

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2134371	(X3) Date Survey Completed 09/30/2019
Name of Provider or Supplier Quest Diagnostics	Street Address, City, State 118 New London Tpke, Norwich, CT	
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
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document centrifuge function checks every 6 months to ensure platelet poor plasma (PPP) for accurate and reliable test results for the Prothrombin Time (PT) test in the specialty of hematology. Findings include: 1. Record review of the Siemens manufacturer package insert for Dade Innovin reagent on 9/30/19 revealed the following statement under the Specimen Collection and Preparation Section: "Please refer to CLSI document H21-A5 for detailed information on sample preparation and storage." 2. Record review on 9/30/19 of the CLSI H21-A5 document, Section 6.2: Processing Suitable Specimens revealed: "The reliability of the centrifugation procedure, to ensure plasma platelet counts are within acceptable limits, should be validated every six months or after modification of the centrifuge." 3. Record review of the laboratory PPP log sheets on 9/30/19 revealed the following: a. Two centrifuges are in use: Fisher Scientific Serial Number (S/N) 72401510308 and Horizon Premier S/N 17056UAB873. b. PPP studies were performed on 9/11/18 and 7/30/19 for S/N 7241510308. c. PPP studies were performed on 9/13/18 and 8/14/19 for S/N 17056UAB873. 4. Staff interview with the technical supervisor #1 (TS1) on 9/30/19 at 12:30 PM confirmed PPP performance for the 6 month check was missed for March 2019 and TS1 was unable to provide the laboratory policy for PPP function check. 5. The laboratory performs 9,830 PT tests annually.</p>