Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2291413	10/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Core Rejuvenation Wellness And Medspa	309 Regency Parkway Sutie 107, Mansfield, TX	

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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's American Proficiency Institute (API) instructions, proficiency testing (PT) records from 2025, and staff interview, the laboratory failed to document a self-grade of chemistry analytes not evaluated or scored by the PT company one of three events in 2025 (Event 3). Findings included: 1 Review of the laboratory's policy "Proficiency Testing" stated: "Upon receipt of proficiency test results the following steps are taken: 1. The Laboratory Director or designee reviews the response. a. Results that were not graded must be addressed with documentation." 2. Review of API performance evaluation instructions revealed: "The American Proficiency Institute evaluation reports consist of four parts: Report Cover, Performance Summary, Comparative Evaluation, and Participant Data Summary. The Performance Summary and Comparative Evaluation are enclosed, and the Participant Data Summary is available on our website. Click on 'Participant Data Summaries' on the left side of the screen, choose a Test Event, and select an analyte and peer group to view the statistics. Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 3. Review of 2025 Chemistry- Core- 3rd Event PT records for

	chemistry analytes revealed the laboratory failed to verify and document accuracy of results obtained for that event as follows: 2025 3rd Event Analyte / Method: Bilirubin, Total (mg/dL)** Abaxis Piccolo / Abaxis Piccolo rgt-mod complex (P31555) Sample: CH-12; Reported Result: 1.5; Expected Result: 1.4-2.3; Performance: Not Graded Sample: CH-15; Reported Result: 1.0; Expected Result: 1.0-1.9; Performance: Not Graded Analyte / Method: LDL Cholesterol (calculated) (mg/dL) Abaxis Piccolo / Abaxis Piccolo calculation (P31555) Sample: CH-12; Reported Result: 0; Expected Result: See Data Summary; Performance: Not Graded 3. During an interview on 10/15 /2025 at 10:27 am, the Technical Consultant, after a review of records, confirmed there was no documentation of review and verification of accuracy for the above-mentioned analytes. Word Key: Rgt- reagent LDL- low-density lipoprotein
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, verification studies, and confirmed in interview, the laboratory failed to have one of one procedure in place for performing verification studies when adding new analyzers or changing analytical methods in the laboratory. Findings included: 1. Review of the laboratory's procedure manual revealed the manual failed to contain procedures for how to perform verification studies when adding new analyzers or changing analytical methods in the laboratory. 2. Review of laboratory verification studies revealed the laboratory added the following analyzers to their test menu: Abaxis Piccolo Xpress chemistry analyzer on 01/2025 Beckman Coulter Access 2 endocrinology and immunology analyzer on 05 /2024 Sysmex pocH-100i hematology analyzer on 05/2024 Further review of the Beckman Coulter Access 2 verification studies revealed the analytical method for the free thyroxine (FT4) analyte was changed by the manufacturer on 12/2024. 3. The laboratory was asked to provide documentation of a procedure for performing verification studies. No documentation was provided. 4. During an interview on 10/16 /2025 at 10:00 a.m., the Technical Consultant confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, patient test reports, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for flags on the Sysmex pocH-100i hematology analyzer for one of ten patients in 2025 (random review October). Findings included: 1. Review of laboratory policy "CBC (pocH-100i)" revealed the laboratory did not instruct how testing personnel

	how to address flagged results obtained on the hematology analyzer. 2. Review of Sysmex pocH-100i operator's manual stated: "2.1.7. Display analysis results ... Numeric value abnormal flag ... * Result is unreliable ... 2.1.8. Histogram flags The pocH-100i extracts the characteristics of the histogram and displays them as histogram flags. If there are histogram flags, repeat analysis. If flags are still displayed, one of the following problems may apply. Flag AG Problem sample cause Prescence of nucleated red blood cells, increase of large platelets, platelet aggregation, or agglutination, precipitation of fibrin, presence of proteins or lipids, etc. Correction Check smear. Warm sample and repeat analysis. Wash blood cells. 3. Review of patient pocHi-100i hematology analyzer test reports and final LIS reports revealed one of ten patient test results with flags were reported in October 2025 (random review). The following flagged result was reported: 10/14/2025 Patient ID 251014018W at 3:14 p.m. with a "AG" and "*" flag on the platelet parameter 4. During an interview on 10/16/2025 at 10:30 a.m., the Technical Consultant stated that there was no policy to address flagged CBC results. She further stated that she sometimes repeats flagged results, however the patient identified above was not repeated, confirming the above findings. The laboratory did not confirm/verify flagged results prior to reporting to physicians and entering the results into the patient chart. The laboratory did not ensure these CBC results were accurate and reliable.