

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2127677	(X3) Date Survey Completed 11/13/2019
Name of Provider or Supplier Anniston Care Plus Llc	Street Address, City, State 700 Quintard Ave, Anniston, AL	
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
D5211	<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 a review of the test menu with the staff, a review of the API (American Proficiency Institute) proficiency testing records, and an interview the Laboratory Manager and the Laboratory Supervisor, the surveyor determined the laboratory failed to review and evaluate results for the second miscellaneous Chemistry event of 2018, due to the failure to obtain the results from the proficiency testing provider. This affected one of twenty testing events reviewed by the surveyor. The findings include: 1. During the initial tour of the laboratory on November 13, 2019 at approximately 10:00 AM, the Laboratory Supervisor stated urine micro-albumin and creatinine were performed on the DCA Vantage and confirmed the tests were moderate-complexity. 2. A review of the API proficiency testing records revealed records for only one event (Chemistry Miscellaneous, #1 2018) for urine creatinine and micro-albumin had been retained by the laboratory. 3. At 12:23 PM on November 13, 2019, the surveyor inquired of the Laboratory Supervisor if the laboratory had participated in more events for the above mentioned analytes, in 2018. The supervisor reviewed the records and confirmed only the first event was retained; and there was no documentation of the second event of 2018 in the proficiency testing manual. At 12:27 PM, the Laboratory Manager printed the results of the miscellaneous Chemistry Event #2 for creatinine and micro-albumin.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p>

This STANDARD is not met as evidenced by:
Based on a review of the API (American Proficiency Institute) proficiency testing records for 2018 -2019, and an interview with the Laboratory Manager and the Laboratory Supervisor, the surveyor determined the laboratory staff failed to document and implement corrective actions for a failed KOH (Potassium Hydrogen Peroxide) Vaginal Wet Prep, due to the staff's failure to identify a true unacceptable response to proficiency testing, rather than documenting a transcription error occurred. This affected one of five proficiency testing events for this analyte, which was reviewed by the surveyor. The finding include: 1. A review of the API proficiency testing records for Hematology Event #3 of 2018 revealed the laboratory scored zero percent (0 %) for the KOH. The Laboratory Supervisor documented the error was a transcription error (indicated the correct response was documented on the worksheet, but entered incorrectly in the computer system of reporting). Further review by the surveyor revealed the testing personnel, (TP) #1 documented on the worksheet "no yeast seen," and also entered this same result in the computer, which was incorrect as determined by API. This was not a clerical error, but a true unacceptable result (0 %). The laboratory failed to document corrective actions for this unacceptable result. 2. In an interview on November 13, 2019 at 11:51AM, the Laboratory Supervisor (with the Laboratory Manager present) confirmed the above noted findings, after reviewing the proficiency testing results.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on a review of the calibration records for the Medonic Hematology analyzer, a review of the manufacturer's package insert for the calibration material, and an interview with the Laboratory Manager and Supervisor, the surveyor determined the laboratory staff used expired calibrators to perform the calibration on the Medonic on 9/25/2019. This affected five calibrations, performed between September 2017 and September 2019, and reviewed by the surveyor. The finding include: 1. A review of the calibration records for the Medonic, including the manufacturer's package insert for the calibration material, revealed the staff performed the calibration on 9/25/2019, using calibrator lot #2190624, with an expiration date of 9/04/2019. 2. In an interview on November 13, 2019 at 2:22 PM, the surveyor inquired of the Laboratory Manager and the Supervisor the date of the calibration and the expiration date of the calibrator. The Laboratory Supervisor reviewed the calibration records and confirmed the staff used expired calibrator material to perform the calibration on 9/25/2019.