Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D2201100	06/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cellnetix Pathology Alaska Regional Hospital	2801 Debarr Rd, 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
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 Hematoxylin and Eosin (H&E) stain procedure, the Frozen Section Stain Maintenance log for March and May 2023, and an interview with the general supervisor, the laboratory failed to have a procedure that included the process for the regular replacement of staining reagents to prevent poor stain quality on patient slides. Findings include: 1. The H&E procedure did not include the process or procedure for regularly replacing the H&E stain components. 2. The Frozen Section Stain Maintenance logs include the statement 'All reagents must be changed at least once per week' and a review of the March and May 2023 logs revealed a complete

	change of reagents was not documented for four (4) of eight (8) weeks. The April 2023 log was missing. 3. An interview conducted on June 5, 2023 at approximately 12: 00 PM with the general supervisor, confirmed that the procedure manual did not include a procedure defining the frequency of changing staining solutions. 4. The laboratory reports performing approximately 5000 patient samples annually.
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 a review of room temperature and humidity logs from April 1 through June 5, 2023, the Cryostat Operator's manual, and an interview with the general supervisor, the laboratory failed to document the relative humidity in the laboratory for from April 1 through June 5, 2023. (45 working days) Findings include: 1. Review of the laboratory's April, May, and June 2023 temperature and humidity logs showed no documentation for the relative humidity during this time frame. 2. The Cryostat Operator's manual established that the laboratory must monitor and document the relative humidity (less than 60%) daily. 3. An interview conducted on June 5, 2023 at approximately 12:00 PM with the general supervisor, confirmed that the laboratory did not have written documentation of the daily humidity levels. 4. The laboratory reports performing approximately 5000 patient samples annually.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a review of the Cryostat Maintenance logs for February, March, and April 2023, and an interview with the general supervisor, the laboratory failed to follow its weekly cryostat decontamination and maintenance activities as directed on the log. Findings include: 1. The Leica CM 1860 Cryostat Maintenance Logs include the schedule for weekly decontamination procedures and instrument maintenance. 2. A review of the February 2023 log revealed no weekly decontamination and maintenance was documented, the March 2023 log revealed weekly decontamination and maintenance documented one (1) out of four (4) weeks, and the April 2023 log revealed no weekly decontamination and maintenance was documented. 3. An

	interview conducted on June 5, 2023 at approximately 12:00 PM with the general supervisor, confirmed that the laboratory did not document weekly decontamination and maintenance as required. 4. The laboratory reports performing approximately 5000 patient samples annually.