

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0451041	(X3) Date Survey Completed 06/30/2022
Name of Provider or Supplier Kiowa County Memorial Hospital	Street Address, City, State 721 West Kansas Ave, Greensburg, 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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the procedure manual, FDA test classification, quality control (QC) records, patient test reports and interview, the laboratory failed to perform a positive and negative control material each day of patient testing on the MedTox Drug of Abuse test system. Findings: 1. Review of the procedure "MEDTOXSCAN DRUGS OF ABUSE" approved for use by the laboratory director on 1/9/18, page 4, second paragraph states "External controls are urine-based materials that contain the drugs to be tested at concentrations above the cutoff (positive control) or contain no drug (negative control) You should run external controls routinely ..." No stated interval of QC testing was found in this procedure. 2. This 13 analyte panel is FDA approved and classified as moderate complexity. 3. Surveyor asked how often external QC was performed. Testing personnel (TP) #1 stated the Positive and Negative QC Test Devices (electronic QC) was performed each day of patient testing. No external QC material was used. 4. Review of patient test reports revealed 89 patient results were reported from 12/20/21 to 6/30/22 without external QC testing. 6. Interview with the TP#1 on 6/30/22 at 310:15a.m. confirmed, the laboratory failed to perform a positive and negative control material each day of patient testing on the MedTox Drug of Abuse test system.</p>