

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2106069	(X3) Date Survey Completed 04/02/2024
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 2, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The specific deficiency cited is as follows:
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, laboratory policy and procedure manual, lack of documentation, and interview, the technical supervisor failed to follow established policy and perform annual competency assessment evaluations for one (1) of one new testing personnel responsible for performing high complexity testing in Chemistry and Hematology in calendar year 2023. The findings include: 1. Review of the CMS 209 form revealed Testing Personnel (TP) A performed high complexity testing. 2. Review of TP A's personnel file revealed TP A was hired and completed initial training/competency in 12/2022 (See Personnel Code Sheet). Further review revealed TP A's file contained a semi-annual competency performed on 6/23/2023. The personnel file lacked documentation of a 2023 annual competency. The surveyor requested to review documentation of TP A's 2023 annual competency. The laboratory provided no documentation to review. 3. Review of the laboratory's policy and procedure manual revealed a policy, "ILS Personnel Competency Policy", with the statement "The competency of personnel performing</p>

non-waived testing is assessed prior to the initiation of independently performing testing, semi-annually during the first year of testing-first assessment within 7 months from initiation of testing and second assessment no later than 12 months from the start of testing during the first year an individual tests patient specimens (new employees)..." 4. In an interview with the technical supervisor on April 2, 2024 at approximately 10:00 AM, the findings were confirmed.