Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0708410	01/29/2019
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	Intakes: TX00299620 Complaint TX00299620 was substantiated. The laboratory was surveyed on January 29, 2019 in response to complaint TX00299620 for compliance with CMS 42 CFR Inspection requirements applicable to all CLIA certified and CLIA-exempt laboratories. The laboratory was found to be out of compliance at: D5200 - 42 C.F.R. 493.1230 Condition: General laboratory systems; D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
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 Uriscan Urine strips. The findings were: 1. Surveyor observation on January 29, 2019 at 0815 during the initial tour of the laboratory revealed 1 vial of Uriscan Urine strips (lot number 38728, expiration date: 9-30-19) was not closed. The container was located on the countertop by the sink and the lid was not screwed on properly and left loosely on top of the container. 2. Review of the manufacturer's instructions for the Uriscan Urine strips (Rev. 12/2016-12-15) under, "Handling Procedure" it stated, " ...After removing a test strip, immediately replace the cap completely." 3. Review of patient test logs from

	January 29, 2019 revealed that no patients had been tested for the day. It could not be determined how long the vial of Uriscan Urine strips had been left open. 4. Interview with the technical consultant at 10:30 hours in the laboratory confirmed the findings.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observation and confirmed in interview of facility personnel, the laboratory failed to meet general laboratory systems requirements (refer to D5201).
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on surveyor observations, and confirmed in interview of facility personnel, the laboratory failed to ensure patient confidentiality was protected throughout all phases of the testing process. The findings were: 1. Surveyor observations made at 09:00 hours and 10:30 hours on January 29, 2019 revealed facility personnel escort patients and visitors through a room that contained patient medical records. The room provided a walkway to get from one side of the clinic to the other. Patient information such as name and date of birth were visible on the outside of the patient's charts. 2. An interview with the nursing administrator on 01/29/2019 at 15:00 hours in the office confirmed the findings. She stated that the records could be sent to storage because those records were for urgent care patients that had electronic medical records.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor observations, review of manufacturer's instructions, review of patient records, and confirmed in interview of facility personnel, the laboratory failed to provide overall quality in its pre-analytic systems as evidenced by: 1. The

	laboratory failed to follow manufacturer's instructions for proper storage of specimens prior to testing. (refer to D5311-I) 2. The laboratory failed to follow its own specimen labeling policy. (refer to D5311-II)
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: I. Based on surveyor observations, review of laboratory policy, review of manufacturer's instructions, review of laboratory environmental records, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to follow manufacturer's instructions for preanalytic specimen handling requirements. NOTE: As of the date of the survey, January 29, 2019, the laboratory was not performing in-house patient testing for Comprehensive Metabolic Panel or Lipid Profile. The laboratory has sent out tests for Comprehensive Metabolic Panel and Lipid Profile since October 8, 2018. The laboratory was performing patient correlations. The findings were: 1. Surveyor observation on January 29, 2019 at 09:00 hours in the room where the laboratory refrigerator was located revealed patient samples were stored in the refrigerator. The refrigerator contained samples that had been previously tested and patient samples that were pending testing. 2. Review of the laboratory's policy titled, "Procedures for Specimen Submission and Handling" approved by the laboratory director on October 1, 2015 stated, "This laboratory will have written policies and procedures for methods used for the preparation of patients, specimen collection, specimen preservation and conditions for transportation ..." The laboratory's policy did not indicate preanalytic specimen storage requirements as required by the manufacturer. 