

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2062413	<b>(X3) Date Survey Completed</b>  12/07/2022
<b>Name of Provider or Supplier</b>  Central Clinical Labs Incorporated	<b>Street Address, City, State</b>  3720 E La Salle St, Suite 103, Phoenix, AZ	
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>D5393</b>	<p><b>PREANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1249(b)(c)</p> <p>The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the monthly Specimen Rejection Logs from 2022 and interview with the facility personnel, the laboratory failed to provide a documented corrective action for rejected specimens. Findings include: 1. The laboratory completes a monthly Specimen Rejection Log to track specimen rejections. The laboratory utilizes the log to quantify the number of rejected specimens based on the following categories: Unlabeled, Mislabeled/Improperly labeled, Hemolyzed, Specimen missing /Not received at the lab, Clotted, QNS (quantity not sufficient), Not received in a timely manner, Specimen handled improperly, Wrong tube or container, and Other. The log also includes an area for the laboratory to document the "Follow up or Corrective Action Taken". 2. Review of the August 2022 Specimen Rejection log indicated above revealed the laboratory documented 4 unlabeled specimens, 9 mislabeled/Improperly labeled specimens, 22 Hemolyzed specimens, 102 specimens missing/not received in the lab, 7 Clotted specimens, 6 QNS, 2 Specimen handled improperly, 11 Wrong tube or container, and 11 Other. 3. The August 2022 specimen rejection log indicated above failed to include documentation of the 'Follow up or Corrective Action Taken' for each category of rejected specimens. 4. The specimen rejection logs reviewed from January through November 2022 failed to include documentation of the 'Follow up or Corrective Action Taken' for each category of rejected specimens. 5. The facility personnel interviewed during the survey on 12/07/22 at 4:15 pm confirmed the laboratory failed to document the corrective action for</p>

each category of rejected specimens during 2022, through the date of the survey. 6. The laboratory performs testing in the specialties of Microbiology, Diagnostic Immunology, Chemistry

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
Based on lack of a written procedure manual for testing performed under the specialty of Diagnostic Immunology and interview with the facility personnel, the laboratory failed to have a written procedure for COVID-19 testing using the Assure (Ecotest) COVID-19 IgG/IgM Rapid Test Device. Findings include: 1. The laboratory began testing patient using the Assure (Ecotest) COVID-19 IgG/IgM Rapid Test Device in August 2022. The laboratory uses serum as the specimen type making the test moderate complexity. The laboratory's approximate annual test volume in the specialty of Diagnostic Immunology is 2,400. 2. No written, approved procedure manual was available for review during the survey conducted on December 7, 2022 for the test, Assure (Ecotest) COVID-19 IgG/IgM Rapid Test Device. 3. The facility personnel interviewed on 12/07/22 at 1:30pm confirmed the laboratory failed to have an established written, approved procedure for the testing indicated above.