

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2106069	(X3) Date Survey Completed 04/26/2018
Name of Provider or Supplier Inova Laboratories At Fair Oaks	Street Address, City, State 3580 Joseph Siewick 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 Inova Laboratories at Fair Oaks on April 26, 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:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records, a total of fifteen (15) events, and interviews, the laboratory failed to rotate proficiency testing among the personnel performing patient testing from calendar year 2016 to the date of the survey, on 4/26/18. Findings include: 1. Review of the CMS 209 laboratory personnel form revealed a total of three (3) laboratory testing personnel were listed as performing patient testing. (See attached Testing Personnel Code Sheet) 2. Review of the laboratory's 2016, 2017, and to date 2018 College of American Pathologists (CAP) hematology, chemistry, and coagulation PT documentation revealed that testing personnel A performed fifteen (15) of fifteen (15) events reviewed. 3. In an exit interview with the laboratory director and technical supervisor on 4/26/18 at approximately 4:00 PM , it was confirmed that the laboratory failed to rotate PT among all personnel responsible for performing patient hematology, chemistry, and coagulation testing for the events and timeframe outlined above.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p>

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's proficiency testing (PT) documentation, and an interview, the laboratory failed to retain documentation of the Abbott iSTAT analyzer results for ten (10) of ten (10) PT events reviewed. Findings include: 1. Review of the laboratory's 2016, 2017, and to date 2018 College of American Pathologists (CAP) chemistry and coagulation PT results, a total of ten (10) events, revealed no Abbott iSTAT instrument result print outs were retained for: 2016 WP3 Event C, 2016 AQ3 Event C, 2017 WP3 Event A, 2017 AQ3 Event A, 2017 WP3 Event B, 2017 AQ3 Event B, 2017 WP3 Event C, 2017 AQ3 Event C, 2018 WP3 Event A, 2018 AQ3 Event A. The inspector requested to review the analyzer result print outs for the PT events listed above. No documentation was available for review. 2. In an exit interview with the laboratory director and technical supervisor on 4/26/18 at approximately 4:00 PM , it was confirmed that the laboratory failed to retain the Abbott iSTAT analyzer printed results for the PT events outlined above in calendar years 2016, 2017, and 2018.

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 policies, maintenance records, and an interview, the laboratory failed to document maintenance protocols for one (1) variable volume single channel pipette located in the hematology area in calendar years 2016 and 2017. Findings include: 1. During a lab tour on April 26, 2017 at approximately 2:00 PM, the inspector noted the following variable volume single channel pipette in the hematology specimen processing area: Fisherbrand 20-200 ul - Serial Number (SN) 23941. 2. Review of the laboratory's policies revealed a protocol that outlined annual pipette calibration requirements to verify accuracy of the device. 3. Review of the available maintenance records from 2016 to the date of the survey revealed one pipette calibration record for the Fisherbrand SN 23941 (calibration dated 4/6/18). The inspector requested to review the pipette calibration records for 2016 and 2017.

No other pipette documentation was available for review. 4. In an interview with the laboratory director and technical supervisor on 4/26/18 at approximately 4:00 PM, it was confirmed that the laboratory failed to document maintenance protocols for the hematology pipette as outlined above in calendar years 2016 and 2017.