

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1073725	(X3) Date Survey Completed 12/14/2021
Name of Provider or Supplier Western Yell County Medical Clinic	Street Address, City, State 310 West Broadway Street, Havana, AR	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Through a review of proficiency testing result reports, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to verify the accuracy of KOH and Urine Formed Element examinations, at least twice annually. Findings follow: A) In a review of the proficiency test result report it was revealed that no proficiency tests for KOH and urine formed element examinations were presented. B) Upon request the laboratory was unable to provide documentation of twice annual evaluation of the accuracy of KOH and urine formed element examinations. C) In an interview, at 12:56 PM on 12/14/21, laboratory employee #3 (as listed on the form CMS-209) confirmed that the accuracy of KOH and urine formed element examinations had not been verified.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in</p>

493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Through review of the laboratory's policy and procedure manual , lack of documentation and interview it was determined that the laboratory did not have policy and procedure specifying proper patient identification and specimen requirement for the collection of complete blood count (CBC) analysis. Findings follow: A) Review of the laboratory's policy and procedure manual revealed that no policy for patient identification or specimen requirements for the performance of CBC analysis was included. B) In an interview on 12/14/21 at 12:56 PM the laboratory staff member, identified as number 3 on the CMS 209 form, confirmed that no policy and procedure for patient identification and CBC analysis was present in the laboratory policy and procedure manual.