

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0482521	<b>(X3) Date Survey Completed</b>  08/25/2023
<b>Name of Provider or Supplier</b>  East Texas Clinic Association	<b>Street Address, City, State</b>  101 Willis Ave, Naples, 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 08/25/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5435</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer instructions, laboratory policy, the Centers For Medicaid and Medicare (CMS) form 116, and confirmed in an interview, the laboratory failed to have a function check protocol in place to ensure equipment performance for accurate and reliable test results for the LW Scientific E8 Portafuge centrifuge used in the preparation of urine sediment for microscopic examination in 2022. The findings included: 1. In a tour of the laboratory on 8/25 /2023 at 10:10 hours surveyor noted the following bench-top centrifuge used to centrifuge urine for urine sediment examination: LW Scientific E8 2. Review of the "USA E8 Portafuge Instruction Manual", section "Specifications" had the following information: "Dial Setting: RPM Range: Low (7:00 position) 500 (+10% - 5%) Medium (12:00 position) 1700 - 1950 Medium (3:00 position) 3150 - 3350 High (5:00 position) 3500 (+10% - 5%)" 3. Review of the laboratory policy manual for urinalysis, section "Microscopic" had the following instructions: "1. Centrifuge the urine specimen at 1750 - 1900 RPM for 2 minutes." The surveyor queried for the 2022</p>

tachometer checks for the verification of the centrifuge speed to ensure that the was accurate and none was provided. 4. A review of the CMS 116 section VIII "Non Waived Testing", lists the annual test volume for urine sediment examination at 178 tests. 5. In an interview in the laboratory on 8/25/2023 at 10:15 hours TP5 confirmed that the laboratory did not have a mechanism in place to verify the centrifuge speed to ensure accurate and reliable test results for urine sediment microscopic examination.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on a review of laboratory documents, laboratory competency assessments, and confirmed in interview, the technical consultant (TC) failed to perform annual competency assessments for three of five testing personnel (TP) in 2022. The findings included: 1. A review of the laboratory document titled "Personnel Assessment" had the following statement in the first paragraph: "Personnel competency must be assessed by the Laboratory Director or Technical Consultant and will be an on-going process at this facility." 2. A review of the competency assessment forms for 2022 had the following personnel competency assessments performed by personnel who could not meet the TC qualifications found at 493.1411: 2022: TP4 competency assessment performed by TP5 on 4/11/2022 TP2 competency assessment performed by TP5 on 3/24/2022 TP3 competency assessment performed by TP5 on 11/21/2022 3. In an interview on 8/25/2023 at 10:45 hours, in the office, TP5 confirmed that the TC had not performed the competency assessments for the above testing personnel in 2022.