Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0708410	10/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mcallen Primary Care Clinic Inc	110 E Savannah Bldg A Suite 204, Mcallen, 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 out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director D6033 - 42 C.F.R. 493.1409 Condition: Technical Consultant
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's American Proficiency Institute's hematology proficiency testing records from 2022, and staff interview, the laboratory failed to have documentation of 1 of 4 personnel participating in proficiency testing. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 4 testing personnel who performed hematology testing. 2. A review of the laboratory's American Proficiency Institute's hematology proficiency testing records from 2022 (events 1, 2 and 3) revealed 1 of 4 testing personnel did not participate in proficiency testing for hematology. They were (as listed on the CMS 209): Testing personnel 4 3. The laboratory was asked to provide documentation of the identified testing personnel participating in hematology proficiency testing in 2022. No documentation was provided. 4. The technical consultant confirmed the findings in an interview on 10/17 /2023 at 1005 hours in the physician assistant's office. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's records and staff interview, the laboratory failed to meet the requirements for analytic systems. The findings include: 1. The laboratory failed to follow its own procedure for flagged CBC results (refer to D5401). 2. The laboratory failed to have documentation of performing calibrations as required (refer to D5437). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021. 3. The laboratory failed to have documentation of performing calibration verifications as required (refer to D5439). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 1/25/2016, 11/15 /2017, 1/29/2020 AND 12/21/2021. 4. The laboratory failed to monitor quality control results over time (refer to D5441). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021. 5. The laboratory failed to verify new lots of quality control material (refer to D5469). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 1/29/2020 AND 12/21/2021. KEY CBC - complete blood count
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 the laboratory's policy for addressing flagged CBC results, review of a sampling of patient test records from September 1, 2023 to October 16, 2023, and staff interview, it was revealed the laboratory failed to have documentation of following its policy for 4 of 8 flagged results. The findings include: 1. A review of the laboratory's policy titled "Policy for Handling Flagged CBC Differentials" (approved by the laboratory director on 03/01/2022) identified: "It will be the policy of this laboratory to rerun flagged CBC results. If the second run still shows flags, then the lab will evaluate flagged differentials according [to] the procedures in the unit's operator manual... If the flags disappear, then report that result. If the flags persist, follow manufacturer's instructions. The lab can also cross out or not report the flagged CBC results in their LIS system." 2. A sampling of patient test records from September 1, 2023 to October 16, 2023 identified 8 patient records with flagged results. The flagged results for 4 of these patients were not retested or not resolved after repeat testing. Further review of the patient test records showed the flagged results were reported to the providers. They were: a) Date: 09/01/2023 Sample ID: 1090123725 Flag: L5 not retested b) Date: 09/13/2023 Sample ID: 1091323129 Flag: L1 flag on initial and retest c) Date: 09/27/2023 Sample ID: 1092723530 Flag: L1 flag on initial and retest d) Date: 10/02/2023 Sample ID: 1100223647 Flag: L5 not retested

	3. The laboratory was asked to provide documentation it followed the policy for resolving flags prior to reported the identified patient results. No documentation was provided. 4. The technical consultant confirmed the findings in an interview on 10/17 /2023 at 1315 hours in the laboratory. Key CBC - complete blood count LIS - laboratory information system
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the storage of BD Vacutainer tubes, surveyor observation of supplies stored in the laboratory, review of laboratory room temperature logs from August 2022 to August 2023, and staff interview, the laboratory failed to ensure supplies were stored at the temperature required by the manufacturer on 23 of 396 days. The findings include: 1. A review of the manufacturer's instructions for the storage of BD Vacutainer tubes identified the manufacturer's defined acceptable storage temperature as 4 - 25C (39.2 - 77.0F). 2. Surveyor observation of supplies stored in the laboratory on 10/17/2023 at 1030 hours identified the following BD Vacutainer tubes: 109 BD K2 EDTA (ref 367861) 100 BD Serum tubes (ref 36781) 100 BD Sodium Citrate (ref 36083) 100 BD SST (ref 367988) 3. A review of the laboratory's room temperature records from August 2022 to August 2023 identified the laboratory's defined acceptable room temperature as 15 -32C (59 - 90F). Further review identified the following days where the documented room temperature exceeded the manufacturer's acceptable range on 23 of 396 days. The days/temperatures were: Date Temperature 8/5/22 79F 8/7/22 80F 8/8/22 79F 8/11 /22 82F 8/12/22 86F 8/13/22 82F 8/14/22 82F 8/15/22 85F 8/16/22 86F 8/26/22 79F 9 /1/22 79F 11/3/22 80F 11/16/22 79F 11/21/22 78F 11/25/22 80F 11/30/22 81F 1/1 /2023 78F 5/26/23 79F 7/19/23 78F 7/22/23 78F 7/23/23 78F 7/27/23 79F 8/20/23 78F 3. The laboratory was asked to provide documentation of performing corrective actions to ensure the tubes were stored at the temperature stated by the manufacturer. No documentation was provided. 4. The technical consultant confirmed the findings in an interview on 10/17/2023 at 1030 hours in the physician assistant's office. Key EDTA - ethylenediaminetetraacetic acid SST - serum separator tube F - degrees Fahrenheit C - degrees Celsius
