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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 37D1099477 | (X3) Date Survey Completed 07/18/2019 |
| 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 | A recertification survey was performed 07/18/19. The findings were reviewed with technical supervisor/general supervisor and the testing person during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1453; D6134 : Clinical Consultant - High Complexity |
| D2015 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical supervisor/general supervisor and the testing person, the laboratory failed to ensure attestation statements had been signed by the laboratory director. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2017, 2018 and 2019 proficiency testing records. The attestation statement for the 2018 Third Chlamydia/Neisseria Gonorrhoeae Event (HCG-C) had not been not signed by the laboratory director; (2) The surveyor reviewed the findings with the technical supervisor/general supervisor and the testing person, and explained that attestation statements must be signed by a qualified laboratory director.</p> |

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

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.

This STANDARD is not met as evidenced by:

Based on a review of records, policies and procedures and interview with the testing person, the laboratory failed to define a function check protocol to ensure the centrifuge was functioning properly. Findings include: (1) At the beginning of the survey, the testing person stated to the surveyor HIV (Human Immunodeficiency Virus) viral load was performed in the laboratory. The 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 and procedure manual and could not locate a function check protocol that defined how often function check (speed and timer check) were to be performed on the centrifuges; (3) The surveyor asked the testing person if the laboratory had a function check protocol for the centrifuge. The general supervisor/testing person #1 stated to the surveyor the laboratory did not have a policy to check the speed and timer of the centrifuges.

D6134

CLINICAL CONSULTANT

CFR(s): 493.1453

The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of records and interview with the technical supervisor/general supervisor and the testing person, the laboratory failed to have a clinical consultant who meets the qualification requirements of 493.1457 of this subpart. Findings include: (1) The laboratory did not have a qualified clinical consultant for high complexity testing. Refer to D6135.

D6135

CLINICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1455

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical supervisor/general supervisor and the testing person, the laboratory failed to have a qualified clinical consultant for high complexity testing. Findings include: (1) At the beginning of the survey, the technical supervisor/general supervisor and the testing person stated the laboratory performed high complexity testing (i.e. *Trichomonas vaginalis*, HIV (Human Immunodeficiency Virus) Viral Load, *Chlamydia trachomatis* and *Neisseria gonorrhoea* testing) using the Panther System; (2) The surveyor reviewed Form CMS-209 (Laboratory Personnel Report) that had been completed prior to the survey by laboratory personnel; (3) The surveyor requested proof (state medical license) that the clinical consultant qualified to consult a laboratory performing high complexity testing. Proof could not be provided by the end of the survey; (4) The surveyor corresponded with the laboratory following the survey to provide evidence of qualifications and the laboratory failed to obtain documentation. NOTE: The regulations for clinical consultant for high complexity are as follows: *Be qualified as a laboratory director under 493.1443(b)(1), (2), or (3)(i); * Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located.