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on review of laboratory's CMS 116 form, laboratory policies, verification studies, and confirmed in interview the laboratory failed to perform complete verification studies for two of two panels tested on the Abaxis Piccolo Xpress analyzer. Findings included: 1. Review of the laboratory's CMS 116 form submitted on the day of the survey revealed the Abaxis Piccolo Xpress analyzer was used to test lipid and CMP panels. Records further revealed the lipid and CMP panels were placed into-use on 01/2025. The analytes tested on the lipid panel included: total CHOL, HDL cholesterol, TRIG, LDL cholesterol (calculated). The analytes tested on the CMP panel included: ALB, ALP, ALT, AST, BUN, Ca, Cl-, CRE, eGFR, GLU, K+, Na, TBIL, tCO2, TP. 2. Review of the laboratory's policy manual revealed the laboratory failed to have a procedure for performing verification studies when implementing new analyzers into the laboratory's test menu. Refer to D5401. 3. Review of the laboratory's verification studies revealed the laboratory failed to include a precision and a reportable range study to ensure a complete verification study of the Piccolo Xpress analyzer for the lipid and CMP panels. The laboratory was asked to provide complete verification studies on the Piccolo Xpress analyzer prior to reporting 9,392 patient test results. No complete verification studies were provided. 4. During an interview on 10/15/2025 at 12:02 p.m., the Technical Consultant, after a review of records, confirmed the laboratory failed to perform complete verification studies for two of two panels tested on the Abaxis Piccolo Xpress analyzer. Word Key: CMS-

Center for Medicare & Medicaid Services CMP- comprehensive metabolic panel CHOL- total cholesterol HDL- high-density lipoprotein TRIG- triglycerides LDL- low density lipoprotein ALB- Albumin ALP- Alkaline phosphatase ALT- Alanine aminotransferase AST- Aspartate aminotransferase BUN- Blood Urea Nitrogen Ca- Calcium Cl- - Chloride CRE- Creatinine eGFR- Estimated Glomerular Filtration Rate (Calculated) GLU- Glucose K+ - Potassium Na- Sodium TBIL- Total bilirubin tCO2- Total carbon dioxide TP- Total protein II. Based on review of laboratory's CMS 116 form, laboratory policies, manufacturer's instructions, verification studies, and confirmed in interview the laboratory failed to perform complete verification studies for 16 of 16 analytes tested on the Beckman Coulter Access 2 analyzer. Findings included: 1. Review of the laboratory's CMS 116 form submitted on the day of the survey revealed the Beckman Coulter Access 2 analyzer was used to test the endocrinology and immunology analytes. Records further revealed the Access 2 analyzer was placed into-use on 04/2024. The endocrinology analytes tested included: cortisol, ferritin, folate, free T3, free T4, hFSH, insulin, progesterone, PSA, sensitive estradiol, SHBG, testosterone, TSH, Vitamin B12, Vitamin D. The immunology analytes included: TPO antibody. 2. Review of the laboratory's policy manual revealed the laboratory failed to have a procedure for performing verification studies when implementing new analyzers into the laboratory's test menu. Refer to D5401. 3. Review of the Beckman Coulter Access 2 installation and implementation guide stated: "1 Performance Verification Studies Overview ... Your laboratory must compile its own policies and procedures manual for method evaluation, in compliance with the appropriate accrediting agencies." 4. Review of the laboratory's verification studies revealed the laboratory failed to include an accuracy study to ensure a complete verification study of the Access 2 analyzer used in the testing of endocrinology and immunology analytes. The laboratory was asked to provide complete verification studies on the Access 2 analyzer prior to reporting 1,396 patient test results. No complete verification studies were provided. 5. During an interview on 10/16/2025 at 10:00 a.m., the Technical Consultant, after a review of records, confirmed the laboratory failed to perform complete verification studies for 16 of 16 analytes tested on the Beckman Coulter Access 2 analyzer. Word Key: T3- free triiodothyronine T4- thyroxine hFSH- Human follicle-stimulating hormone PSA- prostate-specific antigen SHBG- sex hormone-binding globulin TPO- thyroid peroxidase III. Based on review of laboratory's CMS 116 form, laboratory policies, manufacturer's instructions, verification studies, and confirmed in interview the laboratory failed to perform complete verification studies for one of one analyte tested on the Beckman Coulter Access 2 analyzer. Findings included: 1. Review of the laboratory's CMS 116 form submitted on the day of the survey revealed the Beckman Coulter Access 2 analyzer was used to test the free thyroxine (FT4) analyte. 2. Review of the laboratory's policy manual revealed the laboratory failed to have a procedure for performing verification studies when changing analytical methods for analytes tested by the laboratory. Refer to D5401. 3. Review of the Beckman Coulter Access 2 installation and implementation guide stated: "1 Performance Verification Studies Overview ... Your laboratory must compile its own policies and procedures manual for method evaluation, in compliance with the appropriate accrediting agencies." 4. Review of the laboratory's verification studies revealed the laboratory performed a method comparison study for the FT4 analyte on 10/12/2024. However, the study failed to include an accuracy, precision and reportable range study to ensure a complete verification study of the Access 2 analyzer. The laboratory was asked to provide complete verification studies for the FT4 analyte tested on the Access 2 analyzer prior to reporting 408 patient test results. No complete verification studies were provided. 5. During an interview on 10/16/2025 at 10:00 a.m., the Technical Consultant, after a review of records, confirmed the laboratory failed to perform

	complete verification studies for one of one analyte tested on the Beckman Coulter Access 2 analyzer.
