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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 17D0450827 | (X3) Date Survey Completed 04/14/2022 |
| 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 |
|---------------------------|---|
| D5211 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from American Proficiency Institute (API) and interview, the laboratory failed to evaluate its unacceptable proficiency testing results. Findings: The following samples were scored unacceptable by API. No documentation of the laboratory's evaluation was provided at the time of survey. 1. 2021 Microbiology 1st Event-Gram Stain, samples GS01, GS02, and GS03. 2. 2021 Microbiology 2nd Event- Gram Stain, sample GS07. 3. 2021 Microbiology 3rd Event- Gram Stain, sample GS14. 4. 2021 Hematology/Coagulation 1st Event-Vaginal Wet Prep, sample VA01. 5. 2021 Hematology/Coagulation 2nd Event-ESR, sample ESR-03. 6.2021 Chemistry-Core 3rd Event a. BNP sample CM-13 b. LDL Chol samples CH11, CH12, CH13, CH14, & CH15 c. pCO2 i-STAT samples IB13, IB14 7. 2022 Chemistry-Core 1st Event-BUN sample CH02 8. Interview with the General Supervisor on 4/14/22 at 11:10 a.m. confirmed, the laboratory failed to evaluate 16 unacceptable proficiency testing results in 7 of 13 events in 2021 and to date of survey 2022.</p> |
| 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> |

This STANDARD is not met as evidenced by:
 Based on a review of proficiency test (PT) performance evaluation records from American Proficiency Institute (API) and interview, the laboratory failed to self-evaluate its not graded results. Findings: The following samples were not graded by API. No documentation of the laboratory's self evaluation was provided at the time of survey. 1. 2021 Hematology/Coagulation 1st Event. Blood Cell Identification samples DIF01, ECI01, ECI02, ECI03, ECI04, ECI05 2. 2021 Hematology/Coagulation 2nd Event. a. Blood Cell Identification samples BCI07, DIF02, ECI06, ECI07, ECI08, ECI09, ECI10 b. Basophil % samples DXH08, DXH10 c. Lymph % samples DXH07, DXH09 3. 2021 Hematology/Coagulation 3rd Event a. Blood Cell Identification samples DIF03, ECI1, ECI12, ECI13, ECI14, ECI15 b. Vaginal Wet Prep sample VKP03 3. 2021 Chemistry-Core 3rd Event Vancomycin samples CH11, CH12 4. 2022 Chemistry-Core 1st Event Vancomycin samples CH01, CH02, CH03, CH04, CH05 5. Interview with the General Supervisor on 4/14/22 at 11:10 a.m. confirmed, the laboratory failed to self evaluate 31 non graded results from 7 of 13 events in 2021 and to date of survey 2022.

D5400

ANALYTIC SYSTEMS
 CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
 Based on the lack of procedures, failure to determine normal patient geometric mean for prothrombin time reporting, failure to verify normal ranges for the hematology analyzer, failed to perform QC as required for immunohematology testing and interview the laboratory failed to meet the condition: Analytic systems. The laboratory failed to have procedures for the hematology analyzer, chemistry analyzer and immunohematology crossmatch (refer to D5401); failed to follow manufacturer's instructions to determine the normal patient geometric mean (refer to D5411); failed to verify reference ranges for the hematology analyzer prior to patient testing (refer to D5421) and failed to test negative controls for immunohematology testing (D5451).

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 lack of procedures for review and interview, the laboratory failed to have written procedures available to and followed by, laboratory personnel. Findings:

1. No procedures for the following were made available for review at the time of survey. a. Beckman Coulter DXH 520 hematology analyzer b. Cepheid Gene Expert SARS-COV-2, Flu A/B, RSV c. Horiba ABX Pentra C400 chemistry analyzer maintenance, operation, calibration d. Immunohematology Crossmatch of RBC blood product 2. Interview with the GS on 4/14/22 at 9:20 a.m. confirmed, the laboratory failed to have written procedures available to and followed by, laboratory personnel.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on review of instrument type, manufacturer instructions, analyzer test settings, lack of reagent lot normal range evaluation data, patient test volume and interview, the laboratory failed to follow manufacturer's instruction to establish the patient mean with each new lot of reagent for prothrombin time testing. Findings: 1. Prothrombin time testing is performed on the IL ACL Elite analyzer using RecombiPlasTin reagent. 2. Review of the package insert for ReombiPlaTin reagent under "Instrument /test procedure" states "Enter the ISI value from the insert and establish the Mean of the PT Normal Range with each new lot." 3. Review of the ACL Elite settings on the day of survey for prothrombin time testing showed RecombiPlasTin reagent lot #N0512868, normal patient geometric mean set at 12.18 seconds and ISI value of 1.04. 3. Request was made to review the new lot normal patient value study used to determine the patient geometric mean. Testing personnel #3 (TP3) stated that no normal patient value study was performed. Package insert had "into use 3/30/22" written on it. 4. Results for 16 patients have been reported using this lot from 3/30/22 to date of survey. 4. Interview with general supervisor on 4/14/22 at 1:40 p.m. confirmed, the laboratory failed to follow manufacturer's instruction to establish the patient mean with each new lot of reagent for prothrombin time testing. **This a repeat finding from survey performed 1/8/2020.**

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of performance verification documentation for the Beckman Coulter DXH520 hematology analyzer, non-waived test lists, and interview, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population prior to performing patient testing. Findings: 1. Review

of the verification documentation of the Beckman Coulter DXH520 hematology analyzer, S/N BC111130, for the analytes: White Blood Cell Differential, Red Blood Cell Count, Hemoglobin, Hematocrit, White Blood Cell Count, and Platelet testing showed no verification of normal values at time of survey. Document listed patient testing began in April 2020. 2. Review of the KS-CLIA-PS02 non-waived test lists showed the DXH520 annual test volume was 8,726 patient test results. 3. Interview with General Supervisor on 4/14/22 at 9:30 a.m. confirmed, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population prior to performing patient testing.

D5451

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(iii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on the review of immunohematology quality control (QC) records from 1/9/20 to date of survey revealed the laboratory failed to perform QC each day of patient testing for the immunohematology test procedures that produce graded or titered results and includes a negative control. Findings: 1. Review of the immunohematology QC records, revealed the following immunohematology reagent QC testing does not include a negative control: anti-A, anti-B, anti-A,B, A1 cells, B cells, Screening Cell (SC) II, and Combs Check Cells. 2. Interview with the GS#1 on 1/14/22 at 1:40 p.m. confirmed, the laboratory failed to perform QC each day of patient testing for the immunohematology test procedures that produce graded or titered results and include a negative control.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:
Based on the review of instrument verification records and interview with GS, the laboratory director failed to ensure the establishment of acceptable levels of analytical performance of the Beckman Coulter DXH520 hematology analyzer before use in patient testing. 1. Review of instrument verification records for the Beckman Coulter DXH520 hematology analyzer, S/N BC111130 for White Blood Cell Count, Red Blood Cell Count, Hemoglobin, Hematocrit, Platelet Count, and White Blood Cell Differential was performed in March 2020 and placed into use for patient testing in April 2020 (exact date patient testing began was not made available at the time of survey) revealed no approval documentation from the laboratory director or designee.

3. Interview with the GS 4/14/22 at 9:20 a.m. confirmed, the laboratory director failed to ensure the establishment of acceptable levels of analytical performance of the Beckman Coulter DXH520 hematology analyzer before use in patient testing.