

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0721023	(X3) Date Survey Completed 01/23/2020
Name of Provider or Supplier Infusion Clinic Laboratory	Street Address, City, State 228 N Bliss Ave, Tahlequah, 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 01/23/2020. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #1 and technical consultant #2 at the conclusion of the survey.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #3, the laboratory failed to retain centrifuge function check records for at least 2 years. Findings include: (1) At the beginning of the survey, technical consultant #3 stated the following to the surveyor: (a) Urine microscopic testing was performed in the laboratory; (b) The urine specimens were processed in the Hettich Zentrifuge Universal 320 centrifuge at a speed of 1500 rpm (revolutions per minute) for 5 minutes; (c) The centrifuge speed and timer were checked for accuracy annually by the hospital biomedical department (typically in August of each year). (2) The surveyor requested the records for speed and timer checks performed during 2018 and to date. The documentation for the checks that had been performed in August 2018 could not be retrieved. Technical consultant #3 explained the following to the surveyor: (a) The hospital biomedical department entered the results of the speed and timer checks into the computer. In addition, they documented the results on a sticker and affixed it to the centrifuge; (b) When the biomedical department performed the speed and timer checks for the current year, they would remove the sticker from the previous year and discard it; (c) The server crashed in IT (Information Technology) and the Biomedical Department lost the data for the 2018 speed and timer checks; (d) There were no records of the checks since the sticker that had been affixed to the</p>

centrifuge with the 2018 results had been discarded. (3) Therefore, the surveyor could not verify the speed and timer checks had been performed and were acceptable in 2018, since the record had not been maintained by the laboratory.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with technical consultant #2 and technical consultant #3, the laboratory failed to perform maintenance procedures as required by the manufacturer 3 of 4 months. Findings include: (1) At the beginning of the survey, technical consultant #3 stated to the following to the surveyor: (a) Urinalysis testing was performed using the Clinitek 500 analyzer; (b) The clinic was open and routinely performed patient testing Monday through Thursday. (2) Later during the survey, the surveyor reviewed the manufacturer's daily maintenance requirements located in Section 5 of the Operator's Manual, which stated "The fixed platform, moving table, reagent strip hold-down plate, push bar, and the liner should all be cleaned at least once each day or after running 300 strips, whichever is more frequent"; (3) The surveyor then reviewed maintenance records for September 2018, January 2019, July 2019, and November 2019. There was no evidence the daily maintenance had been performed on the following days for 3 of 4 months: (a) September 2018 - 13 of 15 days (days 04,05,06,10,11,12,13,19,20,24,25,26,27) (b) July 2019 - 17 of 18 days (days 01,02,03,08,09,10,11,15,16,17,18,22,23,24,25,30,31) (c) November 2019 - 14 of 15 days (04,05,06,07,11,12,13,14,18,19,20,21,25,26) (4) The surveyor reviewed the records with technical consultant #2 and technical consultant #3. Both stated the daily maintenance had not been documented as performed as indicated above.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with technical consultant #2 and technical consultant #3, the technical consultant failed to ensure evaluations included all moderate complexity testing performed. Findings include: (1) At the beginning of the survey, technical consultant #3 stated to the surveyor urine microscopic and manual differential testing were performed in the laboratory; (2) The surveyor reviewed personnel records for 3 persons performing urine microscopic and manual differential testing during 2018 and to date (testing person #1, testing person #2, and technical consultant #3/testing person #3.). The records showed that annual competency evaluations had been performed as follows: (a) Testing Person #1 - Performed on 12/27/18 and 11/20/19 (b) Testing Person #2 - Performed on 12/27/18 and 11/20/19 (c) Technical Consultant #3/Testing Person #3 - Performed on 12/27/18 and 12/06/19 (3)

There was no evidence the evaluations performed for the above persons, included an assessment of urine microscopic and manual differential testing; (4) The surveyor reviewed the findings with technical consultant #2, who stated the above evaluations did not include urine microscopic and manual differential testing.