

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0893092	<b>(X3) Date Survey Completed</b>  12/18/2020
<b>Name of Provider or Supplier</b>  Biolife Plasma Services	<b>Street Address, City, State</b>  14415 Owen Tech Blvd, Austin, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, calibration verification records, observation, and interview, the laboratory's procedure did not include how to evaluate the calibration verification raw data or include the criteria for acceptability for Total Protein using the Reichert TS Meter -DSP Refractometers. Findings follow. I. Review of the laboratory's Standard Operating Procedures, Refractometer Calibration Verification, Precision and Specification Testing, version # 13.0, effective June 15, 2020, did not include how to evaluate the raw data obtained from the calibration verification or the criteria for acceptability of that data. II. Review of 32 of</p>

32 calibration verifications of the refractometers for 6 of 6 dates of testing, as listed by date and refractometer serial number: A. 8/08/2020: 04201-0111, 03261-0209, 04218-0111, 04181-0111, 04174-0111, 04175-0111, 03264-0209, 04199-0111, 04182-0111; B. 7/11/2020: 04201-0111, 03261-0209, 04218-0111, 04181-0111, 04174-0111; C. 01/23/2020: 04175-0111, 03264-0209; D. 01/16/2020: 04201-0111, 03261-0209, 04218-0111, 04181-0111, 04174-0111, 04199-0111, 04182-0111; E. 7/21/2019: 04201-0111, 03261-0209, 04218-0111, 04181-0111, 04174-0111, 04199-0111, 04182-0111; F. 7/03/2019: 04175-0111, 03264-0209.

1. Review of calibration verification activities performed 8/08/2020 discovered the laboratory used the following Kovatrol control testing each control once to verify the reportable range: Low Control, Lot 302382, acceptable range 3.8 - 4.6 g/dL; Normal Control, Lot 302383, acceptable range 7.4 - 8.2 g/dL; High Control, Lot 303251, acceptable range 10.0 - 10.8. The lab also failed to include a zero point in the standards used to ensure the refractometers were linear. The following refractometers were tested by serial number with the results of the Low (L), Normal (N) and High (H) Controls in g/dL: a. 04201-0111: L 4.3, N 7.8, H 10.3 b. 23261-0209: L 4.4, N 7.7, H 10.3 c. 04218-0111: L 4.3, N 7.8, H 10.3 d. 04181-0111: L 4.5, N 7.9, H 10.4 e. 04174-0111: L 4.4, N 7.8, H 10.2 f. 04175-0111: L 4.4, N 7.9, H 10.4 g. 03264-0209: L 4.3, N 7.9, H 10.4 h. 04199-0111: L 4.3, N 7.9, H 10.4 i. 04182-0111: L 4.4, N 7.8, H 10.3 The individual values were initialed and reviewed by two separate individuals and reviewed by QMR on 8/11/2020.

III. Surveyor observed on December 9, 2020 at 1300 for 36 of 36 calibration verification records, there was no evaluation of the calibration verification data to ensure the refractometers were linear throughout the reportable range of the test system.

IV. The calibration verification was requested from Technical Consultant #2, listed on the CMS form 209, and she reached out to the corporate Quality Department (outside this center) to obtain this information. On December 9, 2020 at 1242 hours, graphs were compiled during the survey of the data from the 8/08/2020 calibration verification that did provide R-squared and intercept data, but included "error bars of 0.4 g/dL" for each value on the graph to accommodate the reference range of the control material instead of using the target value of the control material.

V. Interview with Technical Consultant #2 on December 9, 2020 at 1320 hours in the conference room confirmed there was no evaluation of the raw data apart from checking to see if the value is within the acceptable control range.

NOTE: A "calibration verification" means the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system's calibration throughout the reportable range for patient test results. Based on review of the laboratory's policy and procedure, quality control (QC) records, and interview, the laboratory failed to have a procedure to address shifts and trends as they occur, and failed to have a procedure that monitored over time the accuracy and precision of Total Protein tested using the Reichert TS Meter -DSP Refractometers. Findings follow.

A. Review of the laboratory's Standard Operating Procedure, Control Verification of Refractometer SOP-001629, version 36.0, effective Aug 19, 2019, did not address how QC is monitored for accuracy and precision over time, or how to address shifts and trends as they occurred.

B. Review of the QC records for the Kova Refractrol SP, Serum Protein Control, Low 6.0 and High 9.0 levels from April 2019 - November 2020 showed 18 months of reviewed data of the graphs by the Technical Consultant and Laboratory Director, all performed on the same day, 12/08/2020 [the day before the survey]. No statistical data was included with the graph such as mean, standard deviation and coefficient of variation to monitor accuracy and precision of the test system.

