Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0933273	06/26/2024
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 laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
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 manufacturer's instructions for the Medonic M-series hematology analyzer, review of the laboratory's procedures, review of patient test records from April 2024 to May 2024, and staff interview, the laboratory failed to have documentation of following its procedure for addressing flagged white blood cell differential flags on 4 of 4 patient results. The findings included: 1. A review of the manufacturer's instructions for the Medonic M-series hematology analyzer (July 2019, Article no. 1504547) under the section titled "WBC Differential Abnormalities" determined the manufacturer identified the following flags: BD NM OM TM The manufacturer also included the following instructions for resolving the identified flags: "Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." 2. A review of the laboratory's procedure titled "Policy for Handling Flagged CBC Differentials" determined: "It will be the policy of this laboratory to rerun flagged CBC results. If the second run still shows flags, then the lab will evaluate flagged differentials according to the procedures in the unite's operator manual. See that the sample requirements are met, that the unit is in good working order, and that the testing procedure is correctly followed. If the flags disappear, then report that result. If the flags persist, then it will be considered an abnormal differential and will be invalidated and/or should be sent out for analysis."

	3. A review of patient test records from April 2024 to May 2024 identified the following 4 patient results with flags where the laboratory failed to invalidate the results or send the sample out for analysis: a) Test date: 04/01/2024 Patient: 37055 Flag: OM b) Test date: 04/01/2024 Patient: 73810 Flag: OM c) Test date: 04/01/2024 Patient: 74529 Flag: OM d) Test date: 05/30/2024 Patient: 74466 Flag: OM 4. The technical consultant confirmed the findings in an interview conducted 06/26/2024 at 1330 hours in the conference room.
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, review of manufacturer's instructions and staff interview, the laboratory failed to ensure expired reagent grade water was not available for use in the laboratory. The findings included: 1. Surveyor observation of laboratory supplies currently in use on 06/26/2024 at 1300 hours in the laboratory identified the following reagent grade water currently in use: EKI High Purity Reagent Grade Water 1- 20 Liter Box Lot: 2321601 Opened date: 10-27-2023 2. Review of the manufacturer's instructions for the EKI High Purity Reagent Grade Water determined: "Prolonged storage may have an adverse affect on the quality of this product. To reduce the risk of microbial contamination, consume entire contents within 30 days of opening. Thus, the water expired on 11-26-2023. It was in use for 7 months past its expiration. 3. The technical consultant confirmed the findings in an interview conducted on 06/26/2024 at 1330 in the conference room.
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 procedures, review of patient test records from 02 /01/2024 to 02/16/2024, review of the laboratory's critical value logs from February 2024 and staff interview, the laboratory failed to document the notification of 3 of 3 panic values. The findings included: 1. A review of the laboratory's policy titled "Panic Values" determined: "The Laboratory Personnel will immediately notify the requester or user about lab results in the 'Panic Range'. The laboratory's policy then defined the following Panic Ranges: Hemoglobin: 7.5 - 18 Hematocrit: 25 - 55 2. A review of the laboratory's policy titled "Reporting Panic Values" determined: "It is the policy of this lab to document the reporting of panic values. Document: who was notified, when that person was notified by whom" 3. A review of patient test records from 02/01/2024 to 02/16/2024 identified the following panic values: a) Test date: 02 /01/2024 Patient: 74136 Hematocrit: 23.8 b) Test date: 02/16/2024 Patient: 62436 Hemoglobin: 18.6 Hematocrit: 56.6 4. A review of the laboratory's critical value log from February 2024 determined the notification of the 3 critical values was not

	documented. 5. The technical consultant confirmed the findings in an interview conducted on 06/26/2024 at 1440 hours in the conference room.