Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0708410	**(X3) Date Survey Completed** 01/29/2020
Name of Provider or Supplier Mcallen Primary Care Clinic Inc	**Street Address, City, State** 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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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 surveyor observation, review of manufacturer's instructions, review of laboratory patient test logs, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for monitoring revised expiration dates for HemoCue Glucose 201 Microcuvettes. The findings were: 1. Surveyor observation on January 29, 2020 at 08:45 hours during the initial tour of the laboratory revealed 1 opened vial of HemoCue Glucose 201 Microcuvettes (Lot 1903715, expiration date: 02-04-2020) was stored at 2-8 degrees Celsius with no revised expiration date. The container was located in the refrigerator in the storage room. There were 20 microcuvettes out of 25 left in the vial. 2. Review of the

	manufacturer's instructions for the HemoCue Glucose 201 Microcuvettes (Ref. 110706) under, "Storage for microcuvettes kept in a vial" it stated, "..... Microcuvettes kept in an opened vial are stable for 30 days when stored in a refrigerator at 2-8 degrees Celsius." 3. Review of patient test logs from December 27, 2019 to January 26, 2020 revealed the last five (5) patients tested were as follows: Lab No. Date tested 1912270012 12/27/19 22:01 1912290040 12/29/19 22:42 2001090007 01/09/2020 15:18 2001230004 01/23/2020 10:53 2001260005 01/26/2020 17:24 The patient samples were tested when the revised expiration date of the microcuvettes could not be determined. 4. Interview with the technical consultant on January 29, 2020 at 08:45 hours in the laboratory confirmed the findings.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policies, verification records and confirmed in interview of facility personnel, the laboratory failed to retain the instrument verification records for the Alfa Wasserman ACE Alera analyzer for the life of the instrument plus two years. The findings were: 1. Surveyor observation on January 29, 2020 in the laboratory revealed the laboratory utilizes a Alfa Waserman ACE Alera chemistry analyzer to perform chemistry testing. According to the CMS-116, the laboratory performs 45,360 chemistry tests annually. 2. Review of the laboratory's policy titled, "Validation of a New Test System" approved by the laboratory director on October 1,2015, it stated, "Documentation: All Related forms, printouts, control inserts, and reports will be maintained for the life of the system plus 2 years." 3. On January 29, 2020 at 13:45 hours, the laboratory was asked to provide the verification records for the Alfa Wasserman ACE Alera analyzer. The laboratory was unable to locate the records. 4. The above findings were confirmed in interview of the technical consultant on January 29, 2020 at 14:00 hours in the conference room. Key: CMS - Centers for Medicare and Medicaid Services
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 laboratory policies, surveyor observation of samples in the laboratory, and confirmed in staff interview, it was revealed the laboratory failed to follow its policy to ensure samples are labeled with unique identifiers. The findings were: 1. The laboratory's policy "Specimen Identification" approved by the laboratory director October 1, 2015 stated: "Each specimen must have unique patient identifiers

	such as patient name, birth date, social security number, or other identifying number. The identifiers should be used throughout the testing process, so that results can be confidently used in patient care. This can be done by placing an identification label on each specimen when it is collected and by labeling all related materials (test tubes, slides, etc.) with the same identification information." 2. A surveyor observation of a patient urine samples located in the sink in the laboratory on 01/29/2020 at 17:02 hours revealed 1 of 11 patient samples with no information on the container. 3. An interview with the testing personnel #2 (as listed on Form CMS-209) on 01/29/2020 at 17:02 hours in the laboratory confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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, manufacturer instructions and confirmed in interview with facility personnel, the laboratory failed to document revised expiration dates on multiple reagents used by the laboratory. The findings were: 1. A surveyor observation made on 01/29/2020 at 08:45 hours in the refrigerator room revealed the following six opened reagents. The reagents were available for patient testing. The reagents were not labeled with revised expiration dates. a. Alfa Wasserman Level 1 Chemistry control Lot 123uncm expiration date 2021-05-31 open 7/13/18 (no revised expiration date) b. Alfa Wasserman Level 2 Chemistry control Lot 937uncm expiration date 2021-05-31 open 7/13/18 (no revised expiration date) c. Alfa Wasserman Gemcal reference serum Lot 928uncm expiration date 2021-05-31 open 7 /13/18 (no revised expiration date) d. Alfa Wasserman ACE Carbon Dioxide Lot 18110673 expiration date 2020-11-30 no open date or revised open date e. Alfa Wasserman ACE Alkaline Phosphatase Lot RX2002 expiration date 2021-05-31 no open date or revised open date f. Alfa Wasserman ISE Cleaning Solution Lot SA1028 no open date or revised open date 2. A review of manufacturer's instructions for the six (6) observed quality control materials and reagents stated revised expiration dates were as follows: a. Alpha Wasserman Level 1 Chemistry control "Analytes reconstituted at 2-8 degrees Celsius" ALP stable for 3 days ALT and AST 5 days all other analytes stable for 7 days. The laboratory documented opening the reagent on 7 /13/18. Therefore, the reagent was expired for 544 days. b. Alpha Wasserman Level 2 Chemistry control "Analytes reconstituted at 2-8 degrees Celsius" ALP stable for 3 days ALT and AST 5 days all other analytes stable for 7 days. The laboratory documented opening the reagent on 7/13/18. Therefore, the reagent was expired for 544 days. c. Alpha Wasserman Gemcal Reference Serum "Analytes reconstituted at 2-8 degrees Celsius" Total and direct bilirubin stable for 2 days Triglycerides stable for 4 days all other analytes stable for 5 days. The laboratory documented opening the reagent on 7/13/18. Therefore, the reagent was expired for 542 days. d. Alfa Wasserman ACE Carbon Dioxide Lot 18110673 expiration date 2020-11-30 Once opened, the reagent is stable for 14 days when stored on system (10-14 degrees Celsius). The laboratory did not document the open date. Therefore, the reagent's revised expiration date could not be determined. e. Alfa Wasserman ACE Alkaline Phosphatase Lot RX2002 expiration date 2021-05-31 no open date or revised open date Once opened, the reagent is stable for 7 days when stored on system (10-14