C. Review of the QC records for the Kova Refractrol SP, Serum Protein Control, Low 6.0 and High 9.0 levels from April 2019 - November 2020 showed significant shifts in the graphs. 6 of 6 reports did not include the lot numbers used, but this information could be found on the daily test records.

1. 4/01/2019 - 07/31/2019, evaluated on 5/11

/2020 and submitted to the facility for review on 12/08/2020 showed: a. serial number 03261-0209: Low control- 1 plot at 6.0, and 119 plots above the target value of 6.0 with a shift of 110 consecutive plots above the target value of 6.0; High control- a shift in the high control with 12 consecutive plots below the 9.0 target value; b. serial number 04174-0111: Low control- 11 plots at 6.0, 1 below, and 106 plots above the target value of 6.0 with shifts containing 20, 23, 16, and 14 consecutive plots above the 6.0 target value; c. serial number 04181-0111: Low control- 1 plot at 6.0, and 119 plots above the target value of 6.0 with a shift of 112 consecutive plots above the 6.0 target value; High control- 15 plots at 9.0, 1 below, and 100 plots above the target value of 9.0 with 15, 24, 19, and 19 consecutive plots above the 9.0 target value; d. serial number 04182-0111: Low control- 1 plot at 6.0, and 119 plots above the target value of 6.0 with 112 consecutive plots above the 6.0 target value; e. serial number 04199-0111: Low control- 22 plots at 6.0, 2 below, and 96 plots above the target value of 6.0 with 18 and 44 consecutive plots above the 6.0 target value. 2. 9/01/2019 - 12/31/2019, evaluated on 5/26/2020 and submitted to the facility for review on 12/08/2020: a. serial number 03261-0209: Low control- 9 plots at 6.0, and 109 plots above the target value of 6.0 with shifts containing 24, 19, 17, 12, and 10 consecutive plots above the 6.0 target value; High control- 26, 10 and 11 consecutive plots below the 9.0 target value; b. serial number 04174-0111: High control 12 consecutive plots below the 9.0 target value; c. serial number 04181-0111: Low control-17 consecutive plots above the 6.0 target value; High control- 11 consecutive plots above the 9.0 target value; d. serial number 04182-0111: Low control- 10 consecutive plots above the 6.0 target value; High control- 14, 12, 16, and 24 consecutive plots below the 9.0 target value. 3. 10/01/2019 - 01/31/2020, evaluated on 8/24/2020 and submitted to the facility for review on 12/08/2020; 4. 11/01/2019 - 2/29/2020, evaluated on 12/03/2020 and submitted to the facility for review on 12/08/2020; 5. 3/01/2020 - 6/30/2020, evaluated on 12/03/2020 and submitted to the facility for review on 12/08/2020; 6. 8/01/2020 - 11/30/2020, evaluated on 12/07/2020 and submitted to the facility for review on 12/08/2020. Shifts and trends were not defined nor had corrective action. D. Interview with Technical Consultant #2 on the CMS form 209 on December 9, 2020 at 1430 hours in the conference room confirmed the QC evaluation for the previous 2 years was just provided yesterday via email by a member of the Quality Department outside the Center.

