

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0998002	(X3) Date Survey Completed 04/24/2019
Name of Provider or Supplier Stony Point Surgery Center	Street Address, City, State 8700 Stony Point Parkway Suite 100, Richmond, VA	
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
D0000	An announced CLIA recertification survey was conducted at Stony Point Surgery Center on April 24, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 review of procedures, instrument maintenance documentation, and an interview, the laboratory failed to follow the established procedure for cryostat decontamination in calendar year 2018. Findings include: 1. Review of the laboratory's procedures revealed a quality assurance (QA) policy (Decontamination of the Cryostat) that stated "Decontaminate the cryostat twice annually". 2. Review of the laboratory's Leica CM 1850 Cryostat maintenance documentation revealed one (1) decontamination procedure documented in calendar year 2018 (recorded on 4/4/18). The inspector requested additional decontamination documentation for 2018. No records were available. 3. In an exit interview with the clinical and medical directors at 12:30 PM, the above listed findings were confirmed.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at</p>

least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

A. Based on a review of the manufacturer's operations manual, procedure manual, maintenance and patient test logs, and an interview, the laboratory failed to document performance of daily cryostat instrument maintenance according to the manufacturer's instructions on five (5) days while processing 5 patient tissue cases during the sixteen (16) months reviewed (dates of record review 12/1/17 to 4/24/19). Findings include:

1. Review of the Leica CM 1850 Cryostat Operations Manual revealed Maintenance Instructions in Section 10 that stated: "Perform the cleaning procedures every day: removing frozen section waste from the cryostat with the cold brush every day, remove the section waste, drain the cleaning liquid after cleaning daily, spray disinfection (recommend LEICA Cryofect-note the cryostat has to be disinfected after each daily use)".
2. Review of the laboratory's procedure manual revealed a policy (Preventative Maintenance) that stated "perform routine disinfection cleaning daily following use (typically 1-2 times a week)".
3. Review of the laboratory's Surgery Center Cryostat Temperature and Maintenance logs and patient test logs revealed no documentation of the required daily maintenance on the following 5 days while processing patient tissue case numbers : 07/25/18- DP18-1366 08/29/18- DP18-1440 09/12/18- DP18-1723 12/26/18- DP18-2162 02/27/19- DP19-259 The inspector requested to review the daily maintenance for the dates of patient testing outlined above. No records were available.
4. In an exit interview with the clinical and medical directors at 12:30 PM, the above listed findings were confirmed.

B. Based on a review of the manufacturer's operations manual, maintenance and patient logs, and an interview, the laboratory failed to document performance of the cryostat instrument weekly maintenance according to the manufacturer's instructions for fifty-six (56) of sixty-four (64) weeks reviewed while processing one hundred fifty (150) patient tissue cases. Findings include:

1. Review of the Leica CM 1850 Cryostat Operations Manual revealed Maintenance Instructions in Section 10 that stated: "Perform once per week: lubricate the specimen cylinder".
2. Review of the laboratory's Surgery Center Cryostat Temperature and Maintenance monthly maintenance logs revealed cryostat oil (cylinder lubrication) listed as: "perform weekly". During the maintenance and patient test log review, the inspector noted the required weekly maintenance was not documented as performed on fifty-six (56) weeks while 150 patient test cases were processed (review timeframe 12/1/17 to 4/24/19). Additional documentation of the cylinder lubrication maintenance was requested. No records were available. The Clinical Director in an interview at approximately 11:30 AM, stated "Our histotechnician completes the maintenance but it is not always recorded on the logsheet".
3. In an exit interview with the clinical and medical directors at 12:30 PM, the above listed findings were confirmed.

C. Based on a review of manufacturer's operations manual, procedure manual, equipment maintenance records, and an interview, the laboratory failed to document the cryostat instrument annual preventative maintenance (PM) procedures according to the manufacturer's instructions in calendar year 2018. Findings include:

1. Review of the Leica CM 1850 Cryostat Operations Manual revealed General Maintenance Instructions in Section 10 that stated: "To ensure smooth operation, the instrument is to be inspected by a qualified service engineer once a year for PM procedures."
2. Review of the laboratory's procedure manual revealed a policy that stated the cryostat "preventative maintenance will be performed each year".
3. Review of the laboratory's equipment maintenance records revealed no PM record in calendar year 2018. The inspector requested the documentation. The Clinical Director stated in an interview at approximately 11:30 AM, "we have Leica PM records for 2017 and 2019 but I am

unable to locate the 2018 documentation". 4. In an exit interview with the clinical and medical directors at 12:30 PM, the above listed findings were confirmed.