3. Review of the manufacturer's instructions for Alfa Wasserman chemistry analyzer under, "Specimen Collection, Storage and Handling" stated: ALT (P/N 909060-3 Rev-C 9/17) "Specimen stable for 7 days at 4-8 degrees Celsius and -20 degrees Celsius." Direct Bilirubin (P/N 909060-13 Rev C 9/17) "Specimen stable for 7 months at 4-8 degrees Celsius or 6 months at -20 degrees Celsius." Total Bilirubin (P/N 909060-25 Rev C 9/17) "Specimen stable for 7 days at 4-8 degrees Celsius and for 6 months at -20 degrees Celsius." Calcium-Arsenazo (P/N 909060-7 Rev C 9/17) "Specimen stable for 3 weeks at 4-8 degrees Celsius and for 8 months at -20 degrees Celsius." Albumin (P/N 909060-1 Rev C 9/17) "Specimen stable at 4 degrees Celsius for up to 72 hours and frozen at -20 degrees Celsius for 6 months or indefinitely at -70 Celsius." Total Protein (P/N 909060-28 Rev C 11/15 "Specimen stable at 4 degrees Celsius for up to 72 hours and frozen at -20 degrees Celsius for 6 months or indefinitely at -70 degrees Celsius." Creatinine (P/N 909060-12 Rev E 9/17 "Specimen stable for 7 days when refrigerated (4-8 degrees Celsius) and for 3 months when frozen at -20 degrees Celsius." Total Protein (P/N 909060-28 Rev C 11/15 "Specimen stable at 4 degrees Celsius for up to 72 hours and frozen at -20 degrees Celsius for 6 months or indefinitely at -70 degrees Celsius." Alkaline Phosphatase (P/N 909060-2 Rev C 1/18 "Specimens stable for 7 days at 4-8 degrees Celsius and 2 months at -20 degrees Celsius." Cholesterol (P/N 909060 Rev C 11/17) "Specimen stable for 7 days at 4-8 degrees Celsius and 3 months at -20 degrees

Celsius." Triglycerides (P/N 909060-29 Rev B 9/13 "Specimen stable for 4-7 days at 4 degrees Celsius." BUN/UREA (P/N 909060-6 Rev D 9/17 "Specimen stable at 7 days refrigerated (4-8 degrees Celsius) or frozen at -20 degrees for 1 year. HDL-C (P /N 909060-18 Rev D 9/17 "Specimen stable when stored in the refrigerator at 4 degrees Celsius for 1 to 7 days Avoid repeated freezing and thawing." Glucose (P/N 909060-16 Rev E 12/17 "Specimen stable for 8 hours a 25 degrees Celsius, 72 hours at 4 degrees Celsius." ALT (P/N 909060-3 Rev C 9/17 "Specimen stable for 7 days at 4-8 degrees Celsius and -20 degrees Celsius." Carbon Dioxide (P/N 909060-11 Rev C 9/17 "Specimen stable for 7 days at 4-8 degrees Celsius and for 2 weeks at -20 degrees Celsius." AST (P/N 909060-5 Rev C 9/17 "Specimen activity is stable for 28 days at 4 degrees Celsius and at least one year at -20 degrees Celsius." 4. Review of the laboratory's refrigeration logs from July, August, and September 2018 revealed the laboratory documented temperature readings below the manufacturer's acceptable storage range for 65 out of 65 dates reviewed as follows: July 2, 2018 2.9 degrees Celsius July 3, 2018 3.0 degrees Celsius July 4, 2018 3.2 degrees Celsius July 5, 2018 3.0 degrees Celsius July 6, 2018 2.9 degrees Celsius July 9, 2018 3.3 degrees Celsius July 10, 2018 3.1 degrees Celsius July 11, 2018 2.9 degrees Celsius July 12, 2018 3.1 degrees Celsius July 13, 2018 3.3 degrees Celsius July 16, 2018 3.1 degrees Celsius July 17, 2018 2.8 degrees Celsius July 18, 2018 3.1 degrees Celsius July 19, 2018 3.3 degrees Celsius July 20, 2018 3.4 degrees Celsius Jully 23, 2018 3.3 degrees Celsius July 24, 2018 3.1 degrees Celsius Jully 25, 2018 2.9 degrees Celsius July 26, 2018 3.1 degrees Celsius July 27, 2018 3.3 degrees Celsius July 30, 2018 2.9 degrees Celsius July 31, 2018 3.0 degrees Celsius August 1, 2018 3.7 degrees Celsius August 2, 2018 3.1 degrees Celsius August 3, 2018 2.9 degrees Celsius August 6, 2018 3.1 degrees Celsius August 7, 2018 3.3 degrees Celsius August 8, 2018 2.9 degrees Celsius August 9, 2018 3.1 degrees Celsius August 10, 2018 3.4 degrees Celsius August 13, 2018 2.8 degrees Celsius August 14, 2018 2.9 degrees Celsius August 15, 2018 3.1 degrees Celsius August 16, 2018 3.3 degrees Celsius August 17, 2018 3.4 degrees Celsius August 20, 2018 3.3 degrees Celsius August 21, 2018 3.1 degrees Celsius August 22, 2018 2.9 degrees Celsius August 23, 2018 3.1 degrees Celsius August 24, 2018 3.3 degrees Celsius August 27, 2018 2.9 degrees Celsius August 28, 2018 3.0 degrees Celsius August 29, 2018 3.2 degrees Celsius August 30, 2018 3.0 degrees Celsius August 31, 2018 2.9 degrees Celsius September 3, 2018 3.0 degrees Celsius September 4, 2018 2.9 degrees Celsius September 5, 2018 3.2 degrees Celsius September 6, 2018 3.0 degrees Celsius September 7, 2018 2.9 degrees Celsius September 10, 2018 3.3 degrees Celsius September 11, 2018 3.1 degrees Celsius September 12, 2018 2.9 degrees Celsius September 13, 2018 