Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1080727	(X3) Date Survey Completed 10/02/2018
Name of Provider or Supplier Laser And Skin Surgery Center Of Richmond, Pc	**Street Address, City, State** 7001 Forest Avenue - Suite 301, 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 the Laser and Skin Surgery Center of Richmond on October 2, 2018 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	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 review of policy and interviews, the laboratory failed to document the changing or replacement of the Hematoloxylin and Eosin (H&E) stains as defined in the H&E stain policy for twenty-four (24) of the twenty-four (24) months reviewed. Findings include: 1. Review of the H&E stain policy (signed by the lab director on February 27, 2014) revealed the following statements: "stain timing and solution had ** by 100% alcohol (fixative), water wash- fresh water, Scott's bluing (crisp, clear nuclei). ** denotes needs to be changed daily. Daily empty first 95% alcohol after the eosin, move second 95% alcohol to empty space, fill with fresh 95% alcohol. Daily empty first 100% alcohol, move second and third to next empty station, replace last station with fresh 100% alcohol. Weekly change all alcohols, eosin and xylene substitute. Every two weeks change hematoxylin." There was no documentation available for review for the changing and replacing of the solutions from June 1, 2017 through June 30, 2018. The inspector asked testing personnel (TP) A how the laboratory documents the changing and replacing of the solutions described by the

	policy. TP A stated that he/she does not document the changing and replacing of the solutions. 2. An interview with the laboratory director at approximately 12:20 PM confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the tour of the laboratory, manufacturer recommendations, review of policy and interviews, the laboratory failed to follow the written policy for replacing the Airfiltronix Fume Hood charcoal filter for twenty-four (24) of twenty-four (24) months reviewed. Findings include: 1. The tour of the laboratory revealed that the laboratory utilizes the Airfiltronix Fume hood for tissue processing procedures. 2. Review of the Airfiltronix Fume Hood manufacturer recommendations for replacing the charcoal filter revealed that the estimated life of the charcoal filter (part number FR-4) was 4-6 months. 3. Review of the "Fume Hood" policy (no date of approval available) revealed the following statements: " 2. Dust air vent monthly, document. 3. Replace filter as required by manufacture, document." The inspector reviewed the available documentation for replacing the charcoal filter for the fume hood and noted that the last date of performance was February 25, 2016. There was no additional documentation available for review from June 1, 2016 through June 30, 2018 (a total of 24 months). 4. An interview with the laboratory director at approximately 12:20 PM confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of the quality assurance (QA) policy, quality control (QC) documents and interviews, the laboratory director failed to follow the written QA policy for documenting the review of the QC records to include Hematoloxylin and Eosin (H&E) stain acceptability, temperature records for the two (2) cryostat tissue-processing instruments and the fume hood maintenance for twenty-four (24) of twenty-four (24) months reviewed. Findings include: 1. Review of the QA policy revealed the following statements (no date of approval available): "All quality control (QC) records such as log sheets that have not been reviewed previously will be reviewed by the lab director or an appropriate, designated staff member every month. All QA records such as logs of test requisitions, test reports and receipt and QA of reagents and culture media that have not been reviewed previously will be reviewed by the laboratory director or an appropriate, designated staff member every month." 2. Review of the daily H&E stain acceptability QC documents, temperature records for 2 cryostat tissue-processing instruments and the fume hood maintenance revealed no

	documentation of review by the laboratory director from June 1, 2016 through June 30, 2018 (a total of 24 months). 3. An interview with the laboratory director at approximately 12:20 PM confirmed the findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, and interviews, the technical supervisor (TS) failed to perform the semi-annual competency assessment for one (1) new TP in 2018. Findings include: 1. Review of the CMS-209 Form and personnel records revealed that the laboratory director performs the duties of TS and that TP A performs the inking and grossing of tissue samples. 2. Review of TP A records revealed training and initial assessment performed in June 2017. There was no documentation of the TS performing a semi-annual competency assessment for TP A in 2017 or 2018. (See attached personnel code list.) 3. An interview with the laboratory director approximately 12:20 PM confirmed that the TS failed to perform the semi-annual competency assessment for TP A in 2018.