

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0329764	(X3) Date Survey Completed 06/19/2019
Name of Provider or Supplier Columbus Health Department Laboratory	Street Address, City, State 240 Parsons Avenue, 2nd Floor, Columbus, OH	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, and an interview with the Technical Supervisor (TS), the laboratory failed to follow written policies and procedures for the Quantiferon TB Gold Plus specimen processing. This deficient practice had the potential to affect all samples tested using the Quantiferon TB Gold Plus test system. Findings Include: 1. Review of the laboratory's "Specimen Collection for Quantiferon - TB Gold Plus" policy and procedure, approved, signed, and dated by the Laboratory Director on 05/15/2019, found the following statements: "Handling Conditions: 5. Incubate the QFT-Plus Blood Collection Tubes UPRIGHT at 37 C +/- 1 C for 16 to 24 hours." "Post-incubation of blood collection tubes and harvesting of plasma" * Plasma samples can be stored in centrifuged QFT-Plus Blood Collection Tubes for up to 28 days at 2 C to 8 C. Or harvested harvested plasma samples can be stored for up to 28 days at 2 C to 8 C." 2. The surveyor requested documentation of Quantiferon TB Gold Plus specimen incubation times, plasma sample and harvested plasma sample refrigerated storage dates and times. The TS #1 stated a white board attached to the incubator was used to record times but was erased daily and no date and times were recorded for the refrigerated stored samples. The interview occurred on 06/19/2019 at 2:30 PM. C = degrees Celsius</p>