**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 review of the calibration verification records, observation, and interview, the laboratory failed to include a zero or minimal value and didn't evaluate the calibration verification raw data to ensure the refractometers were acceptable for Total Protein at least once every 6 months in 2019 and 2020 for 36 of 36 calibration verification testing records for the 9 Reichert TS Meter -DSP Refractometers. Findings follow. I. Review of 32 of 32 calibration verifications of the refractometers for 6 of 6 dates of testing, as listed by date and refractometer serial number: A. 8/08/2020: 04201-0111, 03261-0209, 04218-0111, 04181-0111, 04174-0111, 04175-0111, 03264-0209, 04199-0111, 04182-0111; B. 7/11/2020: 04201-0111, 03261-0209, 04218-0111, 04181-0111, 04174-0111; C. 01/23/2020: 04175-0111, 03264-0209; D. 01/16/2020: 04201-0111, 03261-0209, 04218-0111, 04181-0111, 04174-0111, 04199-0111, 04182-0111; E. 7/21/2019: 04201-0111, 03261-0209, 04218-0111, 04181-0111, 04174-0111, 04199-0111, 04182-0111; F. 7/03/2019: 04175-0111, 03264-0209. 1. Review of calibration verification activities performed 8/08/2020 discovered the laboratory used the following Kovatrol control testing each control once to verify the reportable range: Low Control, Lot 302382, acceptable range 3.8 - 4.6 g/dL; Normal Control, Lot 302383, acceptable range 7.4 - 8.2 g/dL; High Control, Lot 303251, acceptable range 10.0 - 10.8. The following refractometers were tested by serial number with the results of the Low (L), Normal (N) and High (H) Controls in g/dL: a. 04201-0111: L 4.3, N 7.8, H 10.3 b. 23261-0209: L 4.4, N 7.7, H 10.3 c. 04218-0111: L 4.3, N 7.8, H 10.3 d. 04181-0111: L 4.5, N 7.9, H 10.4 e. 04174-0111: L 4.4, N 7.8, H 10.2 f. 04175-0111: L 4.4, N 7.9, H 10.4 g. 03264-0209: L 4.3, N 7.9, H 10.4 h. 04199-0111: L 4.3, N 7.9, H 10.4 i. 04182-0111: L 4.4, N 7.8, H 10.3 The individual values were initialed and reviewed by two separate individuals and reviewed by QMR on 8/11/2020. II. Surveyor observed on December 9, 2020 at 1300 for 36 of 36 calibration verification records, there was no zero or minimal value or an evaluation of the calibration verification data to ensure the refractometers were linear throughout the reportable range of the test system. III. The calibration verification was requested from Technical Consultant #2, listed on the CMS form 209, and she reached out to the corporate Quality Department (outside this center) to obtain this information. On December 9, 2020 at 1242 hours, graphs were compiled during the survey of the data from the 8/08/2020 calibration verification that did provide R-squared and intercept data, but included "error bars of 0.4 g/dL" for each value on the graph to accommodate the reference range of the control material instead of using the target value of the control material. The lab also failed to include a zero point in the standards used to ensure the refractometers were linear. IV. Interview with Technical Consultant #2 on December 9, 2020 at 1320 hours in the conference room confirmed there was no zero value or an evaluation of the raw data apart from checking to see if the value is within the acceptable control range. NOTE: A "calibration verification" means the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system's calibration throughout the reportable range for patient test results.

**D5441**

CONTROL PROCEDURES  
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures

that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure, quality control (QC) records, and interview, the laboratory failed to monitor over time the accuracy and precision of Total Protein and failed to define and identify trends and shifts, for 20 of 20 months reviewed from April 2019 - November 2020, tested using the Reichert TS Meter -DSP Refractometers. Findings follow. A. Review of the laboratory's Standard Operating Procedure, Control Verification of Refractometer SOP-001629, version 36.0, effective Aug 19, 2019, did not address how QC is monitored for accuracy and precision over time, or how to address and identify shifts and trends as they occur. B. Review of the QC records for the Kova Refractrol SP, Serum Protein Control, Low 6.0 and High 9.0 levels from April 2019 - November 2020 showed 18 months of reviewed data of the graphs by the Technical Consultant and Laboratory Director, all performed on the same day, 12/08/2020 [the day before the survey]. No statistical data was included with the graph such as mean, standard deviation and coefficient of variation to monitor accuracy and precision of the test system. C. Review of the QC records for the Kova Refractrol SP, Serum Protein Control, Low 6.0 and High 9.0 levels from April 2019 - November 2020 showed significant shifts in the graphs. 6 of 6 reports did not include the lot numbers used, but this information could be found on the daily test records. 1. 4/01/2019 - 07/31/2019, evaluated on 5/11/2020 and submitted to the facility for review on 12/08/2020 showed: a. serial number 03261-0209: Low control- 1 plot at 6.0, and 119 plots above the target value of 6.0 with a shift of 110 consecutive plots above the target value of 6.0; High control- a shift in the high control with 12 consecutive plots below the 9.0 target value; b. serial number 04174-0111: Low control- 11 plots at 6.0, 1 below, and 106 plots above the target value of 6.0 with shifts containing 20, 23, 16, and 14 consecutive plots above the 6.0 target value; c. serial number 04181-0111: Low control- 1 plot at 6.0, and 119 plots above the target value of 6.0 with a shift of 112 consecutive plots above the 6.0 target value; High control- 15 plots at 9.0, 1 below, and 100 plots above the target value of 9.0 with 15, 24, 19, and 19 consecutive plots above the 9.0 target value; d. serial number 04182-0111: Low control- 1 plot at 6.0, and 119 plots above the target value of 6.0 with 112 consecutive plots above the 6.0 target value; e. serial number 04199-0111: Low control- 22 plots at 6.0, 2 below, and 96 plots above the target value of 6.0 with 18 and 44 consecutive plots above the 6.0 target value. 2. 9/01/2019 - 12/31/2019, evaluated on 5/26/2020 and submitted to the facility for review on 12/08/2020: a. serial number 03261-0209: Low control- 9 plots at 6.0, and 109 plots above the target value of 6.0 with shifts containing 24, 19, 17, 12, and 10 consecutive plots above the 6.0 target value; High control- 26, 10 and 11 consecutive plots below the 9.0 target value; b. serial number 04174-0111: High control 12 consecutive plots below the 9.0 target value; c. serial number 04181-0111: Low control-17 consecutive plots above the 6.0 target value; High control- 11 consecutive plots above the 9.0 target value; d. serial number 04182-0111: Low control- 10 consecutive plots above the 6.0 target value; High control- 14, 12, 16, and 24 consecutive plots below the 9.0

