed the analytic issues listed below. The laboratory failed to follow their established policy to document : -the monthly and semi-annual maintenance on the Medonic M-Series Hematology analyzer (see D5429). -the every 6 month calibration during the twenty-four (24) months reviewed (see D5437). -the review of "Corrective Actions for QC and Calibration: Weekly/Monthly, semi-annually" during the 24 months reviewed (see D5793). 2. In an exit interview with the Laboratory Director on October 3, 2024 at 12:15 PM, the findings were confirmed.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, quality control (QC) records, lack of documentation, and an interview, the laboratory failed to follow their established Quality Assurance (QA) policy to identify and correct issues with Hematology QC and calibration for sixteen (16) of eighteen (18) months reviewed from January 2023 until July 2024. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Urgent Care Quality Assessment Plan" (PolicyStat ID 13921811 pages 1-2), with the following statements: "The Laboratory Director will perform weekly and monthly QA reviews of the following....Analytic Assessment-Performance Specifications: Annually; Reference Ranges for In House Testing: Annually; Corrective Actions for QC and Calibration: Weekly/Monthly,

	<p>semiannually; Proficiency Testing: 3 times per year; Personnel records: Orientation, 6 months, every 12 months." 2. Review of the laboratory's "Quality Assessment Review Form" from January 2023 until July 2024 revealed documentation of the weekly /monthly, semi-annual corrective action reviews for QC and calibrations performed on February 2023 and November 2023. The surveyor requested to review documentation of the monthly QC and calibration reviews for January 2023, March 2023 to October 2023 and December 2023 to June 2024 (16 months). The laboratory provided no further documentation to review. 3. In an exit interview with the Laboratory Director on October 3, 2024 at 12:15 PM, the findings were confirmed.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's policies and procedures, proficiency testing (PT), Quality Control (QC), Quality Assessment (QA), maintenance and calibration documentation, Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS-209), personnel records, lack of documentation, and interviews, the laboratory director (LD) failed to ensure: 1. PT results were submitted to the PT agency within the required timeframe (see D2093 and D2123). 2. the temperature logs for 2023 were retained for two (2) years (see D3031). 3. the weekly and semi-annual maintenance for the Medonic M-series was performed (see D5429 A & B). 4. the calibration verification for the Medonic M-series was performed every six months (D5437). 5. the review of the Levy Jennings reports were performed weekly (see D5791 A). 6. the Quality Control and Quality Assessment reviews were performed (see D5791 A&B and D5793). 7. new testing personnel were trained and competent prior to performing testing (see D6029).</p>
<p>D6017</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records (2022 Event 3, 2023 Events 1-3, 2024 Event 1-2) and an interview, the laboratory director failed to ensure one chemistry and one non-chemistry PT modules' analyte results were returned to American Association of Bioanalysts/Medical Laboratory Evaluation (AAB/MLE) within the program's deadline for one (1) of three (3) events in calendar year 2023. (See D2093 and D2123)</p>
<p>D6022</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on the review of laboratory's policy and procedures, maintenance logs, calibration documents, Quality Control (QC) documentation, Quality Assessment (QA), lack of documentation and interviews, the laboratory director failed to ensure that the current QC procedures and QA reviews identified and corrected analytic issues in the specialties of hematology for 24 of 24 months reviewed. (See D5429, D5437, D5791 A & B, and 5793.)

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, the laboratory's policies and procedures, lack of documentation and interviews, the laboratory director failed to follow the laboratory's established policy to ensure one (1) of three (3) new TP had documented training and competency assessments prior to performing patient hematology testing. The findings include: 1. Review of CLIA CMS-209 form revealed 3 TP listed as performing moderate complexity patient testing. (See attached TP Code Sheet.) 2. Review of TP #3's personnel records and an interview with the Laboratory Director (LD) on October 3, 2024 at 9:30 AM revealed TP #3 was hired and began patient testing in August 2023. The surveyor requested to review training and initial competency assessment documents for TP #3. The laboratory provided no documentation of training/initial competency for TP #3 for the Medonic M-Series Hematology analyzer for review. 3. Review of the laboratory's policies and procedures revealed a policy, "Lab Personnel Requirements" (PolicyStat ID 1391843 page 3) with the statement "Step 5. Testing personnel must have documentation of training appropriate for the testing performed prior to analyzing patient specimens." 4. In an exit interview with the LD on October 3, 2024 at 12:15 PM, the findings were confirmed.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory policies and procedures, personnel records, lack of documentation, and interview, the technical consultant (TC) failed follow the established policy to perform semi-annual competency assessments for two of three new laboratory testing personnel (TP). The findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performs the duties of TC and identified eight TP responsible for hematology and chemistry testing. During a discussion with the LD/TC on October 3, 2024 at 9:30 AM regarding the CMS 209, TP #3, #4, & #7 were identified as new TP since the previous inspection in July 2022. (See Personnel Code Sheet.) 2. During a review of personnel records, the surveyor noted the new TP's' initial hematology and chemistry training as: TP #3 - August 2023, no semiannual competency documentation; TP #4 - December 2023, no semiannual competency documentation; TP #7 - June 2023, semiannual competency documentation dated 12/2023. The surveyor requested to view semi-annual competency assessment records for TP #3 and TP #4 documented in calendar year 2024. The laboratory provided no documentation for review. 3. Review of the laboratory's policies and procedures revealed a policy, "Lab Personnel Requirements" (PolicyStat ID 13921843 page 5), with the statement, "Testing personnel must perform competency testing at 6 months, 12 months and then annually." 4. In an exit interview with the LD on October 3, 2024 at 12:15 PM, the findings were confirmed.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory policies and procedures, personnel records, lack of documentation, and an interview, the technical consultant (TC) failed to follow their established policy and perform annual hematology and chemistry competency evaluations for seven of eight testing personnel in calendar year 2023. (See Personnel Code Sheet.) The findings include: 1. Review of the CMS 209 form revealed the laboratory director (LD) also performed the duties of TC and identified TP# 1-8 as responsible for moderate complexity testing on the Medonic M-Series Hematology analyzer and Abbott i-STAT during the timeframe of July 2022 to July 2024. 2. Review of the laboratory personnel files for the timeframe outlined above revealed a lack of documentation of the annual: -Medonic and i-STAT competency evaluations for TP #1, #2, #5 & #8 in calendar year 2023. -Medonic competency evaluations for TP #3, #6, & #7. The surveyor requested to review annual competency assessments for the moderate complexity hematology and chemistry testing performed by the above listed TP during calendar year 2023. The laboratory provided no documentation for review. 3. Review of the laboratory's policies and procedures

revealed a policy, "Lab Personnel Requirements" (PolicyStat ID 13921843 page 5), with the statement, "Testing personnel must perform competency testing at 6 months, 12 months and then annually." 4. In an exit interview with the LD on October 3, 2024 at 12:15 PM, the findings were confirmed.