Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0520056	05/10/2022
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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: . Based on review of proficiency testing (PT) records, review of the laboratory's criteria for repeat testing, and staff interview, the laboratory failed to test proficiency test samples the same number of times that it routinely tested patient samples for 4 of 28 API (American Proficiency Institute) proficiency testing events reviewed from 2020 Event #3 through 2022 Event #1. The findings were: 1. Review of the PT record for API 2021 Hematology Event #1 showed sample #1 was analyzed on 3/12/21 at 1: 27 PM and again at 1:30 PM. 2. Review of the API 2021 Hematology Event #2 showed sample #6 was analyzed on 7/19/21 at 1:32 PM and again at 1:37 PM. Sample #10 was analyzed at 2:06 PM and again at 2:08 PM. 3. Review of the 2021 API Hematology Event #3 showed sample #13 was analyzed on 11/4/21 at 10:05 AM and again at 10:11 AM. 4. Review of the API 2022 Hematology Event #1 showed sample #1 was analyzed on 3/10/22 at 10:03 AM and again at 10:06 AM. 5. Review of the laboratory's "Hematology Lab Action Limits" criteria for repeat testing showed the results of each of the test samples repeated did not meet the criteria for repeat testing. 6. Interview with the laboratory manager on 5/10/22 at 12:41 PM confirmed the PT samples that were repeated did not meet the criteria. .
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State

	Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on the laboratory's COVID-19 patient testing log and staff interview, the laboratory failed to report 1 of 1 SARS-COV-2 patient test results for one month of testing reviewed (April 2022). The findings were: 1. Review of the COVID-19 patient testing log showed 1 patient test had been performed on 4/28/22 using the Mesa BioTech Accula molecular testing platform. There was no evidence the results of the patient's test had been reported to the State of Wyoming Public Health Department. 2. Interview with the laboratory manager on 5/10/22 at 12:41 PM revealed the laboratory had just recently began testing for COVID-19 and she was unaware of the regulation. .
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 CMS-116 form, lack of documentation, and staff interview, the laboratory failed to have a written procedure for reporting SARS-CoV-2 positive and negative test results. The laboratory had performed 1 SARS-CoV-2 patient test using a molecular platform since the test was implemented in April 2022. The findings were: 1. Review of the CMS-116 form showed the laboratory performed molecular testing for SARS-CoV-2 using the Mesa Biotech Accula molecular testing procedure. 2. Review of the laboratory's procedure manuals showed no evidence the laboratory had developed a policy and procedure for reporting SARS-CoV-2 positive and negative test results to the appropriate agencies. 3. Interview with the laboratory manager on 5/10/22 at 12:41 PM confirmed the laboratory did not have a written procedure for reporting positive and negative SARS-CoV-2 patient test results. .
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: . Based on review of personnel files, lack of documentation, and staff interview, the laboratory's technical supervisor failed to ensure an annual competency assessment had been completed for 1 of 1 testing personnel (D6128) performing high complexity testing for two consecutive survey cycles (2020, 2022). .

D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: . Based on review of the CMS-209 Laboratory Personnel Report, review of personnel files, and staff interview, the laboratory technical supervisor failed to evaluate 1 of 1 high complexity testing personnel for competency at least annually for 1 of 2 years of testing reviewed (2021). The findings were. 1. Review of the CMS-209 Laboratory Personnel Report listed 1 testing personnel as performing high complexity patient testing. 2. Review of personnel files showed no evidence a competency assessment was completed in 2021. 3. Interview with the laboratory manager on 5/10/22 at 12:41 PM revealed she unable to locate the competency assessment. THIS IS A REPEAT DEFICIENCY, last cited on 9/2/20.