

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D2021715	<b>(X3) Date Survey Completed</b> 06/08/2022
<b>Name of Provider or Supplier</b> Innovative Pathology Services, Pllc	<b>Street Address, City, State</b> 10820 Parkside Dr, Knoxville, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<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 review of the laboratory's procedures, review of Cryostat daily maintenance logs, documentation on email of dates patient testing was performed, and interview with the lab director, determined the laboratory failed to follow their own written procedure for performing daily maintenance of the Cryostat instrument for 136 out of 145 days from January 2021 through June 8, 2022. Findings included: 1. Review of the "Maintenance /Decontamination of Cryostats &amp; check of Temperature/Humidity" policy and procedure (KNXTCMCQD9457 V2) on page 3 stated, "7. Procedure, Daily Maintenance including routine decontamination and temperature/humidity of room." 2. Review of Cryostat daily maintenance logs revealed daily maintenance was not performed on the following dates that patient testing was performed: 2021-01-20 2021-01-29 2021-02-01 2021-02-02 2021-02-03 2021-02-08 2021-02-17 2021-02-18 2021-02-19 2021-02-22 2021-03-01 2021-03-04 2021-03-08 2021-03-11 2021-03-16 2021-03-25 2021-04-01 2021-04-06 2021-04-08 2021-04-12 2021-04-14 2021-04-15 2021-04-16 2021-04-22 2021-04-23 2021-04-27 2021-04-28 2021-04-29 2021-05-05 2021-05-06 2021-05-11 2021-05-12 2021-05-18 2021-05-19 2021-05-20 2021-06-01 2021-06-08 2021-06-11 2021-06-16 2021-06-22 2021-06-24 2021-06-22 2021-06-22 2021-06-24 2021-06-25 2021-06-30 2021-07-01 2021-07-02 2021-07-06 2021-07-09 2021-07-21 2021-07-26 2021-07-27 2021-07-28 2021-07-30 2021-08-02 2021-08-03 2021-08-06 2021-08-10 2021-08-11 2021-08-12 2021-08-13 2021-08-20 2021-08-25 2021-08-27 2021-09-13 2021-09-16 2021-09-21 2021-09-24 2021-09-27 2021-10-04</p>

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2022-06-07 2022-06-08

3. Review of additional documentation received via email communication on 06.13.2022 from the Anatomic Pathology supervisor revealed Cryostat daily maintenance was not documented on 136 of 145 days that patient testing was performed from January 1, 2022 through June 8,2022. 4. Interview with the laboratory director on June 8, 2022 at approximately 11:30 A.M. in his office confirmed the laboratory failed to follow their own written procedure for performing daily maintenance of the Cryostat instrument, as stated in the procedure, on all days of patient testing from January 2021 through June 8, 2022.

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