| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 17D0452410 | 03/27/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Mitchell County Hospital Health Systems | 400 W 8th St, Beloit, 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 |
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| **D2006** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)<br><br>(b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) documentation and interview with the general supervisor (GS) #1, the laboratory failed to examine or test, as applicable, the proficiency testing samples for Fetal Screen in the same manner as it tests patient specimens in 2024. Findings: 1. Review of the "Proficiency Test Failures Corrective Action" form for the API 2023 Immunohematology 3rd Event corrective action statement signed by GS #1 on January 24, 2024, and signed by the laboratory director (LD) on February 7, 2024, revealed the following for Fetal Screen testing on specimen FET-05: a. Under findings: There were fetal cells present (1-2 fov), which according to our laboratory policy is a negative but according to API, any presence of fetal cells would be a positive." b. Under corrective action: "Currently, laboratory policy will stay as is, however for purposes of API testing we will note a positive sample if there is the presence of any fetal cells." c. The surveyor asked GS #1 if the statement noted in 1. b. was now the method of reporting Fetal Cell screen results for API samples only. Interview with GS #1 on March 27, 2025, at 2:30 p.m. confirmed, the laboratory failed to examine or test, as applicable, the proficiency testing samples for Fetal Screen in the same manner as it tests patient specimens in 2024. |

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| **D5293** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(b)(c)<br><br>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's 2023 API PT performance evaluations, proficiency testing procedure, and interview with GS #1, the laboratory failed to revise proficiency testing procedure to include corrective actions and failed to monitor corrective actions for effectiveness for three test events of unacceptable results when clerical error was the documented cause for the failure. Findings: 1. Review of the laboratory's 2023 API PT Performance Review and Corrective Action forms revealed 5 unacceptable sample results for three separate test events due to clerical error. a. API 2023 Immunohematology 1st Event: Antibody Screen, samples SER-01 and SER-02. Cause listed as clerical error. Corrective action entry: "no correction needed." b. API 2023 Immunohematology 1st Event: ABO Group, sample RED-05. Cause listed as clerical error. Corrective action entry: "One way of correcting is to Label test tubes & typing cards more accurately. Using less abbreviations to cut down the chance of misreading the card labels. Another way would be to re-read SOP's & have other staff double check clerical work." c. API 2023 Hematology/Coagulation 3rd Event: Complete blood count (CBC) parameters, samples XE-12 and XE-13. Cause listed as clerical error. Corrective action entry: "Rerun samples in the correct order with the correct labels." 2. Review of "Proficiency Testing Policy" procedure signed by LD March 20, 2025, revealed: a. No instruction for a review of test results by other staff to double check clerical work. b. No instruction for sample labeling checks for clerical errors. 3. Interview with GS #1 on March 27, 2025, at 2:30 p.m. confirmedthe laboratory failed to revise proficiency testing procedure to include corrective actions and failed to monitor corrective actions for effectiveness for three test events of unacceptable results when clerical error was the documented cause for the failure. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of "Proficiency Testing Policy", " Proficiency Test Failures Corrective Action" form, API evaluation of Beta Natriuretic Peptide (BNP), lack of documentation of patient results look back and interview with GS #1, the laboratory failed to follow written procedures to include a review of patient results generated during the time the unacceptable PT sample results were performed. Findings: 1. Review of "Proficiency Testing Policy", signed by the LD March 20, 2025, revealed the following: a. Page 2: Unacceptable PT Results Investigation: (1) Item 2: "The laboratory must review all patient data generated during the time the unacceptable PT |

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| | sample was performed. The laboratory is to determine whether patient care was compromised and if so, what corrective action is required." (2) Item 3: Every effort to find the cause(s) of an unacceptable results should be made. If an underlying system problem that contributed to the unacceptable result can be identified, actions to improve the laboratory system to minimize the risk of reoccurrence and improve the quality of patient results should be made and documented as a performance improvement plan. 2. Review of the " Proficiency Test Failures Corrective Action" form for 2024 API Chemistry Core 3rd Event for BNP for which all five sample results were unacceptable, revealed the following: a. Under "Findings": "After review of QC for August - the QC was on the low end of our range but still within range. BNP reagent kit near end of on-board expiration" b. Under "Corrective Action": "New lot of reagent was calibrated and all QC values OK. Repeat of API material showed results in the acceptable range." c. Under "Could this error affect Patient Results?" Laboratory documentations showed "N" as circled with no other entries. 3. Review of API comparative evaluation for BNP samples CM-11, CM-12, CM-13, CM-14, and CM-15 revealed all five results as unacceptable with SDI (standard deviation index) of -6.5, -3.6, -4.5, -4.5, and -4.5 respectively which indicates a strong negative shift on all BNP submitted results. The strong negative shift in unacceptable PT results and a negative shift QC results would indicate a need for patient review. 4. No documentation of BNP patient result review for testing done at the time of API PT BNP sample testing was provided at the time of survey. Interview with GS #1 March 27, 2025, at 2:30 p.m. confirmed, the laboratory failed to follow written procedures to include a review of patient results generated during the time the unacceptable PT sample results were performed. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of instrument type and test settings, current reagent lot package insert, current reagent lot evaluation data, and interview, the laboratory failed to follow manufacturer's instructions for the patient normal geometric mean instrument settings in prothrombin time testing prior to reporting patient results. Findings: 1. Prothrombin time testing is performed on the Sysmex CA-600 using Innovin reagent. 2. Sysmex CA-600 instrument settings for prothrombin time testing showed Innovin reagent lot #564643, expiration January 12, 2026, ISI setting of 1.08 and normal patient geometric mean set at 9.5 seconds. The last modification date was March 5, 2025. 3.Review of prothrombin time roll-over data for Innovin lot #564643 signed by the LD December 12, 2024, defined the normal patient geometric mean as 9.8 seconds. 4. Incorrect normal patient geometric mean values input into the CA-600 software would result in the calculation of an incorrect INR value which may impact patient care. 5. Review of patient data revealed 60 patient results were reported from March 5, 2025 to March 27, 2025. 6. Interview with General Supervisor (GS) #1 on March 27, 2025.at 3:40 p.m. confirmed, the laboratory failed to follow manufacturer's instructions for the patient normal geometric mean instrument settings in prothrombin time testing prior to reporting patient results. |