

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0450827	(X3) Date Survey Completed 10/09/2018
Name of Provider or Supplier Hanover Hospital	Street Address, City, State 205 S Hanover St, Hanover, 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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: A review of proficiency testing records from American Proficiency Institute (API) (a year consists of three testing events) and interview with General Supervisor#1 from the CMS form 209 revealed the laboratory failed to verify the accuracy of analyte (MCV) for which the proficiency testing program.. Findings were as follows: a. Proficiency testing records form API for the third event of 2017 second 2018 event, revealed that the proficiency testing program failed to obtain the accuracy of (MCV) two of three events. 2017 event 3: 60% 2018 event 2: 20% At the time of survey (10 /09/2018), there was no evidence of verification activities of accuracy by of the analytes available for review. An interview with the Technical Consultant #1 from the CMS form 209 on 10/08/2018, at 10:30 hrs confirmed that no verification of accuracy.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control</p>

materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based upon a review of quality control (QC) data in the chemistry specialty and staff interview, the laboratory failed to verify the criteria of acceptability of controls by evaluating control results for shifts or trends due to potential instrument malfunction or changes in the analytical system. Findings were: a. During a review of quality control data the delegated technical supervisor could not, upon request, produce evidence that quality control data for QC of analytes performed on the Coulter ACT Pentra C 400 were reviewed for shifts and trending of QC results that could signify a potential instrument malfunction. b. The laboratory did utilize an intra-laboratory comparison service for evaluation of QC results in accordance with statistical parameters. The lab was unable to produce a policy/procedure that defined how that data was utilized for shifts/trends to ensure that the test system was stable. The intra-laboratory comparison data reports were not consistently maintained and there was no evidence of review by the technical supervisor c. The above findings were confirmed by interview with the technical supervisor on 10/09/2018 hours in the laboratory.

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:
A review of the Quality Control (QC) procedure and interview with staff revealed the laboratory failed to produce a policy concerning a failed QC concerning patient results Finding were as follows a. Interview with General Supervisor #1 from the CMS 209 10/09//2018 at 11:30 hrs. confirmed the laboratory failed to have the policy, All patients 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.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

A review of Quality Assessment and Interview with staff revealed the laboratory failed to have a plan that covered all aspects of the laboratory. Finding were as follows: 1. Based upon the Quality Assessment Action plan the laboratory failed to establish a action plan for any manual calculation (INR) for any analyte that is reported . Therefore, the accuracy or reliability of the analyte cannot be verified. This was confirmed in interview with Technical Consultant on 10/09/2018 at 10:30 hrs.