

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0449775	(X3) Date Survey Completed 09/13/2022
Name of Provider or Supplier Holton Community Hospital	Street Address, City, State 1110 Columbine Drive, Holton, 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: Based on a review of proficiency test (PT) performance evaluation records from American Proficiency Institute (API) and interview on 9/13/2022 at 12:30 p.m. with general supervisor #1 (GS#1), the laboratory failed to self-evaluate 5 not graded results from 5 of 28 events from 11/13/2020 to 9/13/2022. Findings: 1. 2021 Hematology/Coagulation 2nd Event not graded results: a. Blood Cell Identification, BCI-01 b. No evidence of self-evaluation was available at the time of survey. 2. 2021 Hematology/Coagulation 3rd Event not graded results: a. Vaginal Wet Preparation (KOH), VKP-03 b. No evidence of self-evaluation was available at the time of survey. 3. 2021 Microbiology 2nd Event not graded results: a. Influenza A, RSP-08 b. No evidence of self-evaluation was available at the time of survey. 4. 2022 Immunology /Immunochemistry 1st Event not graded results: a. Compatibility, SER-05 b. No evidence of self-evaluation was available at the time of survey. 5. 2022 Immunology /Immunochemistry 2nd Event not graded results: a. Compatibility, SER-06 b. No evidence of self-evaluation was available at the time of survey. 6. Interview with GS#1 9/13/2022 at 12:30 p.m. confirmed, the laboratory failed to self-evaluate 5 not graded results from 5 of 28 events from 11/13/2020 to 9/13/2022.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p>

All proficiency testing evaluation and verification activities must be documented.

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 on 9/13/2022 at 12:30 p.m. with general supervisor #1 (GS#1), the laboratory failed to evaluate 4 unacceptable results from 4 of 28 events from 11/13/2020 to 9/13/2022. Findings: 1. 2021 Chemistry Core 1st Event unacceptable results: a. ALT, CH-02 b. No documentation of evaluation, investigation or corrective action was present for the unacceptable result. 2. 2021 Immunology/Immunochemistry 2nd Event unacceptable results: a. C-Reactive Protein, CRP-04 b. No documentation of evaluation, investigation or corrective action was present for the unacceptable result. 3. 2022 Hematology/ Coagulation 2nd Event unacceptable results: a. Mono %, XE-07 b. No documentation of evaluation, investigation or corrective action was present for the unacceptable result. 4. 2022 Microbiology 2nd Event unacceptable results: a. SARS-CoV-2, RSP-10 b. No documentation of evaluation, investigation or corrective action was present for the unacceptable result. 5. Interview with GS#1 on 9/13/2022 at 12:30 p.m. confirmed, the laboratory failed to evaluate 4 unacceptable results from 4 of 28 events from 11/13/2020 to 9/13/2022.

D5559

IMMUNOHEMATOLOGY

CFR(s): 493.1271(e)(f)

(e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on the review of immunochemistry "Transfusion Reaction Report", electronic medical record (EMR) search, and interview with GS#1 9/13/2022 at 3:15 p.m., the laboratory failed to document the transfusion reaction report for 1 of 1 suspected transfusion reaction reports in the patient's EMR from 11/14/2020 to 9/13/2022. Findings: 1. Review of 1 of 1 "Transfusion Reaction Report" revealed the pathologist's interpretive comments for the results of the pre-transfusion and post-transfusion specimens tested and clerical checks. 2. The transfusion reaction reports are paper forms and are scanned to be placed into the patient EMR. Request was made to see the report in the related patient's EMR. 3. An electronic search of the patient's records by General Supervisor #1 was unable to produce an electronic copy for 1 of 1 transfusion reaction reports containing the pathologist's interpretive comments for the results of the pre-transfusion and post-transfusion specimens tested and clerical checks. 4. Interview with GS#1 9/13/2022 at 3:15 p.m. confirmed, the laboratory failed to document the transfusion reaction report for 1 of 1 suspected transfusion reaction reports in the patient's EMR from 11/14/2020 to 9/13/2022.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on the lack of documentation and interview with Technical Consultant (TC) #2, the technical consultant failed to evaluate and document competency on 13 of 14 moderate complexity testing personnel for 2022. Findings: 1. Request was made for competency documentation for moderate complexity testing personnel. No documentation of competency assessment for 13 of 14 moderate complexity testing personnel for 2022 was made available at the time of survey. a. Competency assessments were not available for TP #8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, and 21 for the year 2022. 2. Interview with TC #2 on 9/13/2022 at 10:25 a.m. confirmed, the technical consultant failed to evaluate and document competency on 13 of 14 moderate complexity testing personnel for 2022.