	degrees Celsius). The laboratory did not document the open date. Therefore, the reagent's revised expiration date could not be determined. f. Alfa Wasserman ISE Cleaning Solution " ...Discard after 30 days." The laboratory did not document the open date. Therefore, the reagent's revised expiration date could not be determined. 3. A review of patient records from January 3,2020 to January 29, 2020 found the following random sampling of patients that were tested using expired Control Level 1, Control Level 2 and Gemcal Reference Serum. (See Chemistry Patient Alias List) 4. In an interview with the technical consultant (listed on Form CMS-209) on January 29, 2020 at 10:45 hours, she confirmed the reagents were not labeled with the revised expiration date. Key ALP - Alkaline Phosphatase ALT - Alanine Aminotransferase AST - Aspartate Aminotransferase TP - Testing person
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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: Based on review of the laboratory's instrument verification records for the Abbott Cell-Dyn hematology analyzer review of patient final reports, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to perform complete verification studies prior to patient testing. The findings were: 1. Review of the laboratory's instrument verification records for the Abbott Cell-Dyn hematology analyzer (Serial number 030817-007307 March 2019), revealed the instrument was not approved for use in patient testing by the laboratory director. 2. A random review of patient final reports revealed the laboratory identified two normal patient ranges for CBCs (complete blood count): Normal Range 1 (Male) WBC 4.6 - 10.2 RBC 4.69 - 6.13 HGB 14.1 - 18.1 HCT 43.5 - 53.7 MCV 80.0 - 97.0 MCH 27.0 - 31.2 MCHC 31.8 - 35.4 RDW-SD 37.0 - 54.0 PLT 142 - 424 MPV 7.4 - 10.4 LYMABS # 0.6 - 3.4 LYMD % 10.0 - 50.0 MID # 0.0 - 0.9 MID % 0.0 - 12.0 GRAN# 2.0 - 6.9 GRAN % 37.0 - 80.0 Normal Range 2 (Female) WBC 4.6 - 10.2 RBC 4.04 - 5.48 HGB 12.2 - 16.2 HCT 37.7 - 47.9 MCV 80.0 - 97.0 MCH 27.0 - 31.2 MCHC 31.8 - 35.4 RDW-SD 37.0 - 54.0 PLT 142 - 424 MPV 7.4 - 10.4 LYMABS # 0.6 - 3.4 LYMD % 10.0 - 50.0 MID # 0.0 - 0.9 MID % 0.0 - 12.0 GRAN# 2.0 - 6.9 GRAN % 37.0 - 80.0 3.A review of the manufacturer's instructions for the Cell- Dyn Emerald analyzer titled "Performance Characteristics and Specifications" under "Reference Intervals" it stated "These ranges do not represent globally applicable reference intervals but reflect combined reference ranges tested in the validation study. Each laboratory should establish/verify its own reference intervals. Measurand Sex Range WBC M/F 4.70 -10.3 RBC M/F 4.03 - 5.46 HGB M/F 12.4 - 16.9 HCT M/F 36.6 - 48.3 MCV M/F 81.5 - 96.8 MCH M/F 27.5 - 33.1 MCHC M/F 32.4 - 35.7 RDW (%) M/F 11.8 - 14.9 PLT M/F 165 - 385 MPV M/F 7.2 - 10.2 LYM % M/F 12.7 - 47.8 MID % M/F 6.3 - 14.0 GRA % M/F 43.5 - 78.9 3. The laboratory's normal patient ranges for male and female did not match the manufacturer's ranges. Therefore, the laboratory had not verified the manufacturer's ranges. 4. The laboratory was asked to provide documentation of verifying its patient normal ranges. No

