Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0520056	09/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Medical Arts Laboratory Inc	407 S Medical Arts Ct Ste E, Gillette, WY	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing (PT) results for 4 of 31 proficiency testing events reviewed from June 2022 through August 2024. The findings were: 1. Review of the American Proficiency Institute (API) 2022 Chemistry Core Event #2 PT results showed the laboratory scored an 80% on the serum pregnancy assay. There was no documentation the laboratory had evaluated the proficiency test result. 2. Review of the API 2023 Chemistry Core Event #1 PT results showed the laboratory scored an 80% on carbon dioxide. There was no documentation the laboratory had evaluated the proficiency test result. 3. Review of the API 2024 Chemistry Core Event #1 PT results showed the laboratory scored an 80% on aspartate transaminase. There was no documentation the laboratory had evaluated the proficiency test result. 4. Review of the API 2024 Hematology/Coagulation Event #1 PT results showed the laboratory scored an 80% on the erythrocyte count. There was no documentation the laboratory had evaluated the proficiency test result. 5. Interview with the general supervisor on 9/11/24 at 11:07 AM confirmed an evaluation of the proficiency testing results had not been conducted.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required

	for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to have a system in place for reviewing proficiency test results that received an artificial score of 100% for 10 of 31 API (American Proficiency Institute) proficiency testing events reviewed from June 2022 through August 2024. The findings were: 1. Review of the 2022 API Hematology/Coagulation Event #2 proficiency testing evaluation showed the laboratory received an artificial score of 100% on sample VA-02 (vaginal wet prep) and an artificial score on UA-03 (urobilinogen) due to a lack of consensus. There was no documentation a self-evaluation of sample VA-02 or UA-03 had been completed. 2. Review of the 2022 API Hematology/Coagulation Event #3 proficiency testing evaluation showed the laboratory received an artificial score of 100% on BCI-14 (blood cell identification) due to no consensus. There was no documentation a self-evaluation of sample BCI-14 had been completed. 3. Review of the 2022 API Immunology Event #2 proficiency testing evaluation showed the laboratory received an artificial score of 100% on CRP-04 (C-reactive protein) due to a lack of consensus. There was no documentation a self-evaluation had been completed. 4. Review of the 2023 API Chemistry Core Event #1 proficiency testing evaluation showed the laboratory received an artificial score of 100% on CH-01 (alanine transaminase). There was no documentation a self-evaluation had been completed. 5. Review of the 2023 API Hematology/Coagulation Event #1 proficiency testing evaluation showed the laboratory received an artificial score of 100% on UA-02 (urobilinogen) due to a lack of consensus. There was no documentation a self-evaluation had been completed. 6. Review of the 2023 API Hematology/Coagulation Event #2 proficiency testing evaluation showed the laboratory received an artificial score of 100% on UA-03 (urobilinogen) due to a lack of consensus. There was no documentation a self-evaluation had been completed. 7. Review of the 2023 API Hematology/Coagulation Event #3 proficiency testing evaluation showed the laboratory received an artificial score of 100% on VA-03 (vaginal wet prep) due to a lack of consensus. There was no documentation a self-evaluation had been completed. 8. Review of the 2023 API Immunology Event #3 proficiency testing evaluation showed the laboratory received an artificial score of 100% on CRP-06 (c-reactive protein) due to a lack of consensus. There was no documentation a self-evaluation had been completed. 9. Review of the 2024 API Chemistry Core Event #1 proficiency testing evaluation showed the laboratory received an artificial score of 100% on samples CH-02, CH-03, and CH-05 due to "result variance" on the analyte of total bilirubin. There was no documentation a self-evaluation had been completed. 10. Review of the 2024 API Chemistry Core Event #2 proficiency testing evaluation showed the laboratory received an artificial score of 100% on CH-08 (iron) due to "result variance". There was no documentation a self-evaluation had been completed. 11. Interview with the general supervisor on 9/11/24 at 11:07 AM confirmed a self-evaluation of the non-graded test results had not been conducted.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

	specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and staff interview, the laboratory failed to ensure the procedure manual contained all the required elements for 1 of 1 procedure manual reviewed (erythrocyte sedimentation rate). The findings were: 1. Review of the erythocyte sedimentation rate (ESR) procedure performed on the Streck Diesse Cube analyzer showed the laboratory was using the operator's manual as the procedure manual. The operator's manual failed to include the laboratory's system for entering results in the patient record and a description of the course of action to take if a test system became inoperable. In addition, the operator's manual had not been signed by the laboratory director. 2. Interview with the general supervisor on 9/11/24 at 10:43 AM confirmed the laboratory's procedure for performing ESR testing was incomplete.
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 a new instrument/test verification study, lack of documentation, and staff interview, the laboratory failed to ensure the verification study was complete for 1 of 1 (Streck Diesse Cube erythocyte sedimentation rate (ESR) verification study reviewed. The findings were: 1. Review of the Streck Diesse Cube new instrument verification study used for performing ESRs showed data was collected to verify the performance specification of accuracy; however, the laboratory failed to verify the manufacturer's performance specification for precision and the reportable range for the test system. In addition, the laboratory failed to confirm the reference intervals used for the test system were appropriate for the laboratory's patient population. 2. Interview with the general supervisor on 9/11/24 at 10:43 AM confirmed the verification study was incomplete.