Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2137167	05/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Thrombosis Research Laboratory	3300 Gallows Road, Ihvi, 3rd Floor, Falls Church, 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 Thrombosis Research Lab on May 2, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and an interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to sign two (2) of two (2) PT attestation statements during calendar year 2018. Findings include: 1. Review of the College of American Pathologists (CAP) records for 2018 revealed the following: 2018 CAP PF-B Platelet Aggregation attestation not signed by LD; and 2018 CAP PIA-B Drug specific Platelet Aggregation attestation statement not signed by LD. 2 of 2 attestation statements were not signed by the Laboratory Director. 2. In an exit interview at approximately 1:45 PM, the TC confirmed the above findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and an interview with the Technical Consultant (TC), the laboratory failed to verify the accuracy of platelet aggregation performed on the Chrono-Log Aggregometer and drug-specific platelet aggregation performed on the Accriva VerifyNow analyzer twice annually in calendar year 2017 and 2018. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) PT documentation, a total of two (2) events in 2018, revealed the laboratory utilized PT enrollment to verify the accuracy of platelet aggregation testing on the Chrono-Log Aggregometer and drug-specific platelet aggregation on the VerifyNow. Review of the 2017 and 2018 CAP PT reports revealed: a lack of documentation of PT participation in 2017; participation in the CAP 2018 Event Platelet Aggregation PF-B, and CAP 2018 Drug Specific Platelet Aggregation PIA-B. The surveyor requested documentation of the twice annual accuracy verification for 2017 and documentation of an additional verification in 2018 for platelet aggregation and drug specific platelet aggregation. The laboratory did not provide documentation for review. 2. In an exit interview with the TC and Testing Personnel A (TPA) at approximately 1:45 PM, the TC confirmed the findings.
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 the laboratory's policy and procedure manual, Quality Control records, Quality Assessment records, instrument maintenance records, instrument validation records, and interviews, the laboratory failed: to verify the reportable and normal ranges of the ChronoLog Platelet Aggregometer and VerifyNow PRU test (D5421); to perform and document instrument maintenance (Cross Reference D5429); perform two levels of quality control each day of patient testing for the ChronoLog Platelet Aggregometer and VerifyNow PRU test (Cross Reference D5447 A and B); and address analytic failures in the quality assessment system (Cross Reference D5791).
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: A. Based on review of the instrument validation records, lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to verify the reportable range and normal range (reference range) for platelet aggregation performed on three ChronoLog Platelet Aggregometer 490s prior to testing patients. Record review was from September 7, 2017 until May 2, 2019. Findings include: 1. Review of initial performance verification records for the ChronoLog Platelet Aggregometer analyzers revealed the following: Serial number 2170060 installed 9/7 /17. Accuracy, precision and calibration performed on 9/7/17. Serial number 2170060-01 installed 9/7/17. Accuracy, precision and calibration performed on 9/7/17. Serial number 2180010 installed 8/15/18. Accuracy, precision and calibration performed 1/20 /19. The surveyor requested to review additional verification documentation of the reportable range and reference ranges for each of the above-specified analyzers. The laboratory provided no documentation for review. 2. In an exit interview with the TC and Testing Personnel A (TP A) at approximately 1:45 PM, the TC confirmed the findings. B. Based on review of the instrument validation records, lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to verify the reportable range and normal range (reference range) for drug-specific platelet aggregation PRU (P2Y12) testing performed on the Accriva VerifyNow analyzer prior to testing patients. Dates of record review was from September 7, 2017 until May 2, 2019. Findings include: 1. Review of initial performance verification records for the Accriva VerifyNow PRU test revealed the analyzer (serial number 7235) was installed on 3/5/18. The laboratory performed accuracy, precision and calibration on 3/5/18. The surveyor requested to review additional verification documentation of the reportable range and reference ranges for the VerifyNow PRU test. The laboratory provided no documentation for review. 