

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0453239	(X3) Date Survey Completed 05/17/2023
Name of Provider or Supplier Meade District Hospital	Street Address, City, State 510 E Carthage Street, Meade, KS	
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
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the CMS116 test volumes for bacteria culture, lack of quality control (QC) results from 11/1/21 to 5/17/2023, and interview with the general supervisor (GS) #3 the laboratory failed to check each batch of bacteriology media to ensure it supported the growth, or as appropriate, selected or inhibited specific organisms to produce the intended biochemical responses. Findings: 1. Review of the CMS116 form revealed this laboratory performed approximately 1025 bacterial cultures annually. 1. A request was made for QC of microbiology culture media for each batch and/or shipment for the following microbiology media in use: Blood agar, MacConkey agar; chocolate agar, carrot broth and thioglycollate broth. No documentation was provided to demonstrate that the media used was checked to ensure it supported the growth, or as appropriate, selected or inhibited specific organisms to produce the intended biochemical responses from 11/1/21 to 5/17/23. 2. Interview with the GS #3 on 5/17 /23 at 11:05 a.m. confirmed the lab was not performing quality control on each batch of media with controlled organisms to ensure it supported the growth, or as appropriate, selected or inhibited specific organisms to produce the intended biochemical responses.</p>
D5783	CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) records and calibration records for lipase performed on the Siemens Dimension EXL chemistry analyzer from 5/10/23 to 5/11/23, lack of patient remediation documentation for lipase patient results and interview with GS #3, the laboratory failed to evaluate patient test results since the last acceptable QC test run to determine if patient results had been adversely affected and may require corrective action. Findings: 1. Review of lipase QC records and lipase calibration records from the Siemens Dimension EXL revealed unacceptable QC values on 5/11/23. Repeat QC testing did not resolve the issue. The lipase assay required calibration, which also failed to be acceptable. Siemens tech support was needed to restore a previous calibration in order to obtain acceptable QC values post calibration on 5/11/23 after the 9:01 a.m. calibration failure. 3. Prior to the calibration restoration in item #1, the last acceptable QC was obtained on 5/10/23 at 6:14 a.m. 4. No documentation to demonstrate lipase patient testing was not performed or results were evaluated for possible corrective action was provided at the time of survey. No corrective action documentation was present including notification to the provider and patients of results, and orientation/training for the performing test personnel was provided at the time of survey. 5. Review of patient test results revealed 3 lipase patient results were reported without evaluation for the unacceptable QC and calibration. 6. Interview with GS #3 on 5/17/23 at 4:45 p.m. confirmed, the laboratory failed to evaluate lipase patient test results since the last acceptable test run to determine if patient results had been adversely affected and may require corrective action.