3.1 degrees Celsius September 14, 2018 3.3 degrees Celsius September 17, 2018 2.8 degrees Celsius September 18, 2018 2.9 degrees Celsius September 19, 2018 3.1 degrees Celsius September 20, 2018 3.3 degrees Celsius September 21, 2018 3.4 degrees Celsius September 24, 2018 3.1 degrees Celsius September 25, 2018 3.2 degrees Celsius September 26, 2018 3.1 degrees Celsius September 27, 2018 3.4 degrees Celsius September 28, 2018 2.9 degrees Celsius 5. A random review of patient results from the July, August, and September testing dates revealed the following patient samples were performed when patient samples were not stored according to the manufacturer's instructions (see patient alias list). 6. An interview with the technical consultant on January 29, 2019 at 11:00 hours in the laboratory confirmed the findings. She stated that the facility was preparing to start patient testing again and as part of that process they were reviewing the manufacturer's specimen stability requirements. II. Based on surveyor observations, review of laboratory policy, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy for specimen labeling. The findings were: 1. Surveyor observation on January 29, 2019 at 13:30 hours revealed a patient bring their urine specimen to the laboratory and then leave the area.

	The sample was labeled with the patient's first and last name. The patient's urine sample was placed in the sink with 6 other patient specimens. If the facility had a patient with the same name, the patient's sample could not be uniquely identified. 2. Review of the laboratory's policy titled, "Specimen Identification" approved by the laboratory director on October 1, 2015, it stated, "Each specimen must have unique identifiers such as patient name, birth date, social security number or other identifying number ...patient's name, secondary ID, time and date of collection, initials of specimen collector." 3. An interview with testing person one (as listed on Form CMS-209) on January 29, 2019 at 13:35 hours confirmed the findings. She revealed that sometimes she would label the sample with the sticker that had two identifiers on it but sometimes she would run it as is. She had the specimen recollected. Key: AST - aspartate aminotransferase HDL - high density lipoprotein ALT - alanine aminotransferase BUN/UREA - blood urea nitrogen Rev - revision P/N - part number CMS - Centers for Medicare and Medicaid Services
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 surveyor observation, review of manufacturer's instructions, review of laboratory environmental records, and confirmed in interview of facility personnel, the laboratory failed to define an acceptable temperature range for the storage of patient samples when stored refrigerated. The findings were: 1. Surveyor observation on January 29, 2019 at 08:15 hours during an initial tour of the laboratory revealed the temperature reading for the laboratory refrigerator where patient samples were stored was 1.0 degrees Celsius. 2. Review of the manufacturer's instructions for Alfa Wasserman chemistry analyzer under, "Specimen Collection, Storage and Handling" stated: ALT (P/N 909060-3 Rev-C 9/17) "Specimen stable for 7 days at 4-8 degrees Celsius and -20 degrees Celsius." Direct Bilirubin (P/N 909060-13 Rev C 9/17) "Specimen stable for 7 months at 4-8 degrees Celsius or 6 months at -20 degrees Celsius." Total Bilirubin (P/N 909060-25 Rev C 9/17) "Specimen stable for 7 days at 4-8 degrees Celsius and for 6 months at -20 degrees Celsius." Calcium-Arsenazo (P/N 909060-7 Rev C 9/17) "Specimen stable for 3 weeks at 4-8 degrees Celsius and for 8 months at -20 degrees Celsius." Albumin (P/N 909060-1 Rev C 9/17) "Specimen stable at 4 degrees Celsius for up to 72 hours and frozen at -20 degrees Celsius for 6 months or indefinitely at -70 Celsius." Total Protein (P/N 909060-28 Rev C 11/15 "Specimen stable at 4 degrees Celsius for up to 72 hours and frozen at -20 degrees Celsius for 6 months or indefinitely at -70 degrees Celsius." Creatinine (P/N 909060-12 Rev E 9/17 "Specimen stable for 7 days when refrigerated (4-8 degrees Celsius) and for 3 months when frozen at -20 degrees Celsius." Total Protein (P/N 909060-28 Rev C 11/15 "Specimen stable at 4 degrees Celsius for up to 72 hours and frozen at -20 degrees Celsius for 6 months or indefinitely at -70 degrees Celsius." Alkaline Phosphatase (P/N 909060-2 Rev C 1/18 "Specimens stable for 7 days at 4-8 degrees Celsius and 2 months at -20 degrees Celsius." Cholesterol (P/N 909060 Rev C 11/17)