2. In an exit interview with the TC and Testing Personnel A (TP A) at approximately 1:45 PM, the TC confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the review of the Chrono-Log Platelet Aggregation Procedure, available maintenance documentation, and an interview with the Technical Consultant (TC), the laboratory failed to follow the laboratory's Chrono-log Platelet Aggregation Procedure for performing and documenting instrument maintenance procedures for twelve (12) of twenty-one (21) months from August 1, 2017 to May 2, 2019. 1. Review of the Chrono-Log Platelet Aggregation Procedure revealed the following statements: "A. Daily Maintenance a. Clean Instrument surface with a soft, lint-free cleaning cloth of debris and residual fluids. b. Ensure stir bar speed is set to 1200 RPMs and incubation wells reach 37C. c. Turn off the aggregometer daily after each use. B. Quarterly Maintenance a. Perform optical auto-calibration check procedure. b. Clean aggregometer: Turn of the Aggregometer and any attached peripherals. Disconnect them from the Aggregometer. Unplug the instrument before cleaning to prevent a shock hazard. Use a vacuum cleaner to remove any dust from the slots and holes in the Aggregometer. c. Stirring Motor Speed Check: Visually check the stirring bar by placing an empty cuvette with stir bar into the sample well. Check that the stir bar is

	rotating. C. Annual Maintenance: a. Yearly calibration will be performed by the manufacturer by a factory authorized representative. 2. Review of the available maintenance documentation from 8/1/17 to 5/2/19 revealed a lack of documentation of the daily and quarterly maintenance performed by testing personnel on the Chrono-log Platelet Aggregometers from August 1, 2017 to August 1, 2018. A total of 12 months. The surveyor requested documentation of the daily and quarterly maintenance for the Chrono-Log Platelet Aggregometer from the laboratory. The laboratory provided no documentation for review. In an interview with the TC at approximately 10:30 AM, the TC stated "We do not have the maintenance from August 2017 until August 2018. We discovered the lack of maintenance and have a corrective action plan in place" 3. In an exit interview with the TC and Testing Personnel A (TP A) at approximately 1:45 PM, the TC confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on the review of the Chrono-Log Platelet Aggregation procedure, quality control (QC) records, patient records and interview with the Technical Consultant (TC), the laboratory failed to perform QC procedures each day of patient testing for the Chrono-Log Platelet Aggregometer for ten (10) of fourteen (14) days from March 1, 2019 to April 30, 2019 when performing testing for fourteen (14) patients Findings include: 1. Review of the Chrono-Log Platelet Aggregation procedure revealed the following: "VII. Quality Control B. Bi-weekly Quality Control a. Run quality control once in two week (biweekly)." 2. A random review of the Chrono-log Platelet Aggregation QC documentation and patient records from March 1, 2019 to April 30, 2019 (a total of 14 days of testing) revealed the laboratory failed to perform QC while reporting patients on: 03/07/19 Medical Record number (MR#) 20257327; 03/08/19 MR# 20257327; 03/13/19 MR# 01909470 and 4162795; 03/19/19 MR# 04435891 03 /25/19 MR# 00798659; 03/26/19 MR# 04299539, 00798659, 03657671; 04/08/19 MR# 01909470; 04/16/19 MR# 04435891; 04/22/19 MR# 00798659, 03657671; 04/24 /19 MR# 04299530. A total of 10 days with no QC and 14 patients reported. The surveyor requested QC documentation for the above listed dates when the laboratory did not perform QC while reporting 14 patients. The laboratory provided no documentation to review. The surveyor asked the TC if they had developed an Individual Quality Control Plan (IQCP). In an interview with the TC at approximately 12:45, the TC stated "We perform QC bi-weekly and do not have an IQCP. We perform approximately one thousand (1000) patients per year." 3. In an exit interview with the TC and Testing Personnel A at approximately 1:45 PM, the TC confirmed the findings. B. Based on the review of the VerifyNow PRU Test procedure, quality control (QC) records, patient records and interview with the Technical Consultant, the laboratory failed to perform QC procedures each day of patient testing for the VerifyNow PRU Test for twenty-seven (27) of twenty-nine (29) days from July 1, 2018 to September 6, 2018 when performing testing for forty-six (46) patients. Findings include: 1. Review of the VerifyNow PRU test revealed the following: "V. Performing Quality Control-Wet Quality Control (WQC) is intended to be used with a