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 surveyor observation of supplies stored in the laboratory on 10/17/2023 at 1030 hours and staff interview, the laboratory failed to ensure expired supplies were not available for use. The findings include: 1. Surveyor observation of supplies stored in the drawer by the phlebotomy chair on 10/17/2023 at 1030 hours identified the following expired supplies: 1 BD K2 EDTA tube Lot: 2153653 expiration date: 2023-6-30 5 BD Gold top tubes Lot: 2174197 expiration date: 2023-6-30 2 BD PST Lithium heparin tubes Lot: 2228622 expiration date: 2023-8-31 2 BD Lithium heparin tubes Lot: 2228477 expiration date: 2023-7-31 2. The technical consultant confirmed the findings in an interview on 10/17/2023 at 1030 hours in the laboratory.
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 review of the laboratory's policies, review of the laboratory's calibration records for the CELL-DYN Emerald hematology analyzer from 2022 and 2023, and staff interview, the laboratory failed to have documentation of performing calibrations every six months. The findings include: 1. A review of the laboratory's policy titled "Instrument Operation and Maintenance" (approved by the laboratory director on 10/1/2015) revealed: "Calibration of all laboratory instruments will be every six months...." 2. A review of the laboratory's calibration records for the CELL-DYN Emerald hematology analyzer from January 2022 to September 2023 identified the laboratory failed to ensure calibrations were performed every six months. Calibrations were performed: April 2022 October 2022 3. The laboratory was asked to provide documentation of performing a calibration after the one performed in October 2022. No documentation was provided. Thus, it had been 11 months since the last calibration was performed. 4. The technical consultant confirmed the findings in an interview on 10/17/2023 at 1035 hours in the physician assistant's office. She stated calibration material had been received by the laboratory, but calibration was not performed. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021.
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 laboratory's test menu, review of the laboratory's calibration verification records from November 2021 to October 2023 and staff interview, the laboratory failed to have documentation of: A) performing calibration verification every six months for TSH on the Qualigen FASTPack system, and B) performing calibration verification every six months for 17 of 17 analytes on the Ace Alera system. The findings include: A) Qualigen FASTPack system 1. A review of the laboratory's test menu identified the laboratory performed TSH (thyroid stimulating hormone) testing on the Qualigen FASTPack system which utilized 2 calibrators and 2 levels of quality and thus, required calibration verification every six months. 2. A review of the laboratory's TSH calibration verification records from November 2021 to October 2023 identified the facility failed to perform calibration verification for TSH every six months. Calibration verification was documented: November 2021 October 2023 (23 months later) 3. The laboratory was asked to provide documentation of performing calibration verification every six months. No documentation was provided. 4. The technical consultant confirmed the findings in an interview on 10/17 /2023 at 1020 hours in the physician assistant's office. She stated the facility had not performed calibration verifications for 23 months. B) Ace Alera 1. A review of the laboratory's test menu identified the following 17 analytes tested on the Alfa Wassermann Ace Alera chemistry analyzer which utilized 2 calibrators and 2 levels of quality and thus, required calibration verification every six months: Total Bilirubin Direct Bilirubin Albumin Alkaline Phosphatase Alanine Transaminase Aspartate Transaminase Blood Urea Nitrogen Calcium Chloride Cholesterol, HDL Cholesterol, Total CO2 Creatinine Glucose Potassium Total Protein Sodium 2. A review of the laboratory calibration verification records from January 2022 to October 2023 identified calibration verification was performed at the following times: January 2022 July 2022 (six months later) February 2023 (seven months later) October 2023 (eight months later) 3. The laboratory was asked to provide documentation of performing calibration verification every six months as required. No documentation was provided. 4. The technical consultant confirmed the findings in an interview on 10/17/2023 at 1040 hours in the physician assistant's office. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 1/25/2016, 11/15/2017, 1/29 /2020 AND 12/21/2021.
