Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0450827	11/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hanover Hospital	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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the review of the procedure "Proficiency Testing Policy and Procedure", proficiency testing (PT) "Checklist for Corrective Actions" documents and interview with the general supervisor (GS), the laboratory failed to follow procedure and review PT submission forms prior to uploading to the PT provider, American Proficiency Institute (API). Findings: 1. Review of the procedure "Proficiency Testing Policy and Procedure" signed by the laboratory director (LD) 4/24/22, revealed on page 3 section VIII, item 8 and 8(a) state: "Once results are all entered, PRIOR to submission, print off data entered from API. (a) The results will be double checked and signed off by two (2) laboratory personnel for accuracy of manual entry into website." 2. Review of the "Checklist for Corrective Actions" documents revealed. a. API Chem 2022 3rd Event-Clerical Errors noted "Result was 4.9, it was reported as 2.0." Corrective action section listed "Result acceptable. Discussed double checking results prior to submission. b. API 2022 Hemo/Coag 3rd Event-Clerical Errors noted "Accidently entered EOS# instead of EOS %. No documentation of review policy not followed was present in the corrective action section. c. API Immunohematology 2023 1st Event-Clerical Errors noted "marked results to include pt auto instead of just antibody screen. Corrective action section listed "for future reporting, only report antibody screen results." d. API Chem 2023 2nd Event-Clerical errors noted "clerical error in reporting" Corrective action section listed "Educated techs to slow down and review results before submission. All results moving forward will have to be signed by 2 reviewing techs. Dated 7/23/23. e. API Hemo/Coag 2023 2nd Event-Clerical Errors

	noted "Tech claims he selected calcium oxalate initially. Results must have accidently gotten changed as he tried to scroll down the page." Corrective action section listed "Discussed claim with tech and importance of double checking all answers before saving and submitting. Tech is not normally involved in entering results." f. API Chem 2023 3rd Event-Clerical Errors noted "Tech transposed troponin result. Actual result = 0.40. Corrective action section listed "...Consulted tech on proper transcription of results." 3. Interview with the GS 11/15/23 at 1:10 p.m. confirmed, the laboratory failed to follow procedure and review PT submission forms prior to uploading to the PT provider, American Proficiency Institute (API).
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the review of the ACL Elite coagulation analyzer calibration verification records for the analyte D-dimer, and interview with the GS, the laboratory failed to perform calibration verification once every six months. Findings: 1. Review of the ACL Elite calibration verification records for the analyte D-dimer revealed the laboratory last performed a calibration verification on 4/26/22. No documentation of calibration verification records after 4/46/22 to 11/15/23 were made available at the time of survey. 2. Interview with GS 11/15/23 at 11:30 a.m. confirmed, the laboratory failed to perform calibration verification once every six months.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when

	they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of QC documentation for the Abbott i-STAT, lack of an individualized quality control plan (IQCP), patient test results and interview with GS, the laboratory failed to perform QC at least once each day of patient testing for the Abbott i-STAT for pH, pCO2 and pO2 patient testing. Findings: 1. Review of the pH, pCO2 and pO2 QC documents for the Abbott i-STAT test system revealed the laboratory failed to perform external QC for four of eight patients and five of ten proficiency testing samples from 1/1/23 to 11/15/23. 2. No IQCP for the Abbott i-STAT test system was provided at the time of survey. 3. Interview with the GS on 11 /15/23 at 10:55 a.m. confirmed the laboratory failed to perform QC at least once each day of patient testing for the Abbott i-STAT for pH, pCO2 and pO2 patient testing.