	diluent and an assay device as a basis for quantitative quality control. Specifically, the WQC measures two levels of turbidimetric signal that verify the dynamic range of the instrument. One of these signals is at the level that would be observed in a subject with a minimal amount of platelet aggregation (Level 1), and the other represents a subject who demonstrates a significant amount of aggregation (level 2). Both WQC controls should be run to ensure the instrument and test devices are working properly prior to beginning the project. The specific lot ranges will be on the test device packages. These ranges must be scanned onto the instrument if if is the first time using that specific lot. The instrument will automatically require scanning of the barcode when a new lot is inserted onto the instrument. Level 2 controls should be tested to insure each new lot of test devices or an alternate shipment of the same lot, have not been compromised." 2. A review of the VerifyNow PRU Test QC documentation and patient records from July 1, 2018 to September 6, 2018 (a total of 27 days of testing) revealed the laboratory failed to perform QC while reporting patients on: 07/03/18 Medical Record number (MR#) 01612908; 07/05/18 MR# 02428415; 07/06/18 MR# 00900779; 07/09/18 MR# 01956524, 03774569; 07/10/18 MR# 01612908, 02428415; 07/11/18 MR# 01612908, 02428415; 07/12/18 MR# 00900779, 01956524; 07/13/18 MR# 00900779, 01956524; 07/16/18 MR# 03774569, 04061075, 02921003; 07/17/18 MR# 03774569, 01938221; 07/19/18 MR# 04061075, 02921003, 04165132; 07/20/18 MR# 02921003, 08006088; 07/23/18 MR# 02324897; 07/25/18 MR# 01938221, 04165132, 01393805; 07/26/18 MR# 08006088, 02324897; 07/27/18 MR# 08006088, 02324897; 07/31/18 MR# 03811004, 30483352; 08/07/18 MR# 01919759; 08/08/18 MR# 01919759; 08/10/18 MR# 01612908; 08/13/18 MR# 02428415, 00900779; 08/15/18 MR# 01956524, 03774569; 08/21/18 MR# 02921003; 08/24/18 MR# 01938221, 04165132; 08/29/18 MR# 08006088; 08/30/18 MR# 02324897; and 09/06/18 MR# 01919759. A total of 27 days with no QC and 46 patients reported. The surveyor requested QC documentation for the above listed dates when the laboratory did not perform QC while reporting 46 patients. The laboratory provided no documentation to review. The surveyor asked the TC if they had developed an Individual Quality Control Plan (IQCP). In an interview with the TC at approximately 1:00 PM, the TC stated "We perform internal QC each day of testing and Wet QC once a month or new lot number of device. We do not have an IQCP." 3. In an exit interview with the TC and Testing Personnel A at approximately 1:45 PM, the TC confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of the laboratory's "Quality Plan", instrument maintenance records, and instrument validation records, and an interview with the Technical Consultant (TC), the current quality assurance policy failed to identify and address failures in the analytic phase for the specialty of Hematology (Cross Reference D5421 and D5429). Findings include: 1. Review of the "Quality Plan", signed by the Lab Director in May 1, 2018 and April 23, 2019 revealed the following statements: "Instrument Maintenance-All maintenance will be performed in accordance with manufacturers or laboratory guidelines. Appropriate log sheets will be completed

	(initialed or checked) to confirm that tasks were completed. Supervisory personnel will check logs at least monthly." "Method Performance Specifications-For all new, moderate, or high complexity testing implemented, the following parameters will be evaluated and documented prior to initiation of patient testing: Analytic accuracy and precision; Reportable range of patient test results." 2. The laboratory lacked documentation of the ChronoLog Platelet Aggregrometer maintenance performance from August 1, 2017 until August 1, 2018 (Cross Reference D5429). 3. Review of the laboratory's instrument validation records for the ChronoLog Platelet Aggregometer and VerifyNow PRU Test revealed no verification documentation of the reportable range and normal (reference) range for each instrument (Cross Reference D5421). 4. An exit interview with the TC and Testing Personnel A (TP A) at approximately 1:45 PM, the TC confirmed the findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, Quality Control (QC) records, Quality Assessment (QA) records, instrument validation records, maintenance records and interviews, the Laboratory Director (LD) failed: to ensure two levels of QC were performed each day of patient testing (Cross Reference D6020); and to ensure the current QA policy could identify and address failures in the analytic phase for the specialty of Hematology (Cross Reference D6021).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, Quality Control (QC) records, and interviews, the laboratory director failed to ensure two levels of quality control were performed each day of patient testing for the ChronoLog Platelet Aggregometer and VerifyNow PRU test (Cross Reference D5447).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy and procedures, Quality Control (QC) records, instrument maintenance records, instrument validation records, and an interview with the Technical Consultant (TC), the laboratory director failed to ensure the current Quality Assurance policy could identify and address failures in the analytic phase for the specialty of Hematology (Cross Reference D5791).