

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2043058	(X3) Date Survey Completed 07/06/2023
Name of Provider or Supplier Cellnetix Pathology	Street Address, City, State 2490 S Woodworth Loop Suite 410, Palmer, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Wright's stain Procedure, the Wright's stain Maintenance Charts for January and June 2023, and an interview with the general supervisor, the laboratory failed to follow its procedure for changing the Wright's stain reagents after each case. Findings include: 1. A review of the laboratory's Wright's stain Procedure stated the Wright's stain reagents are changed after each case. 2. A review of the January 2023 Wright's stain Maintenance Chart revealed the stain reagents were not changed for fifteen (15) of nineteen (19) days of patient testing, and the June 2023 chart revealed the stain reagents were not changed for seventeen (17) of twenty-two (22) days of patient testing. 3. An interview conducted on July 6, 2023 at approximately 5:00 PM with the general supervisor, confirmed that the laboratory was not following its policy for changing Wright's stain reagents. 4. The laboratory reports performing approximately 20,000 patient samples annually.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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</p>

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 April and July 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 April 2023 log revealed weekly decontamination and maintenance was not documented one (1) of four (4) weeks, the July 2023 log revealed weekly decontamination and maintenance was not documented three (3) of four (4) weeks. 3. An interview conducted on July 6, 2023 at approximately 5:00 PM with the general supervisor, confirmed that the laboratory did not document weekly decontamination and maintenance as required. 4. The laboratory reports performing approximately 20,000 patient samples annually.

D5617

CYTOLOGY
CFR(s): 493.1274(b)(2)

(b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.

This STANDARD is not met as evidenced by:
Based on a review of laboratory policies and procedures and an interview with the general supervisor, the laboratory failed to have a policy or procedure for the prevention of cross contamination between gynecologic and nongynecologic specimens. Findings include: 1. A request was made to review the policy or procedure referencing cross-contamination prevention in cytology staining and the documentation could not be provided. 2. An interview conducted on July 6, 2023 at approximately 5:00 PM with the general supervisor, confirmed that the laboratory did not have a policy or procedure for the prevention of cross contamination. 3. The laboratory reports performing approximately 20,000 patient samples annually.