

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2263144	(X3) Date Survey Completed 08/14/2024
Name of Provider or Supplier Ppd-Part Of Thermo Fisher Scientific	Street Address, City, State 8700 Quioccasin Road, Richmond, 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 the PPD-Part of ThermoFisher Scientific on 08/14/24 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 the review of the Laboratory Personnel Report Form (CMS-209 Form), policy and procedures (P&P), personnel records, lack of documentation and interview, the laboratory failed to establish a competency assessment policy to evaluate personnel performing job duties for one of one technical supervisor (TS) and two of two general supervisor (GS) listed on the CMS-209 Form at the date of survey on 08/14/24. Findings include: 1. Review of the CMS-209 Form revealed one TS (TS#1) and two GS (GS#1 and GS#2). 2. Review of P&P revealed lack of documentation of an established policy for performing competency assessments of personnel performing job duties of TS and GS. The inspector requested a policy that defined competency assessment(s) for individuals that held supervisory positions of TS and GS. The documentation was not available for review. 3. Review of personnel records revealed TS#1 performed and signed the competency assessments for GS#1 and GS#2 on 11/17/22 and 08/13/24. There was no competency assessment available for review for the calendar year 2023 for GS#1 and GS#2. The personnel records lacked documentation of a competency assessment for TS#1 for the calendar year of 2023 and up to the date of survey on 08/14/24. 4. An exit interview with the TS and Quality Assurance personnel on 08/14/24 at 13:00 confirmed the findings.</p>

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), laboratory personnel records, and interview, the laboratory director failed to delegate, in writing, the job duties and responsibilities of one of one technical supervisor (TS) from 09/09/22 up to the date of the survey on 08/14/24. Findings include: 1. Review of the CLIA CMS-209 Form revealed one TS (TS#1). 2. Review of personnel records revealed lack of documentation of delegation of duties, in writing, by the laboratory director to the TS#1. The inspector requested to review the delegation of duties. The document was not available for review. In an interview with the TS#1 on 08/14/24 at 12:45, they stated, "the date we began patient testing was on 09/09/22." 3. An exit interview with the TS#1 and Quality Assurance personnel on 08/14/24 at 13:00 confirmed the findings.