

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0929132	(X3) Date Survey Completed 08/11/2021
Name of Provider or Supplier Riverside Cancer Specialists Of Tidewater	Street Address, City, State 1200 First Colonial Road - Suite 204a, Virginia Beach, 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 validation survey was conducted at Riverside Cancer Specialists of Tidewater and Infusion Center on August 11, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of procedures, hematology analyzer calibration records, maintenance logs, and an interview, the laboratory failed to retain documentation of calibration procedures per manufacturer's protocol in calendar year 2020. Findings include: 1. Review of the laboratory's procedure manual revealed Beckman Coulter manufacturer's user guide pages were in use for the laboratory's calibration policy which stated "calibrate at least every six months or after major maintenance of components, or when control values are consistently out of range". 2. Review of the laboratory's Beckman Coulter Ac-T Diff hematology analyzer calibration records for calendar year 2020 revealed documentation of two (2) calibration procedures</p>

performed in the month of May (dated 05/01/20 and 05/22/20). No additional 2020 calibration records were available for review. 3. Review of the hematology analyzer maintenance logs for calendar year 2020 revealed a service report dated 09/23/20 performed by a Beckman field service technician. The service report revealed that the technician was dispatched for work order (WO 02059087) for Complete Preventative Maintenance (PM-C) procedures. The field service report indicated a calibration was to be performed: "Customer is to verify by calibration". The inspector requested to review the analyzer's calibration documentation after the PM-C on 09/23/20. No additional calibration documentation was available for review for calendar year 2020. 4. An interview with the lab director at approximately 1:15 PM on 8/11/21 confirmed the above findings.