

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 48D0699866	(X3) Date Survey Completed 08/27/2025
Name of Provider or Supplier Clinical Laboratory Inc	Street Address, City, State Island Med Ctr Suite 6, Sunny Isle, St Croix, VI	
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
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p> <p>This STANDARD is not met as evidenced by: Onsite Revisit 8/27/2025 Based on review of the laboratory's procedures, manufacturer's instructions, four of four patient test requisitions, patient final test reports, and interview with the technical supervisor, the laboratory failed to have a client services manual for referred specimens. Findings included: 1. The laboratory's client services manual lacked: a) Patient preparation b) Conditions of specimen transport c) Specimen storage/preservation d) Acceptability/rejection criteria 2.. Review of the laboratory's procedures and manufacturer's instructions for a random sampling of testing that the laboratory performed included the following for specimen stability: a) The laboratory's written procedure for Sickle Cell testing stated, "Specimens can be kept for 1 to 2 weeks at 2 to 8C." Sickledex manufacturer stated, "Blood samples stored at 1C to 10C for up to 45 days may be used for testing." b) The laboratory's written procedure for rapid plasma reagin (RPR) testing stated, "Serum samples should be tested within five (5) days of collection." The laboratory's procedure was consistent with Arlington Scientific RPR manufacturer's instructions. c) The laboratory's written procedure for Rubella Immunoglobulin G (IgG) testing stated, "If the test cannot be carried out on the same day, the serum must be stored between 2-8C for no longer than 8 days after collection." The laboratory's procedure was consistent with ASI Rubella manufacturer's instructions. d) The laboratory's written procedure for rheumatoid factor/rheumatoid arthritis (RF/RA) Latex testing stated, "If samples cannot be tested immediately, maintain them in their original tubes at 2-8C and test within 48 hours" (or can be frozen -20C or colder). The laboratory's procedure was consistent with Arlington Scientific RF/RA Latex manufacturer's</p>

instructions. e) The laboratory's written procedure for human chorionic gonadotropin (hCG) testing stated, "Serum specimen may be stored at 2-8C for up to 48 hours prior to testing." The laboratory's procedure was consistent with hCG Combo kit manufacturer's instructions. Patient 00195960000 "Date: 02/27/2025" requested Sickle Cell testing, test results were reported on 02/28/2025 at 8:12 AM. Patient 0009145000 "Order Date: 02/24/2025 03:10 PM" requested RPR and Rubella IgG testing, test results were reported on 02/24/2025 at 12:33 PM. Patient 0020720000 "Order Date: 02/03/2025 at 01:02 PM" requested RA Latex testing, test results were reported on 02/04/2025 at 2:50 PM. Patient 205229 "Date: 1/27/25" requested hCG qualitative testing, test results were reported on 01/27/2025 at 12:53 PM. 3. During the exit interview on 08/27/2025 at 12:00 PM, the technical supervisor confirmed the laboratory failed to have a client services manual for referred specimens to ensure correct patient preparation, conditions of specimen transport, specimen storage /preservation, and acceptability/rejection criteria.