

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0656713	(X3) Date Survey Completed 02/11/2020
Name of Provider or Supplier Sam Hider Health Center	Street Address, City, State 859 E Melton Dr, Jay, 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 validation survey was performed on 02/11/2020. The findings were reviewed with the medical director, director of laboratory services, technical consultant #2, and the interim clinic administrator during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to have a written competency policy for the technical consultant and clinical consultant based on the job responsibilities as listed in Subpart M. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records for competency assessments performed during 2018 and to date in 2019. There was no evidence competencies had been performed for the technical consultant and clinical consultant based on their job responsibilities; (2) The surveyor asked technical consultant #2 if a written policy to evaluate the positions based on job responsibilities was available, and if competencies had been performed during the review period. Technical consultant #2 stated a policy to evaluate the technical consultant and clinical consultant based on job responsibilities had not been written; and competencies had not been performed.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</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.

This STANDARD is not met as evidenced by:

Based on a review of records, policy, and interview with technical consultant #2, the laboratory failed to ensure the urine centrifuge was functioning properly for 1 of 1 years. Findings include: (1) At the beginning of the survey, technical consultant #2 stated to the surveyor urine sediment examinations were performed in the laboratory. The specimens were processed in the LW Scientific centrifuge at a speed of 2500 rpm (revolutions per minute) for 5 minutes; (2) The surveyor reviewed the centrifuge function check policy which required annual speed checks be performed on the centrifuge; (3) The surveyor reviewed the centrifuge maintenance record for 2019. The speed had not been checked at the speed the urine specimens were processed, to ensure the centrifuge was functioning properly at that speed, for 1 of 1 checks performed as follows: (a) 05/31/19 - The speed had been checked at 3500 rpm (4) The surveyor reviewed the findings with technical consultant #2. Technical consultant #2 stated the centrifuge speed had not been checked at the speed used to process urine specimens 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, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 5 of 5 testing persons. Findings include: (1) At the beginning of the survey, technical consultant #2 stated to the surveyor wet prep analysis and urine sediment examinations were performed in the laboratory; (2) The surveyor then reviewed personnel records for 5 persons performing wet prep analysis and urine sediment examinations in the laboratory. The records showed that evaluations had been performed as follows: (a) Testing Person #1 - Performed on 09/25/18 and 06/21/19 (b) Testing Person #2 - Performed on 09/25/18 and 10/08/19 (c) Testing Person #3 - Performed on 11/14/18 and 09/26/19 (d) Testing Person #4 - Performed on 12/05/19 (e) Testing Person #5 - Performed on 10/01/19 and 01/22/20 (3) There was no evidence the evaluations, performed for the above persons, included an assessment of the wet prep analysis and urine sediment examinations; (4) The surveyor reviewed the findings with technical consultant #2, who stated the above evaluations did not include wet prep analysis and urine sediment examinations.