

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1099477	(X3) Date Survey Completed 10/24/2023
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 10/24/2023. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the laboratory director and testing person #1 during an exit conference performed at the conclusion of the survey.
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency testing program for two of three MGEN (Mycoplasma genitalium, Molecular) events reviewed in 2022 and 2023. Findings include: (1) On 10/24/2023 a review of MGEN proficiency testing records for 2022 and 2023 identified the following for two of three events: (a) First 2022 Event (MGEN-A 2022) -Three of three results had not been graded by the proficiency testing program (samples MGEN-01, MGEN-02, and MGEN-03). There was no documentation to prove the laboratory performed a self-evaluation of the non-graded results; (b) Second 2022 Event (MGEN-B 2022) -Three of three results had not been graded by the proficiency testing program (samples MGEN-04, MGEN-5 and MGEN-06). There was no documentation to prove the laboratory performed a self-evaluation of the non-graded results. (2) The records were reviewed with the laboratory director who stated on 10/24/2023 at 01:30 pm, the laboratory had not performed a self-evaluation to evaluate the results that were not graded by the proficiency testing program.</p>