target value. 3. 10/01/2019 - 01/31/2020, evaluated on 8/24/2020 and submitted to the facility for review on 12/08/2020; 4. 11/01/2019 - 2/29/2020, evaluated on 12/03/2020 and submitted to the facility for review on 12/08/2020; 5. 3/01/2020 - 6/30/2020, evaluated on 12/03/2020 and submitted to the facility for review on 12/08/2020; 6. 8/01/2020 - 11/30/2020, evaluated on 12/07/2020 and submitted to the facility for review on 12/08/2020. Shifts and trends were not defined nor had corrective action. D. Interview with Technical Consultant #2 on the CMS form 209 on December 9, 2020 at 1430 hours in the conference room confirmed the QC evaluation for the previous 2 years was just provided yesterday via email by a member of the Quality Department outside the Center.

**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 review of the laboratory's policy and procedure, variability testing records, observation, and interview, the laboratory failed to evaluate and define the relationship between 9 Reichert TS Meter -DSP Refractometers used to perform Total Protein. Findings follow. A. Review of the laboratory's Standard Operating Procedure, Refractometer Variability Analysis Using Proficiency Test Samples, SOP-004803, version 4.0, effective Aug 20, 2018, did not include how the laboratory evaluated each instrument to instrument or defined its acceptable criteria. B. Review of 4 of 4 Refractometer Variability Analysis using Proficiency Test Samples studies (performed 10/06/2020, 2/24/2020, 11/26/2019, and 2/02/2019) showed twelve PT testing results for each refractometer, listed by serial number, with statistical data of the entire group of results as a whole to include mean, standard deviation, and coefficient of variation. Review of the Refractometer Variability Analysis using Proficiency Test Samples, evaluation dated 11/02/2020, showed PT results for 6 refractometers as listed by serial number with test results using PT sample #11: 1. Testing records for serial number 04218-0111 dated 10/06/20 showed a. employee #1 obtained the following results: 8.9, 8.8, 8.6; b. employee #2 obtained the following results: 8.7, 8.7, 8.6; c. employee #3 obtained the following results: 8.9, 8.7, 8.6; d. employee #4 obtained the following results: 8.8, 8.7, 8.7. 2. Testing records for serial number 04201-0111 dated 10/06/20 showed a. employee #1 obtained the following results: 8.7, 8.7, 8.7; b. employee #2 obtained the following results: 8.7, 8.7, 8.7; c. employee #3 obtained the following results: 8.9, 8.7, 8.7; d. employee #4 obtained the following results: 8.7, 8.8, 8.7. 3. Testing records for serial number 04181-0111 dated 10/06/20 showed a. employee #1 obtained the following results: 8.7, 8.7, 8.9; b. employee #2 obtained the following results: 8.7, 8.7, 8.7; c. employee #3 obtained the following results: 9.0, 9.0, 8.9; d. employee #4 obtained the following results: 9.2, 8.8, 8.8. 4. Testing records for serial number 03261-0209 dated 10/06/20 showed a. employee #1 obtained the following results: 8.5, 8.5, 8.5; b. employee #2 obtained the following results: 8.5, 8.5, 8.5; c. employee #3 obtained the following results: 8.5, 8.6, 8.6; d. employee #4 obtained the following results: 8.6, 8.7, 8.6. 5. Testing records for serial number 04182-0111 dated 10/06/20 showed a. employee #1 obtained the following results: 8.5, 8.6, 8.6; b. employee #2 obtained the following results: 8.6, 8.6,

