

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0661218	(X3) Date Survey Completed 12/13/2018
Name of Provider or Supplier Endocrinology Laboratory Of Evms Medical Group	Street Address, City, State Jones Institute - Endocrine Lab, Norfolk, 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 Endocrinology Laboratory of EVMS Medical Group on December 13, 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 deficiency cited is as follows:
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 least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, review of maintenance logs, manufacturer's operations manual, and interviews, the laboratory failed to document the performance of the Siemens immunoassay instrument's weekly, monthly, and semi-annual preventative maintenance as recommended by the manufacturer for the twenty-three (23) months reviewed. Findings include: 1. During a tour of the laboratory, the inspector noted a Siemens Immulite 1000 analyzer (Serial Number D0817) in use for patient testing. The general supervisor (GS) confirmed during the tour that the instrument was utilized to report Thyroid Stimulating Hormone (TSH), Human Chorionic Gonadotropin (HCG), Estradiol, Follicle Stimulating Hormone (FSH), Leutenizing Hormone (LH), Progesterone, Prolactin, and Testosterone. 2. Review of the laboratory's Immulite 1000 maintenance logs from January 2017 to the date of the survey 12/13/18 revealed the following required maintenance procedures: - cleaning the fan filter listed as "perform on a weekly basis". The inspector noted that the cleaning was not documented in the following four (4) weeks in calendar year 2018: 09/09/18 to 09/15/18, 09/23/18 to 0929/18, 11/04/18 to 11/10/18, 11/11/18 to 11/17 /19. - "replace small syringe tip" and "change substrate spike" listed as "perform every</p>

month". The inspector noted no documentation that the two (2) monthly procedures were performed during the 23 months reviewed. - "replace large syringe tip/whole plunger assembly" and "replace in-line filters" listed as perform "twice annually". The inspector noted no documentation that the 2 semi-annual procedures were performed during the 23 months reviewed. The inspector requested to review documentation for performance of the five (5) required maintenance procedures for the periodic timeframes outlined above. No additional records were available for review. 3. Review of the manufacturer's Immulite 1000 Operations Manual revealed a maintenance section and instructions of the required maintenance listed above and the following statement recommendation: "The Immulite 1000 Automated Immunoassay System is a continuous, random access instrument that performs automated chemiluminescent immunoassays. Optimal performance relies on daily, weekly, monthly, semi annual and as needed preventative maintenance items being performed. Please perform and utilize the maintenance worksheets in Appendix G". 4. In an interview with the lab director and GS at approximately 3:45 PM, it was confirmed that the laboratory failed to document required weekly, monthly and semi-annual periodic maintenance per the manufacturer's recommendation as outlined above in calendar years 2017 and 2018.