

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1099477	(X3) Date Survey Completed 10/07/2021
Name of Provider or Supplier Osu - Clinical Laboratory	Street Address, City, State 1111 W 17th Street, Tulsa, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 10/07/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory directory, lead laboratory technologist, and testing person #3 at the conclusion of the survey.
D5435	<p>MAINTENANCE AND FUNCTION CHECKS 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 a review of records, written policy, and interview with the lead laboratory technologist, the laboratory failed to follow their written protocol for ensuring the centrifuge was functioning properly for 3 of 3 years. Findings include: (1) On 10/07/2021 at 09:50 am, the lead laboratory technologist stated the following to the surveyor: (a) HIV (Human Immunodeficiency Virus) testing was performed using the Hologic Panther analyzer; (b) Patient specimens were processed in the Fisher Scientific Accuspin 24C centrifuge at a speed of 4500 rpm (revolutions per minute) for 10 minutes. (2) The surveyor reviewed the policy titled, "Centrifuge Calibration SOP" which stated, "Evaluate and document the performance of the centrifuge annually"; (3) The surveyor reviewed the centrifuge records from 2019 through 2021. The records showed that, although the centrifuge speed and timer checks had been performed on 07/25/2019, 07/01/2020, and 06/29/2021; the results for the speed and</p>

timer checks had not been documented to ensure the centrifuge was processing specimens at the appropriate speed and time; (4) The surveyor reviewed the findings with the lead laboratory technologist who stated on 10/07/2021 at 12:00 pm, the results for the centrifuge speed and timer checks had not been documented as stated above.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the lead laboratory technologist, the technical consultant failed to ensure that persons performing moderate complexity testing had been evaluated semiannually during the first year of testing for two of two persons hired after the previous recertification survey. Findings include: (1) The surveyor reviewed personnel records. The following was identified: (a) Testing Person #1 - The initial training for this person was completed on 10/05/2020. There was no evidence that a semiannual evaluation had been performed (the next competency evaluation had been performed on 10/01/2021); (b) Testing Person #3 - The initial training for this person was completed on 10/07/2019. There was no evidence that a semiannual evaluation had been performed (the next competency evaluation had been performed on 10/05/2020). (2) The surveyor reviewed the records with the lead laboratory technologist, who stated on 10/07/2021 at 10:40 am, there were no records to prove the above persons had been evaluated semiannually.