

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0672167	(X3) Date Survey Completed 05/09/2019
Name of Provider or Supplier Bpc Plasma, Inc	Street Address, City, State 1027 Commerce Blvd, Dickson City, PA	
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 the standard operating procedures (SOP), testing personnel (TP) competency assessment records and interview with the Center Manager, Plasma Center QA Manager and Senior Quality Assurance (QA) Specialist, the laboratory failed to establish and follow a written procedure to assess the competency of 31 of 31 TP personnel who performed Total protein examination from 2017 to the date of survey. Findings include: 1. On the day of survey, 05/09/2019 review of the Technical Proficiency Assessment and Retraining form revealed, the laboratory lacked a written procedure to assess: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observations of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. The laboratory provided competency assessments documents for 31 of 31 TP performing total protein examination in 2017, 2018 and 2019, that only covered skill sets assessed. 3. The Center Manager, Plasma Center QA Manager and Senior Quality Assurance (QA) Specialist confirmed the findings above on 05/09/2019 around 10:15 am.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

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 review of the laboratory's procedure manual, instrument maintenance records and interview with interview with the Center Manager, Plasma Center QA Manager and Senior Quality Assurance (QA) Specialist, the laboratory failed to document maintenance activities performed on the 6 of 6 Reichert TS DSP refractometers used to analyze total proteins from 2017 to the date of survey. Findings Include: 1. The Reichert TS DSP refractometers manufactures manual, under 1.0 instructions states, "Please note that a TS Meter D Refractometer is a high precision optical instrument. It is absolutely necessary to properly maintain the instrument to obtain the best possible accuracy. This includes thoroughly cleaning the prism and well after each sample. 2. The Microhematocrit and Total Protein Determination Procedure under 7.3.1.7 states "Digital refractometer - Use a clean cellulose acetate tissue to remove any sample from the prism surface and stainless steel sample well. Rinse the prism surface and stainless steel sample well with distilled water and wipe dry with a second clean cellulose acetate tissue 3. On the date of survey, 05/09/2019, review of maintenance records revealed the laboratory did not document daily maintenance performed on 6 of 6 Reichert TS DSP refractometers in 2017, 2018 and 2019. 4. The Center Manager, Plasma Center QA Manager and Senior Quality Assurance (QA) Specialist confirmed the findings above on 05/09/2019 around 11:20 am.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Center Manager, Plasma Center QA Manager and Senior Quality Assurance (QA) Specialist, the laboratory failed to evaluate the relationship between 6 of 6 Reichert TS DSP refractometers used to analyze Total protein in 2017 to the date of survey. Findings Include: 1. On the day of survey, 05/09/2019, the laboratory could not provide documentation of test result comparisons performed twice yearly, to assess the relationship between 6 of 6 Reichert TS DSP refractometers, stored near the reception area from 2017, 2018 and 2019. 2. About 25,000 to 50,000 tests are performed on a yearly bases. 3. The Center Manager, Plasma Center QA Manager and Senior Quality Assurance (QA) Specialist confirmed the findings above on 05/09/2019 around 11:30 am.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not

limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of competency assessment records, proficiency testing (PT) records and interview with the Center Manager, Plasma Center QA Manager and Senior Quality Assurance (QA) Specialist, the Technical Consultant (Laboratory Director) failed to assess the competency of 28 of 31 TP through internal blind testing samples or external PT samples in 2017 and 2018. Findings Include: 1. At the time of survey, 05/09/2019, review of PT records revealed the laboratory did not assess the test performance of TP through internal blind testing samples or external PT samples in 2017 and 2018: a. In 2017, 3 of 31 TP (#10, #13 and #16) ran the PT samples. b. In 2018, 2 of 31 TP (#6 and #30) ran the in PT samples. c. In 2017 and 2018, 28 of 31 TP were not assessed through internal blind testing samples in lieu of external proficiency testing. 2. The Center Manager, Plasma Center QA Manager and Senior Quality Assurance Specialist confirmed the findings above on 05/09/2019 around 9:50 am.