Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D0708410	12/21/2021

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 to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the HemoCue 201 Microcuvettes, surveyor observation, and staff interview, it was revealed the laboratory failed to follow manufacturer's instructions for monitoring revised expiration dates. The findings include: 1. A review of the manufacturer's instructions for the HemoCue 201 Microcuvettes (Ref. 110706) under the section titled "Storage for microcuvettes kept in a vial" revealed: "Microcuvettes kept in an opened vial are stable for 30 days when stored in a refrigerator at 2 - 8 degrees Celsius." 2. Surveyor observation on 12/21/2021 at 1145 hours identified 1 opened vial of HemoCue 201 Microcuvettes stored open in the refrigerator. The vial did not have an opened date

	documented or a revised expiration date. 3. The laboratory was asked to provide documentation of when the vial was opened or of monitoring when the microcuvettes would expire based on manufacturer's instructions. No documentation was provided. 4. An interview with the technical consultant on 12/21/2021 at 1145 hours in the refrigerator room - after her review of the records- confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 01/29 /2020
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, and staff interview, it was revealed the laboratory failed to have documentation of all personnel participating in proficiency testing. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 6 testing personnel. 2. A review of the laboratory's American Proficiency Institute's hematology proficiency testing records from 2020 (events 1, 2 and 3) and 2021 (events 1, 2, and 3) revealed 3 testing personnel did not participate in proficiency testing for hematology. They were (based on the CMS 209): Testing personnel 4 Testing personnel 5 Testing personnel 6 3. The laboratory was asked to provide documentation of the identified testing personnel participating in hematology proficiency testing. No documentation was provided. 4. An interview with the technical consultant on 12/21/2021 at 930 hours in the office area - after her review of the records- confirmed the findings.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's chemistry proficiency testing records, and staff interview, it was revealed the laboratory failed to have documentation of testing personnel signing 3 of 6 attestation statements. The findings include: 1. A review of the laboratory's American Proficiency Institute's chemistry proficiency testing records from 2020 (events 1, 2, and 3) and 2021 (events 1, 2, and 3) revealed the laboratory failed to have documentation of testing personnel signing 3 of 6 attestation statements. Testing personnel number 1 (as listed on Form CMS 209) was the only person who performed thyroid stimulating hormone (TSH) testing on the Qualigen FastPack analyzer. The laboratory failed to have documentation of testing personnel number 1 signing the following attestation statements for TSH proficiency testing: 2020 event 3 2021 event 1 2021 event 2 2. The laboratory was asked to provide documentation of testing personnel signing the

	identified attestation statements. No documentation was provided. 3. An interview with the technical consultant on 12/21/2021 at 1150 hours in the laboratory - after her review of the records- confirmed the findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of patient test records, and staff interview, it was revealed the laboratory failed to follow manufacturer's instructions for the storage and stability of: A) Thyroid Stimulating Hormone (TSH) testing, and B) Glucose, Triglyceride, and High density lipoprotein testing. The findings include: A) Thyroid Stimulation Hormone 1. A review of the manufacturer's instruction for the Qualigen FastPack TSH Immunoassay (P/N 64000012 Rev. 008, 09 /12) under the section titled "Specimen Collection/Preparation" revealed: "If not tested within 24 hours, the sample should be frozen at -20C or colder." 2. An interview with testing personnel number 2 (as listed on Form CMS 209) on 12/21/2021 at 1330 hours in the laboratory revealed that samples for TSH testing were sometimes batched and tested more than 24 hours after collection. She stated samples were stored in the refrigerator at 2 - 8C until testing could be performed. 3. A sampling of patient test records identified the following patient samples which were tested more than 24 hours past the time of collection, but not stored as required by the manufacturer: a) sample: 08/30/61 collected: 12/14/2021 tested: 12/17/2021 b) sample: 1/23/93 collected: 12/14 /2021 tested: 12/17/2021 c) sample: 8/21/28 collected: 12/15/2021 tested: 12/17/2021 4. An interview with the technical consultant on 12/21/2021 at 1335 hours in the laboratory - after her review of the records- confirmed the findings. B) Glucose, Triglyceride, and High density lipoprotein testing 1. A review of the manufacturer's instructions for the Alfa Wassermann Ace Alera test kits for glucose, triglycerides, and high density lipoprotein revealed the manufacturer stated samples were to only be stored refrigerated at 2 - 8C. Storage at other temperatures was not evaluated by the manufacturer. 2. An interview with testing personnel number 3 (as listed on Form CMS 209) on 12/21/2021 at 1400 hours over the phone revealed samples for the identified tests were collected on Fridays and stored frozen at -20C or colder over the weekend. 3. The laboratory was asked to provide documentation of evaluating the storage of samples at a different temperature than required by the manufacturer. No documentation was provided. 4. A sampling of patient samples from 09/2021 identified the following patient samples which were not stored as required by the manufacturer prior to testing: a) sample: 1090321115 collected: 09/03/2021 tested: 09 /07/2021 b) sample: 1090321118 collected: 09/03/2021 tested: 09/07/2021 c) sample: 1090321120 collected: 09/03/2021 tested: 09/07/2021 d) sample: 109421154 collected: 09/04/2021 tested: 09/07/2021 e) sample: 1090421166 collected: 09/04 /2021 tested: 09/07/2021 f) sample: 1090421156 collected: 09/04/2021 tested: 09/07 /2021 g) sample: 1090421157 collected: 09/04/2021 tested: 09/07/2021 h) sample:

