

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0232897	(X3) Date Survey Completed 10/11/2022
Name of Provider or Supplier F Read Hopkins Pediatric Assoc	Street Address, City, State 1212 Mcconville Rd, Lynchburg, 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 validation survey was conducted at F. Read Hopkins Pediatric Associates October 11, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel records, lack of documentation, and interviews, the technical consultant (TC) failed to document performance of semiannual competency assessment for one of one new laboratory testing personnel (TP) during the twenty-two months reviewed (timeframe: December 2020 to the date of the validation survey on October 11, 2022). *See Personnel Code Sheet. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) identified three (3) TP responsible for non waived patient Hematology Complete Blood Count (CBC), Chemistry Neonatal Bilirubin, and Microbiology Culture (throat /urine) analysis/reporting of test results. During the review of the CMS 209 with the technical consultant (TC) on 10/11/22 at approximately 1:00 PM, the TC stated, "We have one new testing personnel since our last COLA inspection. The new staff member's start date was December 1, 2020." 2. Review of the laboratory personnel records revealed initial training for the new personnel, TP A, was initiated in December 2020. The inspector requested to view semiannual competency assessment</p>

documentation for TP A. The lead testing personnel stated on 10/11/22 at approximately 3 PM, "We are in the process of completing the assessment documentation. We were overwhelmed during the COVID pandemic and failed to complete the semiannual competency assessments as planned." 3. An exit interview with the TC and lead testing personnel on 10/11/22 at approximately 3:30 PM confirmed the above findings.