

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0659993	<b>(X3) Date Survey Completed</b>  02/09/2023
<b>Name of Provider or Supplier</b>  In-Vitro Diagnostics, Inc DbA Serolab	<b>Street Address, City, State</b>  7100 Old McGregor Road Suite A, Waco, TX	
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>D0000</b>	An onsite survey conducted February 9, 2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> 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 manufacturer instructions for use, laboratory policy, and interview with facility personnel, the laboratory failed to establish ambient temperature specimen stability and the effect on overall specimen integrity of multiple freeze-thaw cycles for two of two assays in use since November 2022. The findings included: 1. Based on review of the IMMULITE 2000 Total IGE assay instructions for use, (revision IMMULITE 2000 Total IgE (PIL2KIE-24, 2018-08-24)), the instructions stated the following: "Blood collection tubes from different manufacturers may yield differing values, depending on materials and additives, including gel or physical barriers, clot activators and/or anticoagulants. IMMULITE 2000 Total IgE has not been tested with all possible variations of tube types. Volume Required: 5 L serum Storage: 3 days at 2-8 C, or 6 months at -20 C Based on review of the IMMULITE 2000 3gAllergy Specific IgE Universal Kit (revision IMMULITE 2000 3gAllergy Specific IgE Universal Kit (PIL2KUND-34, 2022-08)), the instructions stated the following: Specimen Collection Blood collection tubes from different manufacturers may yield differing values, depending on materials and additives, including gel or physical barriers, clot activators. Specific IgE has not been tested with</p>

all possible variations of tube types. Volume Required: 50 L serum Storage: 7 days at 2-8C, or 6 months at -20 C" The manufacturer did not provide an ambient temperature specimen stability in the instructions for use. The manufacturer provided a frozen temperature stability at -20C, but did not make any mention of the effect of multiple free/thaw cycles. 2. Based on review of the laboratory policy "Specimen Processing", approved by the laboratory director on 11/11/2022, the policy stated the following: "Specimen collection\* Blood may be collected in red top tubes, SST tubes, or tiger top tubes in order to provide serum for testing. After collection, the blood is allowed to stand at room temperature for 30 minutes then centrifuged to separate serum and cells. After centrifugation, the serum is poured into a plastic screw-cap vial provided by Serolab. It is important that the blood/serum not be stored or shipped in glass vials as covalent binding of antibodies with glass can occur. If a centrifuge is not available, the blood is placed upright in a refrigerator overnight, allowing the clot to retract; the serum is then carefully decanted into the plastic vial provided, taking care not to pour off cells with the serum. \*Serolab does not collect specimens; they are collected at the clinic/lab that orders the testing. Specimen labeling Serum specimens should be labeled at the ordering facility with the patient's name, date of birth, physician's name, and date specimen was drawn. Specimen storage The specimen should be stored at -20C until shipping/mailling. The specimen does not require refrigeration during shipment but is stored under refrigeration 2-8C up to 3 days, while testing is in progress. Once all initial testing is complete, any remaining specimens are stored -20 C for approximately six months in the event additional tests might be ordered." 3. In an interview at 15:49 hours on 2/9/2023 in the front office space, the laboratory manager stated specimens were collected in tiger top blood collection tubes provided by the laboratory, specimens were then either frozen at the collection site or refrigerated at the collection site and then mailed to the laboratory at ambient temperature. Once the specimens arrived in the laboratory, they were frozen at -20C until they could be analyzed. When asked if the laboratory had evaluated or established an ambient temperature stability for specimen integrity, she stated the laboratory had not. When asked if the laboratory had evaluated the effect of repeat freeze/thaw cycles on specimen integrity, the laboratory manager stated they had not performed any specimen stability studies to establish ambient temperature stability or free/thaw cycle stability.