Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2051292	05/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Anesthesiology Coagulation Laboratory	111 South 11th Street, Philadelphia, PA	

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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on review of records, interview of the laboratory director (LD), testing personnel (TP) #1 and #2, the laboratory failed to establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) for Clotting Time testing performed in 2018. Findings Include: 1. On the day of survey, 05/29/2019, the LD stated the laboratory was enrolled in College of American Pathologists (CAP), but was unable to provide proficiency testing (PT) documentation or any other documents regarding demonstration of accuracy for clotting Time in 2018. 2. CAP was contacted Wednesday, May 29, 2019 at 1:42 PM to verify the laboratory's enrollment. The contact stated, " The Thomas Jefferson University Hospital Anesthesia Coagulation Laboratory in Philadelphia did not purchase CAP PT in 2018. 3. In 2018, 1300 clotting time patient tests were analyzed. 4. The LD was contacted by email and phone on Thursday, May 30, 2019 at 7:25 AM to confirm the findings above.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: Based on review of records, interview of the laboratory director (LD), testing personnel (TP) #1 and #2, the laboratory failed to verify the accuracy of Clotting Time tests performed when the laboratory did not receive scores from the College of American Pathologists proficiency testing agency in 2017. Findings Include: 1. On the day of survey, 05/29/2019, the LD stated the laboratory was enrolled in CAP, but were unable to provide PT documentation or any other documents demonstrating the accuracy of clotting time testing performed in 2017. 2. CAP was contacted Wednesday, May 29, 2019 at 1:42 PM to verify the laboratory's enrollment. The contact stated, " The Thomas Jefferson University Hospital Anesthesia Coagulation Laboratory in Philadelphia was last enrolled in CAP PT in 2017. 3. Review of the 2017 the CAP PT records revealed: - Event A: The laboratory did not receive scores, rather received educational Challenge codes. - Event B: Results for this kit were not received. 4. The laboratory did not verify the accuracy of the 2017 events A and B that were not graded. 5. In 2017 (09/07/2017 to 12/31/2017) 425 clotting time patient tests were analyzed. 6. The LD was contacted by email and phone on Thursday, May 30, 2019 at 7:25 AM to confirm the findings above.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of records, interview with the laboratory director (LD), testing personnel (TP) # 1 and #2, the laboratory failed to have a written or electronic request for patient clotting time tests ordered by an authorized personnel from 09/07/2017 to the date of survey. Finding Include: 1. On the day of survey, 05/29/2019, the laboratory could not provide test request forms for patient clotting time tests performed on the Rotem Delta 20 system analyzers in 2017, 2018 and 2019. 2. In 2017 (09/07/2017 to 12/31/2017) 425 clotting time patient tests were analyzed. 3. In 2018, 1300 clotting time patient tests were analyzed. 4. In 2019 (01/01/2019 to 05/29 /2019) 455 clotting time patient tests were analyzed. 5. On 05/29/2019 around 9:50 am, the LD confirmed test request were not documented.
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: Base on review of maintenance records, observation of instrumentation, interview with the laboratory director (LD), testing personnel (TP) #1 and #2, the laboratory failed to perform and document maintenance defined by the manufacturer for 2 of 2 Rotem eLine pipettes, 2 of 2 Rotem Delta 20 system analyzers and 1 of 1 Fisher Scientific Thermometers from 09/07/2017 to the date of survey. Finding Include: 1. The Rotem Manufacturer manual (yearly maintenance section) states " Maintenance

	of the Rotem Delta system must be performed on a yearly basis by authorized service personnel. Please contact your local service provider for yearly maintenance or ask for a maintenance contract". 2. The Rotem Manufacturer manual (functional checks of the Rotem eLIne pipette section) states " Check the Rotem eLine pipette, e.g. every 6-12 months for accuracy and precision, regularly, accordingly the internal regulations (complying with ISO08655)". 3. The Fisher Scientific Thermometer, ISO document stated calibration to be performed every 2 years". 4. On the day of survey, 05/29 /2019, review of laboratory documents and manufacturers documents revealed, the laboratory did not perform the following maintenance: - No documentation of yearly maintenance performed for 2 of 2 Delta 20 system analyzers. - Observation of the Rotem Delta 20 system analyzer # 2591 eLine pipette, revealed a sticker on the pipette stated "calibration due on 11/2016". - Observation of the Rotem Delta 20 system analyzer # 2592 eLine pipette, revealed a sticker on the pipette stated "calibration due on 02/2017". - Observation of the Fisher Scientific Thermometer on the refrigerator, revealed a sticker on the thermometer stated "calibration due on 06/04 /2014". 5. In 2017 (09/07/2017 to 12/31/2017) 425 clotting time patient tests were analyzed. 6. In 2018, 1300 clotting time specimen patient tests were analyzed. 7. In 2019 (01/01/2019 to 05/29/2019) 455 clotting time patient tests were analyzed. 8. The LD confirmed the findings above on 05/29/2018 around 10:00 am.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of Rotem Delta 20 system analyzer records, interview with the laboratory director (LD), testing personnel #1 and #2, the laboratory failed to perform calibration at least once every 6 months on 2 of 2 Delta 20 system analyzers from 2018 to the date of survey. Findings Include: 1. On the day of survey, 05/29/2019 the laboratory could not provide documentation of calibration performed at least once every 6 months on 2 of 2 Rotem Delta 20 system analyzers used to analyze clotting

