Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D0717499	10/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Harbir S Makin Md	3300 Providence Drive 114, Anchorage, AK	

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
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 record review and interview with the laboratory director and testing personnel (TP#1 and TP#2), the laboratory failed to report SARS-CoV-2 test results as required for 25 of 25 days patients were tested from January through October 2022. Findings include: 1. The COVID 19 Antigen Test Result Logs were reviewed from January 3, 2022 through October 20, 2022. 2. Documentation revealed that SARS-CoV-2 test results were not reported as required for 9 days in January, 6 days in February, 1 day in March, 2 days in May, 2 days in June, 3 days in July, 1 day in September, and 1 day in October of 2022. 3. The laboratory was unaware of this reporting requirement and had never attempted to report any SARS-CoV-2 test results as required. 4. The laboratory reports performing 52 SARS-CoV-2 test during the period of review. 5. An interview conducted on 10/20/2022 at 1:00 PM with the laboratory director, TP #1 and TP #2, confirmed the laboratory did not attempt to report SARS-CoV-2 test results as required.
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 the surveyor's review of the written laboratory procedure manual and an interview with the testing personnel, the laboratory failed to have a written procedure for urine microscopy. Findings include: 1. A review of the laboratory's procedure manual revealed there was no written procedure for urine microscopy testing. 2. The laboratory reports performing approximately 490 urine microscopic exams annually. 3. An interview conducted on 10/20/2022 at 1:00 PM with the laboratory director, TP #1 and TP #2, confirmed the laboratory did not have a written procedure for urine microscopic exams.
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 a review of the COVID 19 Antigen Test Results Log, the laboratory's policies and procedures, and interview with the laboratory testing personnel (TP#1, TP#2), the laboratory did not have a written policy or procedure for reporting SARS-CoV-2 test results as required. Findings include: 1. A request was made to review the policy or procedure for reporting SARS-CoV-2 test results and documentation could not be provided. 2. According to the Antigen Test Results Log, results were not reported for 11 patients in January, 6 patients in February, 1 patient in March, 2 patients in May, 2 patients in June, 3 patients in July, 1 patient in September, and on patient in October 2022. 3. The laboratory reports performing 52 SARS-CoV-2 patient tests during the period of review. 4. An interview conducted on 10/7/22 at 1:00 PM with the laboratory director and TP#1 and TP#2 confirmed the laboratory did not have a policy or procedure for reporting SARS-CoV-2 test results.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's package insert, patient test reports, and interview with the testing person (TP#1), the laboratory failed to include follow the manufacturer's instructions for reporting Prostate Specific Antigen (PSA) using the Tosoh AIA-900 analyzer. Findings include: 1. The package insert for PSA, rev. 10/16 states, "It is mandatory that results reported by the laboratory to the physician include the identity of the assay used." 2. A review of a test result report on patients #9192 and #11978 revealed the PSA result did not include the identity of the PSA assay. 3. The laboratory reports performing 300 PSA tests annually. 4. the laboratory director, TP #1, and TP #2 confirmed these findings by interview conducted on 10/20/2022 at 1: 00 PM.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of patient test reports, quality control records January and June of 2022, and interview with testing personnel #1 and #2 (TP#1 and TP#2), the laboratory failed to perform control procedures each day patient specimens are tested for the urine microalbumin and creatinine on the DCA Vantage analyzer. Findings include: 1. A random review of patient urine microalbumin and creatinine results for 1 /7/22 (#7296) and 6/6/22 (#11978) and corresponding quality control records showed the laboratory did not perform quality controls on the day these patients were tested. 2. The laboratory reports performing 72 the urine microalbumin and creatinine tests annually. 3. An interview conducted on 10/20/2022 at 1:00 PM with the laboratory director, TP #1 and TP #2, confirmed the laboratory did perform the quality control each day patients were tested.