8.6; c. employee #3 obtained the following results: 8.6, 8.5, 8.6; d. employee #4 obtained the following results: 8.6, 8.6, 8.6. 6. Testing records for serial number 04174-0111 dated 10/06/20 showed a. employee #1 obtained the following results: 8.6, 8.7, 8.7; b. employee #2 obtained the following results: 8.6, 8.6, 8.7; c. employee #3 obtained the following results: 8.7, 8.7, 8.7; d. employee #4 obtained the following results: 8.8, 8.8, 8.8. Statistical data was performed using all data points listed above into a single graph including statistical data such as mean (8.6875), standard deviation (0.1331) and coefficient of variation (1.53%). C. Surveyor observed on December 9, 2020 at 1345 in the conference room that no statistical data was performed for each refractometer to determine precision or accuracy for each instrument nor any comparison between instruments, but the studies were a compilation of all test results into a single graph showing statistical data for all of the data points for the PT sample tested. D. Interview with Technical Consultant #1 listed on the CMS form 209 on December 9, 2020 at 1345 hours in the conference room verified there were no statistics for each refractometer and no criteria of acceptability for variability of test results between instruments.

**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:

Based on review of the laboratory's policy and procedures, calibration verification records, quality control (QC) records, variability testing records, observation, and interview, the laboratory failed to effectively monitor the quality, assess, and correct problems identified in the analytic systems. Findings follow. 1. Based on review of the laboratory's policy and procedure, calibration verification records, observation, and interview, the laboratory's procedure did not include how to evaluate the calibration verification raw data for Total Protein using the Reichert TS Meter -DSP Refractometers (see D5403). 2. Based on review of the calibration verification records, observation, and interview, the laboratory failed to substantiate the accuracy of the test system throughout the laboratory's reportable range of test results every 6 months for 36 of 36 calibration verification testing records for the 9 Reichert TS Meter -DSP Refractometers (see D5439). 3. Based on review of the laboratory's policy and procedure, QC records, and interview, the laboratory failed to monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance for 20 of 20 months reviewed from April 2019 - November 2020 for the Reichert TS Meter -DSP Refractometers in use at the facility. A. Review of the QC records for the Kova Refractrol SP, Serum Protein Control, Low 6.0 and High 9.0 levels from April 2019 - November 2020 showed 18 months of reviewed data of the graphs by the Technical Consultant and Laboratory Director, all performed on the same day, 12/08/2020 [the day before the survey]. The reports were as follows (and did not include control lot numbers but could be found on the daily testing records): 1. 4/01/2019 - 07/31/2019, evaluated on 5/11/2020 and submitted to the facility for review on 12/08/2020; 2. 9/01/2019 - 12/31/2019, evaluated on 5/26/2020 and submitted to the facility for review on 12/08/2020; 3. 10/01/2019 - 01/31/2020, evaluated on 8/24/2020 and submitted to the facility for review on 12/08/2020; 4. 11/01/2019 - 2/29/2020, evaluated on 12/03/2020 and submitted to the facility for

review on 12/08/2020; 5. 3/01/2020 - 6/30/2020, evaluated on 12/03/2020 and submitted to the facility for review on 12/08/2020; 6. 8/01/2020 - 11/30/2020, evaluated on 12/07/2020 and submitted to the facility for review on 12/08/2020. No statistical data was included with the graph such as mean, standard deviation and coefficient of variation to monitor accuracy and precision of the test system. B. Review of the QC records for the Kova Refractrol SP, Serum Protein Control, Low 6.0 and High 9.0 levels from April 2019 - November 2020 showed significant shifts in the graphs without documentation of corrective action. Shifts and trends were not defined, identified, nor had corrective action (see D5441). 4. Based on review of the laboratory's policy and procedure, variability testing records, observation, and interview, the laboratory failed to have a system that evaluates and defines the relationship between instruments for 9 of 9 Reichert TS Meter -DSP Refractometers with 4 of 4 studies (see D5775).

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:  
Based on review of the calibration verification records, observation, and interview, the Laboratory Director failed to ensure calibration verification procedures were performed to substantiate the accuracy of the test system throughout the laboratory's reportable range of test results and failed to ensure the procedure for calibration verification provided true and accurate reporting (see D5439).

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policy and procedure, quality control (QC) records, and interview, the Laboratory Director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided. Findings follow. The laboratory failed to provide statistical data to the Laboratory Director in a timely manner to determine accuracy and precision over time. The QC reports were made available for review on 12/08/2020 for the previous

20 months of QC data. The reports showed shifts and trends that were not identified, and contained no corrective action. Failures in quality were not identified, investigated, or addressed for the refractometers (see D5441).