Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0933273	10/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Medical Associates Of Brownsville Pa	425 E Los Ebanos Blvd Ste 100, Brownsville, 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 facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 successful participation in a proficiency testing program 493.1403 laboratories performing moderate complexity testing; laboratory director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in interview of facility personnel, it was determined that laboratory has not successfully participated in a proficiency testing program

	approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of chemistry for the analyte Sodium (refer to D2096).
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in interview of facility personnel, it was determined the laboratory failed to attain a score of at least 80% acceptable responses for each analyte in the subspecialty of chemistry. The findings were: 1. Review of the laboratory's API proficiency testing records for Chemistry 2019 (events 1, 2, and 3) and Chemistry 2020 (events 1, 2, and 3) revealed the following failures for Sodium: 2020 (event 2): laboratory scored 60% 2020 (event 3): laboratory scored 60% 2. The findings were confirmed in interview of the technical consultant and the primary testing person on October 21, 2020 at 10:30 hours in the conference room.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in interview of facility personnel, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two consecutive testing events in the specialty of Chemistry for the analyte Sodium (NA). Two out of three unsatisfactory scores results in unsuccessful PT performance. The findings were: 1. Review of the laboratory's API proficiency testing records for Chemistry 2019 (events 1, 2, and 3) and Chemistry 2020 (events 1, 2, and 3) revealed the following failures for Sodium: 2020 (event 2): laboratory scored 60% 2020 (event 3): laboratory scored 60% 2. The findings were confirmed in interview of the technical consultant and the primary testing person on October 21, 2020 at 10:30 hours in the conference room.
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 manufacturer's instructions, review of patient test records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for test performance on the In vitro Nano-Check AMI 3 IN 1 Cardiac Marker Test cTNI, CK-MB, and Myoglobin test kit. The findings were: 1. Review of the manufacturer's instructions for the In vitro Nano-Check AMI 3 IN 1 Cardiac Marker Test cTNI, CK-MB, and Myoglobin test kit (P/N EP-2401 R1 /052015) stated under the 2nd bullet point of Limitations, "A positive test result may only be used as an indicator of myocardial damage and requires further confirmation. Serial sampling of patients suspected of AMI at multiple time points is also recommended due to the delay between onset of symptoms and the release of cardiac marker proteins into the blood stream." 2. Random review of patient test records from January 2019 to October 20, 2020, the date of the survey found the following patient samples that were not confirmed as required by the manufacturer: Last 3 digits of Account Number: 003 Date Tested: 09-18-2020 Myoglobin Result: Abnormal Last 3 digits of Account Number: 832 Date Tested: 06-04-2020 CK-MB Result: Abnormal Myoglobin Result: Abnormal Last 3 digits of Account Number: 787 Date Tested: 04-30-2020 CK-MB Result: Abnormal Myoglobin Result: Abnormal Last 3 digits of Account Number: 679 Date Tested: 08-26-2019 Myoglobin Result: Abnormal Last 3 digits of Account Number: 832 Date Tested: 05-15-2019 CK-MB Result: Abnormal Myoglobin Result: Abnormal Last 3 digits of Account Number: 269 Date Tested: 04-29-2019 Troponin I Result: Abnormal CK-MB Result: Abnormal Myoglobin Result: Abnormal Last 3 digits of Account Number: 696 Date Tested: 04-16-2019 CK-MB Result: Abnormal Myoglobin Result: Abnormal Last 3 digits of Account Number: 162 Date Tested: 04-01-2019 CK-MB Result: Abnormal Last 3 digits of Account number: 265 Date Tested: 03-25-2019 CK-MB Result: Abnormal Last 3 digits of Account number: 997 Date Tested: 03-21-2019 CK-MB Result: Abnormal Myoglobin Result: Abnormal Last 3 digits of Account Number: 295 Date Tested: 02-15-2018 CK-MB Result: Abnormal Myoglobin Result: Abnormal Last 3 digits of Account Number: 296 Date Tested: 02-15-2019 CK-MB Result: Abnormal Myoglobin Result: Abnormal Last 3 digits of Account Number: 260 Date Tested: 02-11-2019 CK-MB Result: Abnormal 3. The laboratory was asked to provide documentation of confirming the results as required by the manufacturer. No documentation was provided. 4. An interview with the technical consultant and the primary testing person on October 21, 2020 at 14:00 hours in the conference room confirmed the findings. Key: CK-MB - creatine kinase primarily found in heart muscle TnI - troponin AMI - acute myocardial infarction
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 manufacturer's instructions for the AIA-Pack 25-OH Vitamin D Control Set, and staff interview, it was revealed the laboratory failed to have documentation of establishing its own means and ranges as required by the manufacturer. The findings were: 1. A review of the manufacturer's instructions for the AIA-Pack 25-OH Vitamin D Control Set (Document No. 100B774001-115D, Rev. 11/15) under the section titled "Assignment of Values" revealed, "The AIA-Pack 25-OH Vitamin D Control Set contains assigned concentration range of 25-OH Vitamin D. The assigned value is determined on a lot-by-lot basis and is designed to provide target control levels of approximately 17 and 66 ng/mL of 25-OH vitamin D. Since the assay values are dependent upon assay procedures as well as several other factors, each laboratory should established its own range for the assay procedure being monitored." 2. The laboratory was asked to provide documentation of establishing the ranges for the AIA-Pack 25-OH Vitamin D Control Set Lot #s A64B745, J24B737, and J84B740. No documentation was provided. 3. An interview with the technical consultant and the primary testing person on October 21, 2020 at 13: 30 hours in the conference room confirmed the findings. Key: OH - hydroxide ng/mL - nanograms per milliliter
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records and confirmed in interview of facility personnel, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records and confirmed in interview of facility pesonnel, it was revealed that the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2096.