

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0993884	<b>(X3) Date Survey Completed</b>  08/14/2018
<b>Name of Provider or Supplier</b>  Proactive Heart And Vascular, Pllc	<b>Street Address, City, State</b>  7751 Wolf River Blvd, Germantown, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5445</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Individualize Quality Control Plan (IQCP), the liquid quality control (LQC) records, the electronic quality control (EQC) records, the patient result log sheet and interview with the laboratory liaison, the laboratory failed to follow the IQCP when liquid (LQC) results were not within acceptable limits and when the electronic quality control (EQC) was not performed and documented, in 2017 and 2018. The findings include: 1) Observation of the laboratory on August 14, 2018 at 10:30 a.m. revealed a Hemochron Signature Elite Whole Blood Microcoagulation System (serial number SE1166) in use for activated clotting time (ACT) testing. The current Hemochron ACT-LR cuvette in use is Lot C8JLR067 expiration date 6-30-19. 2) Review of the IQCP revealed, "Quality Control. A. Electronic Control (performed by testing personnel): Electronic System Verification Cartridges at the normal and abnormal range must be performed once every 8 hours on any shift during which the instrument is utilized." "Liquid Quality Control by POC Personnel or Testing Personnel: Each box of test cuvettes must be validated upon it receipt before being placed into use for patient testing. Two levels, Normal and Abnormal, are used. Both levels of direct CHECK must be acceptable prior to being placed into use. Unacceptable Results: verify cuvette expiration dates. If</p>

liquid controls are out of range, verify their expiration dates and that there are no clots. Check for instrument temperature fault. Verify proper techniques was used. Check cuvette sample size. If liquid controls are unacceptable, try new controls. If results are still unacceptable, try another box in the shipment. If results are still unacceptable, contact Technical support to check on shipping problems." 3) Review of the LQC log revealed the following: Cuvette F6JLR198 level 3 lot number B7DCA003 was not acceptable for the following dates (acceptable range 334-594) : December 1, 2016 result 304; January 3, 2017 result 301; February 2, 2017 result 322; March 1, 2017 result 308; April 1, 2017 result 310; and May 6, 2017 result 308. The in use date is not documented. No LQC for levels one and two were documented for June, July, November, December 2017 and January 2018. August 18, 2017 no cuvette lot and expiration date listed; and, LQC B7DCA003 exp 12/17 level two no value documented; August 24, 2017 two levels of LQC not acceptable: cuvette M6JLR319 exp 3/18 level 1 LQC B7DNA001 exp 4/18 result 69 (124-220) ; level 2 B7DCA003 result "out of range" (334-594). The technical consultant wrote, "no patients no testing done 11.1.17". No cuvette lot numbers and expiration dates were documented for February, March, April, May, June, July 2018, when LQC was performed acceptable and documented. 4) Review of the EQC records and patient result log sheet revealed no daily EQC documented with patient testing for the following dates: June 15, June 22, July 20, July 27, September 4, September 14 of 2017. 5) Interview on August 14, 2018 at 10:30 a.m. with the laboratory liaison confirmed the IQCP did not include reassessment for the validation of the IQCP less frequency than daily, when LQC and EQC is not within acceptable limits or performed with patient testing. The LQC cuvette lot numbers, in use dates and expiration dates were not documented/ performed/ unacceptable randomly. The EQC was not documented with patient testing.