	documentation was provided. 5. An interview with the Testing person #1 (as listed on Form CMS-209) on 01/29/2020 at 13:15 hours in the laboratory failed perform complete verification studies prior to patient testing. The laboratory only used the range for male patients. Key WBC - White Blood Cell RBC - Red Blood Cell HGB - Hemoglobin HCT - Hematocrit MCV - Mean Corpuscular Volume MCH - Mean Corpuscular Hemoglobin MCHC- Mean Corpuscular Hemoglobin concentration RDW - Red Cell Distribution Width PLT - Platelet MPV - Mean platelet volume LYM % - Lymphocyte percentage MID % - Combined value of the other types of white blood cells not classified GRA % - Granulocyte percentage M - Male F- Female CMS - Centers for Medicare and Medicaid Services
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 calibration verification records from 2018 and 2019, review of manufacturer's instructions, and staff interview, it was revealed the laboratory failed to have documentation of performing the calibration verification for the Alpha Wasserman Ace Alera instrument. The findings were: 1.A review of the laboratory's calibration verification records from 2018 and 2019 revealed the laboratory failed to have documentation of performing calibration verification for the Alpha Wasserman Ace Alera instrument every six months as required. The analytes tested are as follows: Glucose BUN Creatinine Albumin Sodium Potassium Chloride ALT (SGPT) AST (SGOT) ALK PHOS BILI Calcium Cholesterol Total Protein Triglyceride 2. Review of manufacturer's instructions for the Alpha Wasserman Ace Alera, revealed calibrations were performed utilizing the one-point calibrator Gemcal Reference Serum. In addition, the laboratory performed quality control testing utilizing 2 control levels (Level 1 and Level 2) every 24 hours of patient testing. Therefore, calibration verification procedures are required at least every six months. 3. The laboratory was asked to provide documentation of performing calibration for the Alpha Wasserman Ace Alera instrument for 2018 and 2019. No documentation was provided. 4. An interview with the technical consultant on January 29, 2020 at 14:45

	hours in the office confirmed the findings. She reviewed and verified that calibrations were not performed every 6 months.
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: The findings were: 1. Review of laboratory policy titled "Quantitative CBC control Verification Policy"(approved and signed by the laboratory director (10/01/15) under Policy: " It is the policy of this lab to validate quantitative controls prior to replacing them into use for patient testing" it states "New controls shall be run once a day for 5 days along with current controls. If current controls are within range and new controls are within their range, then new controls will be acceptable for use for patient testing." 2. A review of the laboratory's quality control records from May 2019 to January 2020 revealed the laboratory performed quality control testing utilizing 3 different lots of control material. Lot 9182 expiration 2019-10-18 Lot 9266 expiration 2020-01-10 Lot 9350 expiration 2020-04-03 3. A review of the laboratory's quality control records from May 2019 to January 2020 revealed the laboratory failed to have documentation verifying 3 of 3 lots. The lots without documentation of verification were: Lot 9182 expiration 2019-10-18 Lot 9266 expiration 2020-01-10 Lot 9350 expiration 2020-04-03 4. The laboratory did not perform overlap lot studies with the controls prior to patient testing. 5. An interview with the technical consultant on 01/29/2020 at 1300 hours in the office revealed the laboratory did not verify new lots of controls prior to use. She stated new lots were put into use without assessing if they were working properly.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

	This STANDARD is not met as evidenced by: Based on surveyor observations, laboratory policies, instrument records, patient records, manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory director failed to ensure test system provide quality laboratory services (refer to D5311 and D5403)
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the laboratory's verification records and staff interview, it was revealed that the laboratory director failed approve and ensure complete verification studies were complete and approved prior to performing patient testing (refer to D5421).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on a review of the laboratory's verification records and staff interview, it was revealed the technical consultant failed to ensure verification studies of the Cell- Dyn hematology analyzer were complete for normal patient ranges prior to patient testing. (refer to D5421).
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 policies and procedures, quality control records, patient test records, surveyor observation, and confirmed in interview, testing personnel failed to follow the laboratory's procedures for storing, testing and maintaing records. Refer to (D5311, D5403, D5417, D5469.)