

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0670586	(X3) Date Survey Completed 03/23/2018
Name of Provider or Supplier Fairfax County Health Dept Laboratory	Street Address, City, State 10310 Layton Hall Drive, Fairfax, 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 Fairfax County Health Department Laboratory on March 22 - 23, 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:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Laboratory Personnel Report Form (CMS 209), procedure and policy manual, laboratory personnel files, and interviews, the laboratory did not establish and follow a policy for the technical consultant's competency assessment in calendar years 2016 and 2017. Findings include: 1. Review of the CMS 209, revealed that Testing Personnel A serves as Technical Consultant (TC). (See Personnel Code Sheet) 2. Review of the laboratory procedure and policy manual revealed no protocol outlining documentation of the competency assessment of the laboratory's TC. 3. Review of the personnel files revealed that the laboratory director (LD) failed to document competency assessments in 2016 and 2017 for Testing Personnel A in the role of TC. 4. In an interview with the LD at approximately 11:30 AM on 3/22/18, and with the TC and nurse manager at approximately 2:30 PM on 3/23/18, it was confirmed that laboratory director did not document competency assessment for the TC in calendar years 2016 and 2017.</p>
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on a review of manufacturer's package inserts, instrument quality assurance (QA) protocols and logs, and interviews, the laboratory failed to follow the manufacturer's instructions for Aptima Gen-Probe specimen test contamination monitoring protocols for ten (10) of fourteen (14) months reviewed. Findings include: 1. Review of the Panther Aptima package inserts revealed a Lab Contamination Monitoring Protocol that stated "Many laboratory specific factors may contribute to contamination and should be taken into consideration when contamination monitoring frequency is established. Intervals for contamination monitoring should be established in the laboratory's practice and procedures". 2. Review of the laboratory's Panther instrument QA protocol revealed a contamination and monitoring log sheet that stated "a total of 14 environmental samples will be run each month as required with normal patient testing". The inspector noted that the following environmental samples were outlined for monitoring: Immunology accessioning bench, Aptima room light switch, computer keyboard, reagent prep bench, sample prep bench, Panther computer screen, Panther reagent door, Panther sample door, Panther Target Capture Reagent door, Panther Left Tip drawer, Panther Right Tip drawer, Panther MTU drawer, Panther Fluid drawer, and Panther Waste drawer. The inspector reviewed the laboratory's Gen-Probe Aptima Panther Monthly Environmental Control Logs from January 2017 to the date of the survey on March 23, 2018. The inspector noted that there was no documentation of the QA protocols for the following months: 2017- January, February, March, April, May, June, July, October, and November; 2018- February. The inspector requested to review the QA logs. The laboratory technical consultant (TC) and general supervisor (GS) stated, on 3/23/18 at approximately 1:00 PM, that the lab had experienced a staffing turnover and that the contamination protocols had been overlooked during the transition. No records were available to review. 3. In an interview with the nurse manager, TC, and GS on 3/23/2018 at approximately 2:30 PM, it was confirmed that the laboratory failed to follow the manufacturer's Aptima Gen-Probe instructions for test contamination monitoring protocols in ten (10) of fourteen (14) months reviewed, while reporting patient test panels on the Panther analyzer as outlined above.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

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 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 laboratory tour, review of manufacturer's user guide, the laboratory procedure and policy manual, equipment maintenance records, patient test logs, and

an interview, the laboratory failed to follow the Biorad Evolis immunology analyzer's monthly maintenance protocols four (4) of twenty-four (24) months reviewed in calendar years 2016 and 2017. Findings include: 1. During a laboratory tour, the inspector noted a Biorad Evolis System analyzer (Serial Number 9163700330R) in use for patient immunology panel testing that include: Hepatitis (Hepatitis B Surface Antibody, Hepatitis B Surface Antigen, Hepatitis B Core Antibody), Human Immunodeficiency Virus Panel (HIV 1/2 Combo), and Syphilis. 2. Review of the Evolis analyzer user guide revealed five (5) required monthly maintenance protocols. The user's guide states: "monthly maintenance procedures should be performed monthly to ensure ongoing trouble-free operation". The manufacturer's guide outlined the following required monthly protocols: Disinfect the System Liquid Container, Pipette, and Wash Module (make fresh wash solution and replenish the water after clean), Disinfect the Sample and Reagent Racks, Clean the Plate Transport Area and Room Temperature Incubators, Inspect the Reagent Racks, Clean the Washer Plate Sensor. 3. Review of the laboratory's procedure and policy manual revealed a written quality assurance (QA) policy that stated "all instrument maintenance will be performed as required". 4. Review of the laboratory's 2016 and 2017 Evolis analyzer maintenance records revealed no documentation of the required monthly maintenance protocols in January 2016, December 2016, February 2017, and October 2017. The inspector requested to review the maintenance documentation for the four (4) months listed above. No documentation was available for review. 5. In an interview with the nurse manager, technical consultant, and general supervisor on 3/23/18, at approximately 2:30 PM, it was confirmed that the laboratory failed to follow the Biorad Evolis System analyzer's monthly maintenance protocols for the months outlined above in 2016 and 2017.