

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2049739	(X3) Date Survey Completed 10/03/2018
Name of Provider or Supplier Carenow Urgent Care Llc - Harbour Pointe	Street Address, City, State 6100 Harbourside Centre Loop, Midlothian, 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 recertification survey was conducted at BetterMed Urgent Care on October 3, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, patient test logs, procedures, and interviews, the laboratory failed to retain Alere Triage manufacturer's assay information inserts documenting Troponin and D Dimer acceptable ranges for eighteen (18) of twenty-one (21) QC lot numbers utilized in the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's QC and patient test logs for Troponin and D Dimer from October 10, 2016 to October 3, 2018 revealed 21 lot numbers of "Alere Total 5" QC material were utilized to document and evaluate patient testing on the Alere Triage instrument. The following 18 utilized QC lot numbers had no acceptable ranges or manufacturer's package inserts documented: 03233, 03243, 03269, 03270, 03272, 03277, 03305, 03306, 03344, 03351, 03354, 03358, 03366, 03368, 03369, 03401, 03404, and 03431. 2. During an interview, at approximately 1:00 PM, the inspector requested to review the package inserts with acceptable ranges for the 18 lot numbers listed above. The site manager stated the laboratory failed to retain all of the "Alere Total 5" inserts. 3. Review of the policy and procedure manuals revealed Troponin and D Dimer procedures with instructions to "retain all control lot inserts". 4. In an exit interview with the site manager at approximately 2:30 PM, it was confirmed that the laboratory failed to retain the</p>

manufacturer's assay information package inserts documenting acceptable QC ranges for Troponin and D Dimer for the 18 lot numbers as outlined above.

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:

Based on a review of manufacturer's Operations Manual, instrument maintenance records, and an interview, the laboratory failed to perform and document Abbott Emerald hematology instrument semi-annual maintenance from October 18, 2017 to the date of the survey on October 2, 2018. Findings include: 1. Review of the Emerald Operations Manual revealed manufacturer's instructions to "perform the Lubricating Syringe Pistons procedure semi-annually". 2. Review of the laboratory's 2016, 2017, and year to date 2018 Abbott hematology maintenance logs revealed no semi-annual maintenance documented after October 18, 2017. The inspector requested additional documentation of the maintenance. The site manager stated, at approximately 1:30 PM, "We had a field service technician come in for service recently and I thought he did this procedure. I do not have documentation". 3. In an exit interview with the site manager at approximately 2:30 PM, it was confirmed that the laboratory failed to perform and document the Abbott Emerald semi-annual preventative maintenance for the timeframe outlined above.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of policies, manufacturer's users manual, calibration verification

documentation, and interviews, the laboratory failed to perform calibration verification of their reportable range for Troponin and D Dimer Alere Triage assays for twenty-one (21) of twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a Troponin and D Dimer procedure which outlined that "Level 1 and Level 2 controls are to completed every 30 days or when a new lot number is opened, daily QC is done with Alere electronic QC device". The procedures included a quality assurance (QA) policy to "perform calibration verification with three or more points for Troponin and D Dimer per the Alere Manual". 2. Review of the Alere user's manual revealed no calibration verification instructions. The inspector called the manufacturer's technical support phone line at approximately 2 PM. The technical support specialist stated "We recommend that the user follow their state regulatory guides for calibration verification. We provide a five point kit for calibration verification" 3. Review of the laboratory's Troponin and D Dimer calibration verification documentation from October 3, 2016 to the date of the survey on October 3, 2018 revealed one (1) calibration verification record on 7/16/18 that included five (5) set points including minimal (or zero) value, mid-point values, and a maximum upper limit of the reportable range. The inspector requested to review additional calibration verification records. The documentation was not available for review. 4. In an exit interview with the site manager at approximately 2:30 PM, it was confirmed that the laboratory failed to document performance of calibration verification every six (6) months to verify their reportable test result range for the two (2) Alere assays for the timeframe outlined above.