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 quality control records for the Qualigen FASTPack system from 2022 and 2023, and staff interview, the laboratory failed to have documentation of monitoring quality control values for 2 of 2 lot numbers over time to identify shifts and trends. The findings include: 1. A review of the laboratory's quality control records from January 2022 to October 2023 identified the laboratory utilized the following lots of quality control material for TSH (thyroid stimulating hormone) testing: 2107002-1 2210005-1 Each lot was comprised of two different levels of control material. 2. The laboratory was asked to provide documentation of monitoring the control values over time to identify shifts and trends. No documentation was provided. 3. The technical consultant confirmed the findings in an interview on 10/17/2023 at 1144 hours in the physician assistant's office. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21 /2021.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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-- Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's quality control records from 2022 and 2023, and staff interview, the laboratory failed to have documentation of verifying: A) 4 of 8 lots of hematology controls, and B) 2 of 2 lots of TSH controls. The findings include: A) Hematology controls 1. A review of the laboratory's policy titled "Quantitative Control Validations" (approved by the laboratory director on 10/01/2015) revealed: "Policy: It is the policy of this lab to validate quantitative controls prior to placing them into use for patient testing. Method: New controls shall be run at least once a day for 5 days along with current controls. If current controls are within range and the new controls are within their

	range, then the new controls will be acceptable for use for patient testing." 2. A review of the laboratory's hematology quality control records from 2022 and 2023 identified the following 4 of 8 lots of quality control material which were not verified prior to use: a) Lot: 2346 In use: 1/2/2023 b) Lot: 3065 In use: 4/1/2023 c) Lot: 3149 In use: 6/24/2023 d) Lot: 3233 In use: 8/28/2023 3. The laboratory was asked to provide documentation of verifying the identified lots prior to use. No documentation was provided. 4. The technical consultant confirmed the findings in an interview on 10 /17/2023 at 1137 hours in the physician assistant's office. B) TSH controls 1. A review of the laboratory's policy titled "Quantitative Control Validations" (approved by the laboratory director on 10/01/2015) revealed: "Policy: It is the policy of this lab to validate quantitative controls prior to placing them into use for patient testing. Method: New controls shall be run at least once a day for 5 days along with current controls. If current controls are within range and the new controls are within their range, then the new controls will be acceptable for use for patient testing." 2. A review of the laboratory's TSH quality control records from 2022 and 2023 identified the following two lots were placed into use: Lot: 2107002-1 Lot: 2210005-1 3. The laboratory was asked to provide documentation of verifying the identified lots prior to use. No documentation was provided. 4. The technical consultant confirmed the findings in an interview on 10/17/2023 at 1320 hours in the physician assistant's office. Key TSH - thyroid stimulating hormone NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 1/29/2020 AND 12/21/2021.
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 records, and staff interview, it was revealed the laboratory quality assurance plan failed to identify and correct problems in analytic systems. The findings include: 1. The laboratory's quality assurance plan failed to ensure the facility performed calibrations every six months (refer to D5437). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21 /2021. 2. The laboratory's quality assurance plan failed to ensure the facility performed calibration verification every six months (refer to D5439). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 1/25/2016, 11/15 /2017, 1/29/2020 AND 12/21/2021. 3. The laboratory's quality assurance plan failed to ensure the facility monitored quality control values over time (refer to D5441). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021. 4. The laboratory's quality assurance plan failed to ensure the facility verified new lots of quality control material (refer to D5469). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 1/29/2020 AND 12 /21/2021.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result

	indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient test records from September 1, 2023 to October 16, 2023, and staff interview, the laboratory failed to have documentation of the notification of 1 of 1 critical values. The findings include: 1. A review of the laboratory's policy titled "Reporting Critical Values" (approved by the laboratory director on 10/01/2015) stated: "It is the policy of this laboratory to document the reporting of Critical Values. Document: 1. Who was notified 2. When was the person notified 3. By whom was the person notified" 2. A review of the laboratory's policy titled "Critical Values" (approved by the laboratory director on 10 /01/2015) revealed the laboratory defined the following values as 'critical': WBC under 2 or over 20 HGB under 7.5 or over 18 HCT under 25 or over 55 Platelets under 50 or over 800 3. A sampling of patient results from September 1, 2023 to October 16, 2023 identified the following patient result with critical values for which the laboratory did not document the notification of the critical value: a) 09/14/2023 Specimen ID: 1091423201 HCT: 24.7 4. The laboratory was asked to provide documentation of the notification of the critical value as stated in its policy. No documentation was provided. 5. During an interview with testing personnel number 1 (as listed on Form CMS 209) on 10/17/2023 at 1230 hours she stated the laboratory had stopped documenting the notifications of critical values at the end of 2022. This confirmed the findings. KEY HCT- hematocrit NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to provide overall management. The findings include: 1. The laboratory director failed to ensure a quality control plan was developed and followed (refer to D6020). 2. The laboratory director failed to ensure the laboratory's quality assurance plan could identify and correct problems (refer to D6021).
