Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0708410	01/20/2026
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 McAllen Primary Care Clinic INC laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a recertification survey on 1/20/2026 and recertification is recommended. Standard level deficiencies were cited.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of laboratory's policies, the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, test records, and staff interview, the laboratory failed to have documentation of the date the proficiency samples were tested for Thyroid Stimulating Hormone (TSH) for three of three events in 2025. Findings include: 1. A review of the laboratory's policy titled 'Proficiency Testing' revealed the following: "The lab should document all steps taken in PT performance. All records, reports, and corrective actions should be retained for 2 years. The attestation statement shall be signed and dated by testing personnel and the Lab Director at the time of testing." 2. A review of laboratory's API PT records from 2025 revealed the testing personnel failed to include the date on the attestation statements (indicating the date the samples were tested) for TSH testing in the following 3 PT events: - 2025 Chemistry- Core- 1st Event - 2025 Chemistry- Core- 2nd Event - 2025 Chemistry- Core- 3rd Event 3. Further review of the laboratory's API PT records

	revealed the date of testing was not documented on the API report forms for any of the PT events listed above. 4. A review of the laboratory's test records from 2025 revealed no documentation (instrument printouts, downtime forms) of the API PT samples being tested for TSH. 5. In an interview on 1/20/26 at 10:50 a.m. in the conference room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, quality control records, and staff interview, the laboratory failed to retain the Complete Blood Count (CBC) quality control records on the Cell-Dyn Emerald hematology analyzer for 90 of 90 days from January 29, 2024 to April 28, 2024. Findings include: 1. A review of the laboratory's policy titled 'Control Policy' revealed the following: "All control results and remedial actions must be recorded and records kept for at least two (2) years." 2. A review of the laboratory's quality control records revealed the laboratory failed to retain the CBC quality control records on the Cell-Dyn Emerald hematology analyzer from January 29, 2024 to April 28, 2024. 3. In an interview on 1/20/26 at 10:40 a.m. in the conference room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(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 (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(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 a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to have documentation of performing two of two calibration procedures on the Cell-Dyn Emerald hematology analyzer in 2025. Findings include: 1. A review of the laboratory's policy titled 'Instrument Operation and Maintenance' revealed the following: "Calibration of all laboratory instruments will be every six months, every time there is a complete change in lot numbers, or when controls don't give desired results." 2. A review of the laboratory's records

	revealed a calibration was performed on the Cell-Dyn Emerald hematology analyzer (SN: 030824-010866) on the following date: 12/17/24 3. Further review of the laboratory's records revealed the laboratory failed to have documentation of performing calibrations on the hematology analyzer in 2025. Laboratory was missing documentation of calibration for the following dates: June 2025 (six months after the last calibration) December 2025 4. In an interview on 1/20/26 at 11:15 a.m. in the break room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/21/2021 AND 10/17/2023.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's quality control records for Complete Blood Count (CBC) testing on the Cell-Dyn Emerald hematology analyzer and staff interview, the laboratory failed to have documentation of monitoring one of one lot number of quality control material over time to detect shifts and trends in May 2025. Findings include: 1. A review of the laboratory's quality control records for CBC testing on the Cell-Dyn Emerald hematology analyzer revealed the laboratory tested 3 levels (Low, Normal, High) of the following lot number of Cell- Dyn 18 Plus Control each day of patient testing in May 2025: - Lot number 5062 2. Further review of the laboratory's quality control records revealed the laboratory failed to monitor quality control values over time to detect and shifts or trends for the lot number 5062 from May 1, 2025 to May 31, 2025. 3. In an interview on 1/20/26 at 10:40 a.m. in the conference room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings. II. Based on a review of the laboratory's quality control records for the Qualigen FastPack IP System, the laboratory's records, and confirmed in interview, the laboratory failed to have a mechanism in place to monitor accuracy for the FastPack IP Quality Controls run for 24 of 24 months from January 1, 2024 to January 13, 2026. Findings include: 1. A review of the laboratory's quality control records for the Qualigen FastPack IP System used for Thyroid Stimulating Hormone (TSH) testing revealed the laboratory documented the date, the quantitative values for Control 1 and Control 2, and the acceptable ranges for the quality control material. 2. Further review of the quality control records revealed the laboratory failed to include the lot number and expiration date of the quality control used from January 1, 2024 to January 13, 2026. 3. A review of the laboratory's records revealed the laboratory failed to retain the Control Range Cards for the Qualigen FastPack IP System quality control material and there were no printed Control Labels with the values for Control 1 and Control 2. 4. In an interview

	on 1/20/26 at 10:45 a.m. in the conference room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed that there is not a mechanism in place to monitor the accuracy of the quality control testing for TSH.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, quality control records, and staff interview, the laboratory failed to verify three of three new lot numbers of quality control material for Complete Blood Count (CBC) testing on the Cell-Dyn Emerald hematology analyzer in 2025 before placing them into use. Findings include: 1. A review of the laboratory's policy titled 'Quantitative Control Validation' revealed the following: "It is the policy of this lab to validate quantitative controls prior to placing them into use for patient testing. New controls shall be fun at least once a day for 5 days along with current controls." 2. A review of the laboratory's quality control records revealed the following 3 new lot numbers of quality control material were not verified (run concurrently with patients for at least 5 days) on the Cell-Dyn Emerald hematology analyzer before placing them into use: Cell-Dyn 18 Plus Controls (Levels Low, Normal, High): - Lot number 5174 Start date: 7/31/25 - Lot number 5230 Start date: 10/11/25 - Lot number 5286 Start date: 12/4/25 3. In an interview on 1/20/26 at 10:45 a.m. in the break room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 1/29/2020, 12/21/2021 AND 10/17/2023.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's quality control records, and staff interview, the technical consultant failed to ensure a quality control plan was followed to ensure accurate and reliable results for two of two specialties in 2024 and 2025. Findings include: 1. The laboratory failed to have documentation of monitoring quality control material over time to detect shifts and trends. (Refer to D5441 I) 2.

	The laboratory failed to have a mechanism in place to monitor accuracy for the FastPack IP Quality Controls. (Refer to D5441 II) 3. The laboratory failed to verify new lot numbers of quality control material for Complete Blood Count (CBC) testing on the Cell-Dyn Emerald hematology analyzer in 2025 before placing them into use. (Refer to D5469)