Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0520056	(X3) Date Survey Completed 08/01/2018
Name of Provider or Supplier Medical Arts Laboratory Inc	**Street Address, City, State** 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on proficiency testing records review, lack of documentation and interview with staff, the laboratory failed to enroll in proficiency testing for the specialty of Bacteriology for throat culture negative confirmation testing for 2018. The laboratory performed approximately 100 throat culture confirmation tests per month. Findings include: 1. Proficiency testing records review failed to include documentation the laboratory enrolled in an approved proficiency testing program for the specialty of Bacteriology for Throat culture testing to determine the presence or absence of Group A Streptococcus. 2. In an interview with staff on 08/01/2018 at approximately 4:45 P. M., staff confirmed the laboratory had not enrolled in proficiency testing for Bacteriology in 2018.
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 confirmation by staff, the laboratory failed to establish a written procedure for the step by step performance of Group A Streptococcus (GAS) confirmatory testing for the presence or absence of GAS. The laboratory performed approximately 1500 tests per year. Findings include: 1. The laboratory procedure manual review failed to include a procedure for GAS confirmatory testing following a negative rapid GAS antigen screening test. 2. In an interview with staff on 08/01/2018 at approximately 4:45 P.M., staff stated that due to the laboratory's discontinuance of throat culture testing they performed GAS waived screens and followed-up with a confirmatory culture for the presence or absence of GAS by culture. The procedure for GAS confirmatory testing was not written.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and confirmation by staff, the laboratory failed to test Wright's staining material each day of testing for white blood cell differentials to ensure satisfactory staining characteristics. The laboratory performed approximately 12-15 manual differentials per month. Findings include: 1. The laboratory lacked documentation they checked Wright's stain reagent each day of testing for predictable staining characteristics. 2. In an interview conducted on 08/01/2018 at approximately 5:00 P.M. staff stated they did not document Wright's staining characteristics were adequate each day staining was performed.