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. This STANDARD is not met as evidenced by: I. Based on review of laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, laboratory records, and confirmed in staff interview, the laboratory failed to monitor the accuracy and precision of Bioresource Technology (BRT) chemistry QC material over time for the comprehensive metabolic panels (CMP) and lipid panels tested on the Abaxis Piccolo Xpress chemistry analyzer two of two QC lots reviewed (May 2025 through September 2025) to ensure accurate and reliable test results. Findings included: 1. Review of laboratory's IQCP for the CMP and lipid panels tested on the Piccolo Xpress chemistry analyzer stated: "3. Quality Assessment Plan ... QC Review Laboratory Director will review QC records monthly for trends or errors." 2. A random review of the following lots of QC tested in May 2025 through September 2025 revealed no documentation monitoring QC over time: Lot #2406022 (levels 1 and 2) expiration date: 11/30/2025; date in use: 01/02/2025 Lot #2409018 (levels 1 and 2) expiration date: 02/28/2026; date in use: 09/17/2025 The laboratory was asked to provide documentation of monitoring QC over time for the CMP and lipid panels tested on the Piccolo Xpress analyzer using the BRT chemistry QC material. None was provided. 3. Review of laboratory records revealed the laboratory had an annual volume of 9,392 tests performed. 4 During an interview on 10/15/2025 at 1:25 p.m., the Technical Consultant confirmed the laboratory failed to monitor the accuracy and precision of BRT chemistry QC material over time to ensure accurate and reliable test results. II. Based on review of laboratory's quality control (QC) policy, BIO-RAD control material manufacturer's instructions, assignment of value sheets, Access 2 QC data (random review), and in interview with staff, the laboratory failed to ensure their control procedures detected immediate error for one of one set of current lot numbers (random review). Findings included: 1. Review of the laboratory's policy "Access 2" stated: "6. Quality Control ... d. Bio-Rad Immunoassay, Bio-Rad Specialty immunoassay [sic], and Access SHBG QC are used. Follow manufacturer IFU for instructions on use. Manufacturer IFU includes ranges for each test and lot number ... h. Use Westgard rules to interpret QC results and review LJ charts. i. Acceptable results should fall within 3 SD of the mean. Re-evaluate peer group mean and SD if results should fall outside of this. Review manufacturer values and results per the package insert and lot number." 2. Review of BIO-RAD Liquichek Immunoassay Plus Control manufacturer's instructions (package insert) stated: "ASSIGNMENT OF VALUES The means and values and corresponding +/-3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of

	product... It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control." Further review of the Assignment of Values revealed the following sampling of analyte QC ranges: Liquichek Immunoassay Plus Control Level 1 Lot #1003931; expiration date: 05/27/2027 Level 3 Lot #1003933; expiration date: 05/27/2027 Ferritin Level 1 Mean: 24.3; Range: 19.8-28.7 Free Triiodothyronine (T3) Level 1 Mean: 2.09; Range: 1.65-2.52 Free Thyroxine (T4) Level 1 Mean: 0.858; Range: 0.714-1.00 Level 3 Mean: 3.45; Range: 2.96-3.93 3. Review of Access 2 endocrinology analyzer QC data (random review 09 /2025 through 10/2025) revealed the ranges used did not detect immediate error, as follows (random sampling of analytes): Liquichek Immunoassay Plus Control (put into use 09/01/2025): Level 1 Lot #1003931; expiration date: 05/27/2027 Level 3 Lot #1003933; expiration date: 05/27/2027 Laboratory Ferritin ranges used for day-to-day acceptability: Level 1 Mean: 22.50; Range: 19.26-25.74 Free T3 Level 1 Mean: 2.130; Range: 1.794-2.466 Free T4 Level 1 Mean: 0.858; Range: 0.694-1.022 Level 3 Mean: 3.370; Range: 2.856-3.884 The laboratory's QC ranges were too wide to detect immediate error. 4. During an interview on 10/16/2025 at 10:42 a.m., the Technical Consultant, after a review of records, confirmed the laboratory failed to ensure their control procedures detected immediate error for one of one set of current lot numbers.