D6020	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 the quality control program is 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 policies, review of the laboratory's quality control

	records and staff interview, it was determined the laboratory director failed to ensure a quality control plan was developed and followed to ensure accurate and reliable results. The findings include: 1. The laboratory director failed to ensure control values were monitored over time to identify shifts and trends (refer to D5441). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021. 2. The laboratory director failed to ensure new lots of controls were verified prior to use (refer to D5469). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021.
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 records, and staff interview, it was revealed the laboratory director failed to ensure a quality assurance plan identified and corrected problems in analytic systems. The findings include: 1. The laboratory's quality assurance plan failed to ensure the facility performed calibrations every six months (refer to D5791-1). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021. 2. The laboratory's quality assurance plan failed to ensure the facility performed calibration verification every six months (refer to D5791 -2). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 1/25/2016, 11/15/2017, 1/29/2020 AND 12/21/2021. 3. The laboratory's quality assurance plan failed to ensure the facility monitored quality control values over time (refer to D5791-3). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021. 4. The laboratory's quality assurance plan failed to ensure the facility verified new lots of quality control material (refer to D5791-4). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 1/29/2020 AND 12/21/2021.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the technical consultant failed to provide technical oversight for the laboratory. The findings include: 1. The technical consultant failed to ensure calibrations and calibration verifications were performed as required (refer to D6036). 2. The technical consultant failed to ensure a quality control plan was established and followed (refer to D6042). 3. The technical consultant failed to identify training needs for testing personnel (refer to D6045).

D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the technical consultant failed provide technical oversight for the laboratory. The findings include: 1. The technical consultant failed to ensure the facility performed calibrations every six months (refer to D5437). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021. 2. The technical consultant failed to ensure the facility performed calibration verification every six months (refer to D5439). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 1/25/2016, 11/15/2017, 1/29/2020 AND 12/21/2021.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (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 policies, review of the laboratory's quality control records and staff interview, it was determined the technical consultant failed to ensure a quality control plan was developed and followed to ensure accurate and reliable results. The findings include: 1. The technical consultant failed to ensure control values were monitored over time to identify shifts and trends (refer to D5441). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21 /2021. 2. The technical consultant failed to ensure new lots of controls were verified prior to use (refer to D5469). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of laboratory records, manufacturer's instructions, patient reports, and confirmed in interview with laboratory personnel, the technical consultant failed to identify training needs of testing personnel. The findings include: Testing personnel were not: 1. Following the laboratory's policies (refer to D5401 and D5813). 2. Performing calibrations every six months (refer to D5437). 3. Performing Calibration

	verifications (refer to D5439). 4. Monitoring quality control values over time (refer to D5441) 5. Verifying new lots of quality control prior to use (D5469). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of training for 1 of 4 testing personnel on the Qualigen FASTPack system for TSH testing. The findings include: 1. A review of the laboratory's submitted Form CMS 209 identified 4 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training on the Qualigen FASTPack system for TSH testing for testing personnel number 4. Testing personnel number 4 had been performing TSH testing since March 2022. 3. The laboratory was asked to provide documentation of training. No documentation was provided. 4. The technical consultant confirmed the findings in an interview on 10/17/2023 at 0930 hours in the physician assistant's office.