	1090421158 collected: 09/04/2021 tested: 09/07/2021 5. An interview with the technical consultant on 12/21/2021 at 1405 hours in the laboratory - after her review of the records- confirmed the findings.
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, it was determined the laboratory failed to meet the requirements for analytic systems. The findings include: 1. The laboratory failed to follow its own procedures (refer to D5401). 2. The laboratory failed to have a policy to resolve flags on CBC results (refer to D5403). 3. The laboratory failed to follow manufacturer's instructions (refer to D5411). 4. The laboratory failed to have documentation of performing required maintenance (refer to D5429). 5. The laboratory failed to have documentation of performing calibrations as required (refer to D5437). 6. The laboratory failed to have documentation of performing calibration verifications as required (refer to D5439). 7. The laboratory failed to monitor quality control results over time (refer to D5441). 8. The laboratory failed to follow its own Individual Quality Control Plan (refer to D5447). 9. The laboratory failed to have documentation of verifying new lots of control material (refer to D5469).
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 policies, review of patient test records, and staff interview, it was revealed the laboratory failed to follow it policies for repeating complete blood count (CBC) results. The findings include: 1. A review of the laboratory's policy titled "Policy for Repeating CBC Tests" (approved by the laboratory director on 10/01/2015 and posted in the laboratory above the analyzer) revealed: "In an effort to ensure accuracy in patient CBC testing, it is the policy of this laboratory to repeat tests when patient results are outside the following range: RBC Less than 4 or greater than 6 million WBC Less than 4 or greater than 20 thousand HCT Less than 30% or greater than 50% HBG Less than 10 or greater than 18 mg/% PLT Less than 150 or greater than 450 thousand" 2. A sampling of patient test results from 2020 and 2021 identified the following patient results which met the laboratory's criteria for repeat testing, however the laboratory failed to have documentation of repeat testing being performed: a) Sample 1011321272 tested: 01/13/2021 PLT: 946

	b) Sample: 2011230001 tested: 11/23/2020 RBC: 2.84 HGB: 7.2 HCT: 23.7 c) Sample: 1072021380 tested: 07/20/2021 RBC: 3.09 HGB: 5.02 HCT: 18.0 d) Sample: 1010521218 tested: 01/05/2021 RBC: 1.83 HGB: 5.3 HCT: 16.6 PLT: 73 e) Sample: 1072721523 tested: 07/27/2021 RBC: 7.20 HGB: 20.8 HCT: 63.5 PLT: 91 f) Sample: 1102621574 tested: 10/26/2021 RBC: 6.21 HGB: 19.0 HCT: 55.1 g) Sample: 1121720149 tested: 12/17/2020 RBC: 6.18 HGB: 18.5 HCT: 55.3 h) Sample: 1011321272 tested: 1/13/2021 PLT: 946 i) Sample: 2011020003 tested: 11/02/2020 RBC: 6.02 HGB: 19.3 HCT: 57.8 3. The laboratory was asked to provide documentation of repeating the tests as required by its policy. No documentation was provided. 4. An interview with the technical consultant on 12/21/2021 at 1010 hours in the office - after her review of the records - confirmed the findings. KEY RBC - red blood cell HGB - hemoglobin HCT - hematocrit
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the CELL-DYN Emerald hematology analyzer, review of the laboratory's policies, review of patient test records and staff interview, it was revealed the laboratory failed to have a policy to address flagged results. The findings include: 1. A review of the manufacturer's instructions for the CELL-DYN Emerald hematology analyzer (9140847G - November 2013) identified the following possible flags on complete blood count results with actions to take to address the flags: a) Flag: * Text box: L1 Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required. b) Flag: s Text box: L2 Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required. c) Flag: s Text box: L3 Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required. d) Flag: * Text box: L5 Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential