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policy, the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to support its reduction in frequency to every 30 days and failed to perform two levels of liquid QC material each day of patient testing on the Abaxis Piccolo Xpress analyzer for the comprehensive metabolic panel (CMP) for 17 of 17 days in 2025 (random sampling 05/2025-10/2025). Findings included: 1. Review of the laboratory's policy "Comprehensive Metabolic Panel -Piccolo Xpress" stated: "8. Quality Control (QC) ... External QC: Use manufacturer-approved liquid controls at least monthly, any time environment changes, each new reagent lot /shipment, and per CLIA/regulatory requirements. Do not report patient results when QC fails." 2. Review of the laboratory's IQCP stated: "2. Quality Control Plan QC Component Plan Frequency Two levels of liquid QC will be run once per calendar month. Triggers for Additional QC Additional QC will be run: -When a new shipment or lot of reagent disks (CMP or Lipid) is opened -After instrument maintenance -If monthly QC is out of range" Further review of the laboratory's IQCP Plan for the CMP cartridge tested on the Abaxis Piccolo analyzer revealed no documentation of the quality control study that included at least two levels of external quality control material for a minimum of 30 days. The IQCP failed to support its reduction in

frequency to every 30 days for the CMP cartridge tested on the Abaxis Piccolo analyzer. 3. The laboratory implemented the CMP cartridge tested on the Abaxis Piccolo as a moderate complexity analyzer into use on January 2025. The analytes tested on the CMP cartridge were ALB, ALP, ALT, AST, BUN, Ca, Cl-, CRE, eGFR, GLU, K+, Na, TBIL, tCO2, TP. The laboratory did not perform external quality control at least once each day patient specimens were tested, as required per CFR 493.1256. 4. Review of CMP cartridge QC logs from 05/2025-10/2025 revealed external QC was performed on the following days: Control lot # 2406022; expiration date 11/30/25 05/02/2025: level 1 and 2 were tested 06/13/2025: level 1 and 2 were tested 07/14/2025: level 1 and 2 were tested 08/12/2025: level 1 and 2 were tested 08 /29/2025: level 1 and 2 were tested 09/16/2025: level 1 and 2 were tested Control lot # 2409018; expiration date 02/28/2026 09/17/2025: level 1 and 2 were tested The laboratory did not implement an IQCP to lessen the frequency of required external QC. The laboratory did not analyze external QC for 30 consecutive days to ensure stability of material to lessen the frequency of QC. 5. A random review of patient records identified the following 24 patients who were tested and reported when external quality control was not performed: 06/26/2025 Patient ID: 250625007 07/18 /2025 Patient ID: 250718001 07/21/2025 Patient ID: 250721010 07/24/2025 Patient ID: 250723008 07/29/2025 Patient ID: 250729007 08/14/2025 Patient ID: 250814001 08/22/2025 Patient IDs: 25082003, 250822003 08/26/2025 Patient ID: 250826009 09 /09/2025 Patient IDs: 250909009, 250909002 09/11/2025 Patient ID: 250911005 09 /18/2025 Patient ID: 250918007 09/19/2025 Patient ID: 250919003 09/25/2025 Patient IDs: 250924002, 250925013 10/02/2025 Patient ID: 251002009 10/09/2025 Patient IDs: 251009004, 251009008, 251008009 10/10/2025 Patient IDs: 251010004, 251010003, 251010007 10/14/2025 Patient ID: 251014018 The laboratory did not perform external quality control at least once each day patient specimens were assayed, as required per CFR 493.1256. The laboratory did not analyze external QC for 30 consecutive days to ensure stability of material to lessen the frequency of QC. 4. During an interview on 10/15/2025 at 12:02 p.m., the Technical Consultant stated that she did not perform a QC study, confirming the laboratory failed to support its reduction in frequency to every 30 days and failed to perform two levels of liquid QC material each day of patient testing on the Abaxis Piccolo Xpress analyzer for the CMP cartridge. Word Key: ALB- Albumin ALP- Alkaline phosphatase ALT- Alanine aminotransferase AST- Aspartate aminotransferase BUN- Blood Urea Nitrogen Ca- Calcium Cl- - Chloride CRE- Creatinine eGFR- Estimated Glomerular Filtration Rate (Calculated) GLU- Glucose K+ - Potassium Na- Sodium TBIL- Total bilirubin tCO2- Total carbon dioxide TP- Total protein II. Based on review of the laboratory's policy, the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to support its reduction in frequency to every 30 days and failed to perform two levels of liquid QC material each day of patient testing on the Abaxis Piccolo Xpress analyzer for the lipid panel for 15 of 15 days in 2025 (random sampling 05/2025-10/2025). Findings included: 1. Review of the laboratory's policy "Lipid Panel -Piccolo Xpress" stated: "8. Quality Control (QC) ... External QC: Run liquid QC materials (at least two levels) monthly, new lot/shipment, per CLIA/regulatory requirements, and lab policy. Review and document ranges before releasing results." 