

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0673541	<b>(X3) Date Survey Completed</b>  10/23/2018
<b>Name of Provider or Supplier</b>  East Texas Family Medicine Pa	<b>Street Address, City, State</b>  4201 South Loop 256, Palestine, 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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on review of laboratory procedures, confirmed by staff interview, the laboratory failed to utilize a written procedure for the microscopic examination of urine sediment. Findings: 1. Laboratory procedures were reviewed. In the course of an interview during the review on 10-23-2018, testing person 7 (CMS form 209) stated that providers performed microscopic urine sediment examinations on an estimated 50 patient specimens a year. A copy of the procedure was requested; none was available or could be provided during the survey. .</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: . Based on review of laboratory procedure for hematology testing using the Sysmex XN-330 analyzer, the laboratory director failed to approve, sign and date the procedure manual before use. Findings: 1. Laboratory procedure documentation for hematology testing was requested. In an interview at the site on 10-23-2018, testing person 7 stated that the manufacturer-supplied operator's manual was being used as a</p>

procedure manual. 2. The operator's manual showed no evidence of laboratory director approval. No documentation of approval was available or could be provided during the survey. .

**D6066**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:  
. Based on review of testing personnel education and training documentation, confirmed by surveyor observation and staff interview, the laboratory failed to document training on the operation of the Sysmex XN-330 hematology analyzer for 6 of 7 testing personnel. 1. Laboratory personnel documentation was reviewed. A certificate of training for testing person 7 on the operation of the Sysmex XN-330 hematology analyzer, put in operation 08-19-2018, was found. For testing personnel 1 through 6, no evidence of training was found. 2. In an interview at the site on 10-23-2018, testing person 7 stated that other testing personnel had attended training sessions provided by the instrument manufacturer, but documentary evidence was not available and could not be provided at the time of the survey.