	time in 2018 and 2019. 2. In 2018, 1300 clotting time patient tests were analyzed. 3. In 2019 (01/01/2019 to 05/29/2019) 455 clotting time patient tests were analyzed. 3. The LD confirmed the findings above on 05/29/2019 around 9:50 am.
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: Based on review of quality control (QC) records, interview with the laboratory director (LD), testing personnel #1 and #2, the laboratory failed to perform external liquid QC of different concentrations, each day of patient testing for Clotting Time tests analyzed on the Rotem Delta 20 system analyzers from 09/07/2017 to the date of survey. Findings Include: 1. On the day of survey, 05/29/2019, review of the Rotem Delta 20 system analyzers QC records revealed that laboratory performed external QC on a weekly bases. 2. In 2017 (09/07/2017 to 12/31/2017) 425 clotting time patient tests were analyzed. 3. In 2018, 1300 clotting time patient tests were analyzed. 4. In 2019 (01/01/2019 to 05/29/2019) 455 clotting time patient tests were analyzed. 5. The LD confirmed the findings above on 03/07/2019 around 12:30 pm.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of records, interview with the laboratory director (LD), testing personnel #1 and #2, the laboratory failed to perform and evaluate relationship comparison studies between 2 of 2 Rotem Delta 20 analyzers in 2018 and 2019. Findings Include: 1. On the day of survey, 05/29/2019, the laboratory could not provide documentation of relationship comparison studies performed on 2 of 2 Rotem Delta 20 analyzers used to test clotting time from 2018 and 2019. 2. In 2018, 1300 clotting time patient tests were analyzed. 3. In 2019 (01/01/2019 to 05/29/2019) 455 clotting time patient tests were analyzed. 4. The LD confirmed the findings above on 05/29/2019 around 9:45 am.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),

	which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of refrigerator temperature logs, interview with the laboratory director (LD), testing personnel (TP) #1 and #2, the laboratory failed to document all corrective actions taken when acceptable refrigerator temperature (8 of 17 months reviewed) were exceeded from January 2018 to May 2019. Findings Include: 1. The Refrigerator Temperature Log under corrective action states, "Record on reverse - Record name, time and temperature. Call Maintenance and nursing supervisor and indicate this action by placing a "check mark" in column labeled accordingly. 2. Review of the refrigerator temperature logs revealed that the acceptable temperatures stated by the hospital were, 36 - 46 degree Fahrenheit. 3. The follow temperatures were exceeded and no corrective actions were documented: - 16 of 20 days in July, 2018 - Temperature below 36 degrees Fahrenheit. - 22 of 23 days in August, 2018 - Temperature below 36 degrees Fahrenheit. - 10 of 19 days in September, 2018 - Temperature below 36 degrees Fahrenheit. - 22 of 24 days in October, 2018 - Temperature below 36 degrees Fahrenheit. - 16 of 20 days in November, 2018 - Temperature below 36 degrees Fahrenheit. - 3 of 17 days in December, 2018 - Temperature below 36 degrees Fahrenheit. - 10 of 21 days in January, 2019 - Temperature below 36 degrees Fahrenheit. - 8 of 20 days in February, 2019 - Temperature below 36 degrees Fahrenheit. 4. The following ROTEM reagents were held in the refrigerator. - 1 of 1 box of ROTROL N. - 1of 1 box of ROTROL P. - 1 of 1 box of Star-Tem 20 - 1 of 1 box of Ex-Tem. - 1 of 1 box of Fib-Tem. - 2 of 2 boxes of In- Tem. - 2 of 2 boxes of Ap- Tem. - 2 of 2 boxes of Hep-Tem. 5. In 2018, 1300 clotting time patient tests were analyzed. 6. In 2019 (01/01/2019 to 05/29/2019) 455 clotting time patient tests were analyzed 7. The LD confirmed the findings above on 05/29/2019 around 9:30 am.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the CLIA ' s laboratory Personnel Report (Form CMS-209), review of Personnel Qualification records, and interview with laboratory director (LD), testing personnel (TP) #1 and #2, the laboratory failed to ensure that each individual preforming moderate complexity testing is qualified. Refer to D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the

	laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CLIA' s laboratory Personnel Report (Form CMS-209), review of Personnel Qualification records, and interview with laboratory director (LD), testing personnel (TP) #1 and #2, the laboratory failed to ensure that each individual performing moderate complexity testing is qualified. Findings Include: 1. The CMS 209 form signed by the Laboratory Director (5/08/2019), lists Individual #2, #4, #5 and #6 as TP. 2. On the day of survey, 05/29/2019, The LD could not provide education credentials for TP #2, #4, #5 and #6 who perform clotting time tests. The labortaory was given until the end of business day of 06/05/2019 to provide documentation. 3. The LD provided education credential documentation for TP#2, #4 and #5 but not TP#6 on 06/05/2019. 4. The LD was contacted by emailed Thursday, June 6th 2019 at 3:32 PM to confirm the findings above.