

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0898826	(X3) Date Survey Completed 03/28/2018
Name of Provider or Supplier Pricare Pa	Street Address, City, State 44 Aliant Parkway, Alexander City, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing records and an interview with the Technical Consultant (also Testing Personnel #1), the surveyor determined the laboratory failed to ensure proficiency testing was rotated among all laboratory testing personnel (four were listed on the personnel form #209), who perform moderate complexity testing on patient specimens. This affected 6 of 6 Hematology proficiency testing events reviewed by the surveyor. The findings include: 1. A review of the API proficiency testing records for 2016 and 2017, revealed Testing Personnel #1 (TP #1) performed all six of the Hematology testing events. 2. In an interview on 3/28/18 at 2:30 PM, TP #1 confirmed she performed all of the proficiency testing. TP #1 further confirmed other personnel were trained and qualified to perform Hematology testing and periodically performed testing on patient specimens.</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing records and an interview with the Technical Consultant (also Testing Personnel #1), the</p>

surveyor determined the laboratory failed to ensure all proficiency testing records for the survey review period, 3/2016 - 3/2018, were retained (must be retained for at least 2 years). This affected 3 of 6 testing events reviewed by the surveyor. The findings include: 1. A review of the API proficiency testing records revealed the following: a) the records failed to include the Hematology instrument printouts for Event #2, 2016. b) no attestation statement was included for core Chemistry Event #1, 2017. c) only the score sheets for the failing scores (creatinine, TSH (Thyroid Stimulating Hormone), PSA (Prostate Specific Antigen) and Free T4 (free - Thyroxine) were printed and retained for Chemistry Event #3 of 2016. 2. In an interview on 3/28/18 at 2:30 PM, the missing records and retention requirements were discussed with the Technical Consultant.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

Based on a review of the Policy and Procedure Manual (Employee Competency), a review of the laboratory personnel records, and an interview with the Technical Consultant (also Testing Personnel #1), the surveyor determined the laboratory failed to follow its policy and the CLIA regulations to ensure the competency of the Technical Consultant was assessed. The laboratory director did not ensure the Technical Consultant's competency was assessed semiannually, during the first year of employment, nor annually thereafter. This affected 1 of 1 technical consultants and 1 of 4 laboratory testing personnel. The findings include: 1. A review of the laboratory's policy and procedure manual, signed by the laboratory director, revealed a policy, titled "EMPLOYEE COMPETENCY," which included the following: "1. It is the laboratory director's responsibility to determine if and when an employee is competent to perform patient sample testing. ...3. ... New employees will have a documented competency assessment initially, at 6 months, one year and annually thereafter." 2. A review of the personnel records revealed Testing Personnel #1 (TP #1), who became the Technical Consultant in 2017, was initially trained in March of 2016. The record did not include a semi-annual competency assessment nor an annual assessment for this testing personnel. 3. In an interview on 3/28/18 at 2:30 PM, testing personnel stated the former technical consultant terminated employment in the middle of 2017 and she (TP #1) became the technical consultant. TP#1 also stated she had performed continuing education during the year; but confirmed her competency had not been assessed semiannually, during her first year of employment, nor annually since hired.

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 Policy and Procedure Manual, a review of the calibration records for the Hematology analyzer, Cell Dyn 1800, and an interview with the Technical Consultant (also Testing Personnel #1), the surveyor determined the laboratory failed to ensure calibrations for the analyzer were performed and documented, at least every six months, according to the laboratory's policies and procedures. The findings include: 1. A review of the laboratory policies revealed a calibration verification for the Cell Dyn 1800 should be performed at least every six months. 2. A review of the calibration records for the survey period, 3/2016 - 3/2018, revealed calibrations were performed on 6/02/16, 8/23/16, 3/24/17 and 3/21/18. Following the March of 2017 calibration, the laboratory should have calibrated the instrument (or verified the calibration) around the month of September. 3. In an interview on 3/28/18 at 2:30 PM, the Technical Consultant (also Testing Personnel #1) stated the calibrations are usually performed every six months. TP #1 also stated she thought she calibrated the Hematology analyzer in August of 2017, and she searched for the documentation. TP #1 did not provide documentation of a second calibration performed in 2017. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor