Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2263144	02/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ppd-Part Of Thermo Fisher Scientific	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 initial survey was conducted at PPD-Part of ThermoFisher Scientific on February 22-23, 2023 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 and includes the Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of policies and maintenance records, Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments Certification form, tour, review of assay run records, analyzer performance verification records, lack of documentation, and interviews, the laboratory failed to: 1. follow an established water quality policy for daily water quality mOhm resistivity monitoring for four (4) of 4 months reviewed (timeframe November 2022 to 2/22/23); 2. document laboratory director approval/review of updated written procedures for high performance liquid chromatography-mass spectrometry (HPLC-MS) Apixaban quantitation testing after a physical move into a new facility as of the date of the initial inspection 2/22/23-2/23 /23; and 3. document an evaluation/verification of accuracy and precision for two

	Sciex API Apixaban testing methods after a physical move/installation to a new facility from November 2022 of the date of the inspection 2/22/23-2/23/23. SEE D5401, D5407, D5421.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of policies and maintenance records, lack of documentation, and interviews, the laboratory failed to follow an established water quality policy for daily water quality mOhm resistivity monitoring for four (4) of 4 months reviewed (timeframe November 2022 to 2/22/23). Findings include: 1. Review of the laboratory's Standard Operating Procedures (SOP) revealed a "Water Quality Testing" (SOP Number CLIA PAL 230) that stated "This SOP describes the process for checking the quality of the sterile water produced by the Milli-Q water purification system. Daily Resistivity Check will be recorded at the start of each workday. The Milli-Q pump should be allowed to run until the resistivity reaches 16 Megohm-cm. If the resistivity does not reach the designated value, water from another source should be used until the problem can be fixed. Notify the CLIA Technical Supervisor if resistivity problems exist." 2. Review of the laboratory's Water Quality Monitor Maintenance logs (review timeframe 11/1/22 to 2/22/23) revealed no daily resistivity check records. The inspector requested to review the water quality testing maintenance documentation noted above. The General Supervisor (GS) provided records for monthly microbial testing on 2/23/23. No records for water quality mOhm resistivity monitoring were provided. 3. Interviews with the Technical Supervisor on 2 /22/23 at approximately 3:30 PM and GS on 2/23/23 at approximately 4:00 PM confirmed the above findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments Certification form (CMS 116), tour, review of policies, and an interview, the laboratory director (LD) failed to document review/approval of updated written procedures for high performance liquid chromatography-mass spectrometry (HPLC-MS) Apixaban quantitation after a physical move into a new facility as of the date of the initial inspection on February 22-23, 2023. Findings include: 1. A pre-inspection review of the laboratory's initial inspection submitted CMS 116 form revealed a physical address as 8700 Quiocassin Road in Richmond, Virginia. The LD indicated on the CMS 116 form performance of two high complexity HPLC-MS test platforms for Apixaban quantitation utilizing Sciex API 4000/5000 analyzers. 2. During a tour of the facility on 2/22/23 at approximately 1

	PM, the inspector made an inquiry regarding Apixaban specimen receiving/processing /storage. The technical supervisor (TS) and general supervisor (GS) stated that humidity monitored specimen storage for the dried blood samples for Apixaban testing had been modified after the move into the new laboratory facility. The TS stated in 2/22/23 at approximately 3 PM, "We have identified a cabinet for the sample storage so that humidity can be monitored. I am planning to get the LD in soon to review and sign all the new updates." 3. Review of the laboratory's available policies revealed protocol/procedures for two high performance liquid chromatography-mass spectrometry (HPLC-MS) Apixaban quantitation methods approved for PPD Development, LC located at 2244 Dabney Road in Richmond, Virginia. The inspector inquired regarding LD's approval/signature for updated procedures for the new laboratory facility at 8700 Quiocassin Road in Richmond, Virginia. No documentation was available for review. 4. Interviews with the TS on 2/22/23 at approximately 3:30 PM and general supervisor on 2/23/23 at approximately 4:00 PM confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments Certification form (CMS 116), tour, review of assay logs, analyzer performance verification records, lack of documentation, and an interview, the laboratory failed to document an evaluation/verification of accuracy and precision for their Sciex API Apixaban testing after a physical move/installation in a new facility from November 2022 of the date of the inspection on February 22-23, 2023. Findings include: 1. In a pre-inspection review of the laboratory's initial inspection CMS 116 form, the inspector noted the physical address as 8700 Quiocassin Road in Richmond, Virginia. The laboratory director (LD) indicated on the CMS 116 form performance of two high performance liquid chromatography-mass spectrometry (HPLC-MS) test platforms for Apixaban quantitation utilizing Sciex API 4000/5000 analyzers. 2. During a tour on 2/22/23 at approximately 1:00 PM, the inspector inquired of the timeframe of the Sciex API 4000/5000 validation studies in the new facility. The technical supervisor (TS) stated: "We moved from previous location into this new building last year and had some delays, but the validation was done in November 2022." 3. Review of the two Apixaban methods' assay logs revealed a set of runs for accuracy were assayed in the following timeframes: Apixaban Method 733.1 on 11/4/22; Apixaban Method 733 1.01 on 1/4/23-1/9/23. The inspector requested to review records of a LD evaluation/review/approval for the performance specification verification records outlined above. No records were available for review. 4. Review of the available protocols/policy manuals revealed a LD's approved /evaluation of the Sciex API 4000/5000 HPLC-MS Apixaban quantitation verification documented in 2021 while the analyzer's were located at 2244 Dabney Road in Richmond, Virginia. The inspector requested to review an assessment of the

	performance verification after the test systems were relocated to 8700 Quiocassin Road in Richmond, Virginia. The record was not available for review. 5. Interviews with the TS on 2/22/23 at approximately 3:30 PM and general supervisor on 2/23/23 at approximately 4:00 PM confirmed the above findings
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on the review of the laboratory's Centers for Medicare and Medicaid Services (CMS) 116 form, twenty (20) randomly selected Apixaban test reports, and interviews, the laboratory's test reports failed to include the performing facility address during the timeframe of November 2022 to the date of the inspection on February 22-23, 2023. Findings include: 1. Review of the laboratory's CMS 116 form revealed a physical facility location address that was confirmed by the inspector as 8700 Quiocassin Road in Richmond, Virginia. The LD indicated on the CMS 116 form performance of two high complexity high performance liquid chromatography-mass spectrometry test platforms for Apixaban quantitation utilizing Sciex API 4000 /5000 analyzers. 2. Review of 20 randomly selected patient reports for Apixaban quantification assayed between November 1, 2022 and February 22, 2023 revealed no field category on the reports for performing lab name/address. The inspector noted that the patient reports included an attachment statement: "Data file uploaded by Data Manager (Eastern Time), Clinical Research, Chromatographic Services Department, PPD, part of Thermo Fisher Scientific, 2244 Dabney Rd Richmond, VA, 23230, USA." 3. The inspector inquired regarding if chromatographic instrument printed reports for the 20 random Apixaban results included the performing laboratory name. The review of chromatographic instrument printed reports revealed that they did not include the correct laboratory address. No version of the 20 randomly selected reports were available that included the performing laboratory address during the timeframe of November 2022 to the date of the inspection on February 22-23, 2023 . 4. Interviews with the technical supervisor (TS) on 2/22/23 at approximately 3:30 PM and a follow up interview with TS and general supervisor on 2/27/23 at approximately 4:00 PM confirmed the above findings.