	"Specimen stable for 7 days at 4-8 degrees Celsius and 3 months at -20 degrees Celsius." Triglycerides (P/N 909060-29 Rev B 9/13 "Specimen stable for 4-7 days at 4 degrees Celsius." BUN/UREA (P/N 909060-6 Rev D 9/17 "Specimen stable at 7 days refrigerated (4-8 degrees Celsius) or frozen at -20 degrees for 1 year. HDL-C (P /N 909060-18 Rev D 9/17 "Specimen stable when stored in the refrigerator at 4 degrees Celsius for 1 to 7 days Avoid repeated freezing and thawing." Glucose (P/N 909060-16 Rev E 12/17 "Specimen stable for 8 hours a 25 degrees Celsius, 72 hours at 4 degrees Celsius." ALT (P/N 909060-3 Rev C 9/17 "Specimen stable for 7 days at 4-8 degrees Celsius and -20 degrees Celsius." Carbon Dioxide (P/N 909060-11 Rev C 9/17 "Specimen stable for 7 days at 4-8 degrees Celsius and for 2 weeks at -20 degrees Celsius." AST (P/N 909060-5 Rev C 9/17 "Specimen activity is stable for 28 days at 4 degrees Celsius and at least one year at -20 degrees Celsius." 3. Review of laboratory refrigeration records from July, August, September 2018 and January 2019 revealed the laboratory had defined its acceptable refrigerator range as "2-8 Celsius." 4. The laboratory failed to define an acceptable refrigeration range according to the manufacturer's instructions. 5. Review of patient results from July, August, and September 2018 revealed the following patients were tested when the laboratory had stored specimens outside the manufacturer's acceptable refrigeration range (see patient alias list). 6. An interview with the technical consultant on January 29, 2019 at 11:00 hours in the laboratory confirmed the findings. Key: AST - aspartate aminotransferase HDL - high density lipoprotein ALT - alanine aminotransferase BUN/UREA - blood urea nitrogen Rev - revision P/N - part number
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observations and confirmed in interview of facility personnel, the laboratory failed to ensure reagents were labeled with identification, concentration, storage, and dates. The findings were: 1. Surveyor observation January 29, 2019 at 08: 15 hours during an initial tour of the facility revealed a clear container with a green lid sitting on top of the Sysmex hematology analyzer. The contents were clear. The container was not labeled with any identifying information on it. 2. The laboratory failed to ensure reagents were properly labeled with identifying information as to concentration, storage requirements, and dates. 3. An interview with the technical consultant at 10:30 hours in the laboratory confirmed the findings.
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 surveyor observations, review of laboratory policy, review of manufacturer's instructions, review of environmental records, review of patient results, and confirmed in interview of facility personnel, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6007 and D6011)
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, review of laboratory policy, review of manufacturer's instructions, review of environmental records, review of patient results, and confirmed in interview of facility personnel, the laboratory director failed to ensure the laboratory followed manufacturer's instructions for preanalytic specimen handling. (refer to D5311)
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on surveyor observations, review of laboratory policy, and confirmed in interview of facility personnel, the laboratory director failed to provide a physically safe environment for laboratory personnel. The findings were: 1. Surveyor observation made on January 29, 2019 at 08:15 hours in the laboratory during the initial tour of the laboratory revealed the phlebotomy chair was located in the laboratory entrance. 2. The surveyor observed facility personnel (laboratory testing persons and non-testing persons) turn sideways to enter or leave the laboratory if a patient blood collection was being performed. Further, the surveyor observed patients in the laboratory for phlebotomy draws throughout the survey process. 3. Review of the laboratory's policy titled, "Laboratory Safety" approved by the laboratory director on October 1, 2015, stated, "Only staff members who work in the lab should be allowed in the lab. Patients should not be allowed in the lab." The laboratory did not follow its own policy to ensure patients were not allowed in the laboratory. 4. The above findings were confirmed in interview of the Nursing Administrator on January 29, 2019 at 15:00 hours. When asked if there was documentation or occasions of employee exposures in the laboratory, she stated, "Yes."