2. Review of the laboratory's IQCP stated: "2. Quality Control Plan QC Component Plan Frequency Two levels of liquid QC will be run once per calendar month. Triggers for Additional QC Additional QC will be run: -When a new shipment or lot of reagent disks (CMP or Lipid) is opened -After instrument maintenance -If monthly QC is out of range" Further review of the laboratory's IQCP Plan for the lipid panel cartridge tested on the Abaxis Piccolo analyzer revealed no documentation of the quality control study that included at least two levels of external quality control material for a minimum of 30 days. The IQCP

	failed to support its reduction in frequency to every 30 days for the lipid panel cartridge tested on the Abaxis Piccolo analyzer. 3. The laboratory implemented the lipid panel cartridge tested on the Abaxis Piccolo as a moderate complexity analyzer into use on January 2025. The analytes tested on the lipid panel cartridge were total CHOL, HDL cholesterol, TRIG, LDL cholesterol. The laboratory did not perform external quality control at least once each day patient specimens were tested, as required per CFR 493.1256. 4. Review of lipid panel cartridge QC logs from 05/2025-10/2025 revealed external QC was performed on the following days: Control lot # 2406022; expiration date 11/30/25 05/01/2025: level 1 and 2 were tested 06/13/2025: level 1 and 2 were tested 07/14/2025: level 1 and 2 were tested 08/07/2025: level 1 and 2 were tested 08/19/2025: level 1 and 2 were tested 08/27/2025: level 1 and 2 were tested 09/10/2025: level 1 and 2 were tested The laboratory did not implement an IQCP to lessen the frequency of required external QC. The laboratory did not analyze external QC for 30 consecutive days to ensure stability of material to lessen the frequency of QC. 5. A random review of patient records identified the following 20 patients who were tested and reported when external quality control was not performed: 06/26/2025 Patient ID: 250625007 07/07/2025 Patient ID: 250705005 07 /18/2025 Patient ID: 250718001 07/24/2025 Patient ID: 250723008 07/29/2025 Patient ID: 250729007 08/14/2025 Patient ID: 250814001 08/22/2025 Patient IDs: 250820003, 250822003 08/26/2025 Patient ID: 250826009 09/09/2025 Patient IDs: 250909009, 250909002 09/19/2025 Patient ID: 250919003 09/25/2025 Patient ID: 250925013 10/02/2025 Patient ID: 251002009 10/09/2025 Patient IDs: 251009004, 251009008, 251008009 10/10/2025 Patient IDs: 251010004, 251010003 10/14/2025 Patient ID: 251014018 The laboratory did not perform external quality control at least once each day patient specimens were assayed, as required per CFR 493.1256. The laboratory did not analyze external QC for 30 consecutive days to ensure stability of material to lessen the frequency of QC. 4. During an interview on 10/15/2025 at 12:02 p.m., the Technical Consultant stated that she did not perform a QC study, confirming the laboratory failed to support its reduction in frequency to every 30 days and failed to perform two levels of liquid QC material each day of patient testing on the Abaxis Piccolo Xpress analyzer for the lipid panel cartridge. Word Key: CHOL- cholesterol HDL- high-density lipoprotein TRIG- triglycerides LDL- low density lipoprotein
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy, Unity Manufacturer Report, quality control (QC) records, and confirmed in interview, the laboratory failed to establish the statistical parameters for unassayed materials used on the Access 2 analyzer for one of one lot of QC in 2025. Findings included: 1. Review of BIO-RAD Liquichek Immunoassay Plus Control manufacturer's instructions (package insert)