	results and verify the WBC count. Redraw and retest the specimen as required. e) Flag: * Text box: P1 Action: Check the background count. Refer to section 5: Operating Instructions. If the background count is within limits, perform another run on the same specimen. If the flag persists, review a stained smear to determine the cause of the interference and verify the PLT count by a different method. f) Flag: * Text box: P2 Action: Review a stained smear to determine the cause and confirm the PLT count. g) Flag: * Text box: P3 Action: Review a stained smear to determine the cause and confirm the PLT count. 2. A review of the laboratory's policies revealed the facility failed to have documentation of a policy address the review and resolution of flagged results prior to reporting the results to the provider. 3. A sampling of patient test records from January 2021 to July 2021 identified the following flagged CBC results which were reported without corrective actions taken on flagged results. They were: a) Patient: MEDAL007 test date: 07/07/2021 Flag: * Text box: L5 b) Patient: GONDI023 test date: 07/20/2021 Flag: * Text box: P2 c) Patient: AVIMA008 test date: 01/13/2021 Flag: s Text box: L3 4. The laboratory was asked to provide documentation review the flagged results or resolving them prior to reporting the results. No documentation was provided. 5. An interview with the technical consultant on 12/21/2021 at 1010 hours in the office - after her review of the records- confirmed the findings. KEY WBC- white blood cell PLT- platelet CBC - complete blood count
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 the manufacturer's instructions, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of following manufacturer's instructions for the CELL-DYN Emerald hematology analyzer. The findings include: 1. A review of the manufacturer's instructions for the CELL-DYN Emerald hematology analyzer (9140853F-August 2012) under the section titled "Calibration Guidelines" revealed: a) Calibration verification Procedure: Calibration verification is done to verify the accuracy of the calibration. It is accomplished by running the second tube of calibrator in the same manner as the first and comparing the results to the Assay Values." 2. Further review of the manufacturer's instructions for the CELL-DYN Emerald hematology analyzer (9140861E - August 2012) under the Calibration Procedure Checklist revealed: "7. Verify instrument precision by running a fresh, normal whole blood specimen ten time into the PRECISION file." 3. A review of the laboratory's CELL-DYN Emerald calibration records from November 2019 to October 2021 revealed the laboratory failed to have documentation of performing the following: a) Calibration verification for the calibration performed in October 2021 b) Precision for the calibration performed in October 2021 4. An interview with the technical consultant on 12/21 /2021 at 1130 hours in the office - after her review of the records- confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the CELL-DYN Emerald hematology analyzer, review of the laboratory's maintenance records from 2020 and 2021, and staff interview, it was revealed the laboratory failed to have documentation of performing semi-annual maintenance. The findings include: 1. A review of the manufacturer's instructions for the CELL-DYN Emerald analyzer (9140853F- August 2012) under the section titled Semi-Annual Maintenance revealed the manufacturer required the syringe pistons to be lubricated every 6 months. 2. A review of the laboratory's maintenance records from January 2020 to December 2021 revealed the laboratory failed to have documentation of lubricating the syringe pistons. 3. An interview with the technical consultant on 12/21/2/2021 at 1130 hours in the office - after her review of the records- confirmed the findings.
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 2019 to 2021, and staff interview, it was revealed 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 November 2019 to December 2021 revealed the laboratory failed to ensure calibration were performed every six months. Calibrations were performed: December 2019 April 2020 (5 months later) July 2020 (3 months later) October 2021 (16 months later) 3. The laboratory was asked to provide documentation of performing calibrations every six months as stated in its policy. No documentation was provided. 4. An interview with the technical consultant on 12/21/2021 at 1115 hours in the office - after her review of the records- confirmed the findings.
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 January 2020 to December 2021 and staff interview, it was revealed the laboratory failed to have documentation of: A) performing calibration verification for TSH on the Qualigen FASTPack system, and B) performing calibration verifications every six months for analytes on the Ace Alera. 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 records revealed the facility failed to have documentation of performing calibration verification for TSH in 2020 and 2021. 3. The laboratory was asked to provide documentation of performing calibration verification. No documentation was provided. 4. An interview with the technical consultant on 12/21/2021 at 1345 hours in the office revealed the facility did not perform calibration verification as required. This confirmed the findings. B) Ace Alera 1. A review of the laboratory's test menu identified the following 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 2020 to 2021 revealed calibration verification was performed at the following time: January 2020 July 2020 (six months later) May 2021 (ten months later) December 2021 (seven months later) 3. The laboratory was asked to provide documentation of performing calibration verification every six months as required. No documentation was provided. 4. An interview with the technical consultant on 12/21/2021 at 1510 hours in the office - after her review of the records - confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 01/29/2020
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, and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control values over time to identify shifts and trends. The findings were: 1. A review of the laboratory's quality control records from May 2019 to present revealed the laboratory utilized the following lots of quality control material for TSH (thyroid stimulating hormone) testing: 1903003-4 1910046-3 2001037-4 2007010-2 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. An interview with the technical consultant on 12/21/2021 at 1345 hours in the office revealed the facility did not monitor the values over time as required. This confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's IQCP (Individualized Quality Control Plan) for TSH (thyroid stimulating hormone) testing on the Qualigen FASTPack system, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to following its defined frequency for quality control testing. The findings include: 1. A review of the laboratory's IQCP for Qualigen FASTpack TSH quality control (approved by the laboratory director on 05/01/2017) revealed the laboratory's defined frequency for quality control testing was opening of each kit, weekly and each new lot. 2. A review of TSH quality control testing from June 2021 to August 2021 identified quality control was tested on the following days: June 1, 2021 June 16, 2021 (15 days later) July 1, 2021 (16 days later) July 13, 2021 (12 days later) July 28, 2021 (15 days later) August 12, 2021 (15 days later) 3. A review of patient test records from June 2021 to August 2021 identified the following patients whose samples were tested when the time between quality control testing exceeded 1 week: a) June 24 - 30, 2021 Patient IDs 1062421143 1062821155 1062821153

