

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1086442	<b>(X3) Date Survey Completed</b>  04/18/2023
<b>Name of Provider or Supplier</b>  Texas Oncology Cedar Park	<b>Street Address, City, State</b>  1401 Medical Parkway Bldg C Ste 200, Cedar Park, 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>	Based on an announced validation inspection, the laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780.
<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 the laboratory's textbook procedure, the laboratory's policy and procedure, test reports, utilization report, and interview, the laboratory failed to follow textbook procedure for the centrifugation time for microscopic urinalysis for 22 of 22 months reviewed. Findings follow. A. Review of the laboratory's textbook procedure from Urinalysis and Body Fluids1, Chapter on Urinalysis starting on page 168, under Centrifugation stated, "The speed of the centrifuge and the length of time the specimen is centrifuged should be consistent. Centrifugation for 5 minutes at a relative centrifugal force (RCF) of 400 produces an optimum amount of sediment with the least chance of damaging the elements. To correct for differences in the diameter of centrifuge heads, RCF rather than revolutions per minute (RPM) is used. The RPM value shown on the centrifuge tachometer can be converted to RCF using nomograms available in many laboratory manuals or by using the formula: <math>RCF = 1.118 \times 10</math> to the <math>-5</math> x radius in centimeters x RPM squared Centrifugation calibration should be performed routinely. Use of the braking mechanism to slow the centrifuge causes disruption of the sediment before decantation and should be avoided. To prevent biohazardous aerosols, all specimens must be centrifuged in capped tubes." B. Review</p>

of the laboratory's policy and procedure titled, Routine Urinalysis with Reflex to Microscopic, revised 06/02/2021, at Microscopic Exam under Procedure stated, "1. After performing the macroscopic and the chemical tests, if indicated, centrifuge the urine at a minimum of 1500 PRM for two to five minutes..." C. Review of randomly selected patient test reports from November and December 2022 showed the following patients listed by accession number were tested for microscopic urinalysis: 1. 221432152 2. 221503287 3. 221385718 4. 221426570 D. Review of the utilization report from 04/14/2022 - 04/14/2023 showed the laboratory performed 60 microscopic urinalysis tests. E. Interview with testing personnel #2, as listed on the CMS form 209, on April 18, 2023 at 1430 hours in the laboratory acknowledged she spun urine samples for microscopic urinalysis for 10 minutes. Interview with the Lab Manager on April 18, 2023 at 1440 hours in the laboratory acknowledged she spun urine samples for microscopic urinalysis for 10 minutes. 1. Strasinger, Susan K, and Marjorie S Di Lorenzo. Urinalysis and Body Fluids, 7th Edition. F.A. Davis Company, 2021.