	stated: "ASSIGNMENT OF VALUES The means and values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product... It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control." 2. Review of the laboratory's policy "Access 2" stated: "6. Quality Control ... d. Bio-Rad Immunoassay, Bio-Rad Specialty immunoassay [sic], and Access SHBG QC are used. Follow manufacturer IFU for instructions on use. Manufacturer IFU includes ranges for each test and lot number ... h. Use Westgard rules to interpret QC results and review LJ charts. i. Acceptable results should fall within 3 SD of the mean. Re-evaluate peer group mean and SD if results should fall outside of this. Review manufacturer values and results per the package insert and lot number." The policy failed to state the laboratory must establish its own mean and acceptability ranges for BioRad quality control materials. 3. Review of QC data and the "Unity Manufacturer Report for Beckman Coulter" revealed the laboratory was utilizing the range of means and standard deviation (SD) from the Unity report for the acceptability of QC. The laboratory did not establish means and limits for each parameter for the following lots (random review): BIO-RAD Liquichek Immunoassay Plus Control Level 1 Lot 1003931, expiration date: 05/31 /2027, date put into use: 09/01/2025 Level 3 Lot 1003933, expiration date: 05/31 /2027, date put into use: 09/01/2025 Analytes tested using the BIO-RAD Liquichek Immunoassay Plus Control: cortisol, estradiol, ferritin, folate, follicle stimulating hormone (FSH), insulin, progesterone, prostate-stimulating antigen (PSA), free triiodothyronine (FT3), free thyroxine, (FT4), testosterone, thyroid stimulating hormone (TSH), Vitamin B12 4. During an interview on 10/16/2025 at 12:00 p.m., the Technical Consultant stated that the BioRad IFU assignment of values for each lot number did not have an SD and therefore used the mean and SD from the Unity report to establish the QC ranges used for everyday acceptability. These statements confirmed that the laboratory failed to establish statistical parameters for unassayed control materials used on the Access 2 analyzer.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of laboratory's CMS 116 form, laboratory policies, manufacturer's instructions, verification studies, and confirmed in interview the laboratory director failed to ensure verification studies for each test system were complete. Refer to D5421-I, D5421-II, D5421-III.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) (b)(2) Verification of the test procedures performed and the establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by:

	Based on review of laboratory's CMS 116 form, laboratory policies, manufacturer's instructions, verification studies, and confirmed in interview the technical consultant failed to ensure verification studies for each test system were complete. Refer to D5421-I, D5421-II, D5421-III.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, the laboratory's Individualized Quality Control Plan (IQCP), manufacturer's instructions, Unity Manufacturer Report, quality control (QC) records, patient records, and confirmed in interview, technical consultant failed to ensure a quality control program was developed and followed as evidenced by: 1. The laboratory failed to monitor the accuracy and precision of Bioresource Technology (BRT) chemistry QC material over time for the comprehensive metabolic panels (CMP) and lipid panels tested on the Abaxis Piccolo Xpress chemistry analyzer two of two QC lots reviewed (May 2025 through September 2025) to ensure accurate and reliable test results. Refer to D5441, I. 2. The laboratory failed to ensure their control procedures detected immediate error for one of one set of current lot numbers (random review). Refer to D5441, II. 3. The laboratory failed to support its reduction in frequency to every 30 days and failed to perform two levels of liquid QC material each day of patient testing on the Abaxis Piccolo Xpress analyzer for the comprehensive metabolic panel (CMP) for 17 of 17 days in 2025 (random sampling 05/2025-10/2025). Refer to D5445, I. 4. The laboratory failed to support its reduction in frequency to every 30 days and failed to perform two levels of liquid QC material each day of patient testing on the Abaxis Piccolo Xpress analyzer for the lipid panel for 15 of 15 days in 2025 (random sampling 05/2025-10/2025). Refer to D5445, II. 5. The laboratory failed to establish the statistical parameters for unassayed materials used on the Access 2 analyzer for one of one lot of QC in 2025. Refer to D5469.