	1062521148 1062521161 1062521160 1062521162 1062521163 1062521157 1063021165 b) July 21 - 27, 2021 Patient IDs 1072121403 1072121408 1072121409 1072121400 1072221422 1072221424 1072221425 1072321449 1072621504 1072621498 1072621499 1072621500 1072321445 1072721516 1072721528 1072721519 1072721525 c) August 5 - 12, 2021 Patient IDs 1080521840 1080521845 1080521836 1080521834 1080521830 1080521846 1080521839 1080621894 1080621892 1080621871 1080621872 1080621867 1081021054 1081221137 1081221135 4. An interview with the technical consultant on 12/21/2021 at 1434 hours in the office - after her review of the records- confirmed the findings.
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 and staff interview, it was determined that the laboratory failed to have documentation of following its policy to verify new lots of quality control material prior to use. The findings include: 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 2020 and 2021 identified the following lots of quality control material which were not tested according to the laboratory's policy: a) Lot 9350 started: March 2020 tested over 3 days b) Lot 0069 started: June 2020 tested over 3 days c) Lot 0237 started August 2020 not tested d) Lot 0321 started December 2020 not tested e) Lot 1207 started August 2021 tested over 2 days f) Lot 1291 started November 2021 tested over 3 days 3. A review of the laboratory's quality control records for chemistry testing performed on the Ace Alera chemistry analyzer from 2021 revealed the following lot of quality control material which was not verified prior to use: a) Lot: 1501UNCM started June 2021 4. A review of the laboratory's quality control records for TSH (thyroid stimulating hormone) testing performed on the Qualigen FASTPack revealed the following lots of quality control material which were not verified prior to use: a) Lot 1903003-4 b) Lot 1910046-3 c) Lot 2001037-4 d) Lot 2007010-2 5. The laboratory was asked to provide documentation of verifying the identified lots as stated in its policy. No documentation was provided. 6. An interview with the technical consultant on 12/21/2021 at 1434 hours in the office -

	after her review of the records- confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 01/29/2020.
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, and staff interview, it was revealed the laboratory failed to have documentation of documenting the notification of critical values. The findings were: 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 November 2020 to October 2021 identified the following patient results with critical values for which the laboratory did not have documentation of the reporting of the critical values: a) 11/02/2020 lab no: 2011020003 HGB: 19.3 HCT: 57.8 b) 11/23/2020 lab no. 2011230001 HGB: 7.2 HCT: 23.7 c) 12/17/2020 patient ID: RUIJO008 HGB: 18.5 HCT: 55.3 d) 01/05/2021 patient ID: GRAVI000 HGB: 5.3 HCT: 16.6 e) 01/13/2021 patient ID: AVIMA008 Platelet: 946 f) 07/20/2021 patient ID: GONDI023 HGB: 5.2 HCT: 18.0 g) 07/27/2021 patient ID: URIDA001 HGB: 20.8 HCT: 63.5 h) 10/26/2021 patient ID: GARRO070 HGB: 19.0 HCT: 55.1 4. The laboratory was asked to provide documentation of the notification of the critical values as stated in its policy. No documentation was provided. 5. An interview with the technical consultant on 12/21/2021 at 1500 hours in the laboratory - after her review of the records- confirmed the findings. KEY WBC - white blood cell HGB - hemoglobin HCT- hematocrit
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 (refer to D5441, D5447 and D5469).

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 Quality Assurance Plan, review of the laboratory's quality assurance records, and staff interview, it was revealed the laboratory director failed to ensure the laboratory's Quality Assurance Plan was followed. The findings include: 1. A review of the laboratory's Quality Assurance Plan (approved by the laboratory director on 10/01/2015) under the section titled "Quality Assurance Records" revealed: "The record of our Quality Assurance reviews are filed with this plan and are available for review by the Director, Consultant, staff, and Laboratory Surveyors. All records are dated and initialed by the staff performing the review, by the Technical Consultant, and by the Laboratory Director." 2. A review of the laboratory's quality assurance records from December 2019 to October 2021 revealed the laboratory failed to have documentation of the laboratory director initial and dating 23 of 23 monthly quality assurance reports. 3. The laboratory was asked to provide documentation of the laboratory director initialing and dating the 23 reports. No documentation was provided. 4. An interview with the technical consultant on 12 /21/2021 at 1525 hours in the office - after her review of the records- confirmed the findings.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of laboratory records, manufacturer's instructions, patient reports, and confirmed in interview of laboratory personnel, the laboratory director failed to identify training needs of testing personnel. The findings include: Testing personnel were not: 1. Following the laboratory's policies (refer to D5401, D5437). 2. Resolving flags on complete blood count. (refer to D5403). 3. Following manufacturer's instructions (refer to D5411, D5429). 4. Performing Calibration verifications (refer to D5439). 5. Following the laboratory's quality control plans (refer to D5447 and D5469).

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 (refer to D5441, D5447 and D5469).
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 of 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, D5437, and D5813). 2. Resolving flags on complete blood count. (refer to D5403). 3. Following manufacturer's instructions (refer to D5411, D5429). 4. Performing Calibration verifications (refer to D5439). 5. Following the laboratory's quality control plans (refer to D5447 and D5469).
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory records, manufacturer's instructions, patient reports, and confirmed in interview, testing personnel failed to follow the laboratory's policies. The findings include: Testing personnel were not: 1. Following the laboratory's policies (refer to D5401, D5437). 2. Resolving flags on complete blood count. (refer to D5403). 3. Following manufacturer's instructions (refer to D5411, D5429). 4. Performing Calibration verifications (refer to D5439). 5. Following the laboratory's quality control plans (refer to D5447 and D5469). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 01/29/2020

D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control policies, and staff interview, it was revealed the testing personnel failed to follow the laboratory's quality control policies. The findings include: 1. Testing personnel failed to follow the laboratory's policy for its Individual Quality Control Plan (refer to D5447). 2. Testing personnel failed to follow the laboratory's policy for verifying new lots of control material (refer to D5469).