

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0034973	(X3) Date Survey Completed 08/05/2025
Name of Provider or Supplier Cameron Memorial Community Hospital	Street Address, City, State 416 E Maumee Street, Angola, IN	
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
D5309	<p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to ensure patient information was entered accurately into the Laboratory Information System (LIS) for two (pt#7 and pt#12) of twelve medical records (MR) reviewed. Findings include: 1. The following patients (pt#7 and pt#12) had identification errors for the date(s) listed: pt #7 4-28-2025 ordered under wrong MRN pt #12 4-28-2025 No results in chart, ordered in error a) A test order, test requisition, and final test reports for blood draw date of 4-28-2025 for patient (pt#7) included three tests, Methicillin-resistant Staphylococcus aureus (MRSA), hemoglobin A1C(A1C), and Basic Metabolic w/ Total Calcium that include analytes: Glucose (GLU), Blood Urea Nitrogen (BUN), Creatinine (Crea), Sodium (NA), Potassium(K), Chloride (Cl), Carbon Dioxide (CO2), Hemoglobin A1C(A1C), (MRSA) and hemoglobin A1C(A1C). b) The order and results for pt#7 were entered into the LIS under pt#12 on 4-28-2025. The phlebotomist who entered the test results was SP-10 (phlebotomist). Labels on the test requisition, blood sample(s) and nasal swab printed on 4-28-2025 had pt#12's name, date of birth (DOB), and medical record number (MRN). c) A test requisition was entered for pt#7 on 5-07-2025 with a collection date/ time of 4-28-2025 at 9:17 am. Laboratory Identifiers (labels) with the correct patient's name and date of birth (DOB) were placed over the incorrect labels with the same draw date, testing person initials, and time. The incorrect labels for PT#12 were visible under the correct labels. d) The final test report for pt#7 indicated results were manually entered by SP-03 (Technical Supervisor) on 5-07-2025 at 10:16 am. e) The final test report for pt#12 indicated under "Results-Narrative" "wrong patient". Test results for pt#12 indicated test results</p>

"inaccessible in MyChart" were not released into the patient's chart. The report did not contain any documentation on communication with the provider. 2. In an interview on 8-05-2025 at 9:07 am, SP-03 confirmed the phlebotomist SP-10 used the wrong medical record number (MRN) and ordered the laboratory (lab) tests under the wrong patient. SP-03 acknowledged no error report/quality assurance was issued for the clerical error regarding pt#7 and pt#12 or reported in error system (Midas). 3. Review of PolicyStat ID: 16305354 on pages 1 and 2 of 3, titled, " Phlebotomy-Outpatient Identification " review/ approved on 07/2024 under Procedures (3-6) requires the following: 3. Laboratorian verify the orders match the paper order and/or Released Stored Orders (RSO). 4. Laboratorians will generate labels for samples being collected. 5. Prior to blood draw, the laboratorian will ask the patient to state their first and last name and date of birth (DOB). 6. After sample collection, phlebotomist will label sample(s) in the presence of the patient followed by the patient looking at each sample collected for accuracy. Procedure guidelines also included that "any identification errors noted prior to sample collection must be corrected before collecting the patient sample" and "any errors with sample labeling must be corrected prior to patient leaving the presence of their own samples. 4. Total test volume for chemistry is 395,498.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1249(a)

(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on record review, and interview, the laboratory failed to follow their policy on reviewing and documenting errors in reporting for two (pt#7 and pt#12) of twelve patients reviewed. Findings include: 1. The following patients (pt#7 and pt#12) had identification errors for the date(s) listed: pt #7 4-28-2025 ordered under wrong MRN pt #12 4-28-2025 No results in chart, ordered in error a) Final test reports for patient (pt#7) blood draw on 4-28-2025 included three tests, Methicillin-resistant Staphylococcus aureus (MRSA), hemoglobin A1C(A1C), and Basic Metabolic w/ Total Calcium that include analytes: Glucose (GLU), Blood Urea Nitrogen (BUN), Creatinine (Crea), Sodium (NA), Potassium(K), Chloride (Cl), Carbon Dioxide (CO2), Hemoglobin A1C(A1C), (MRSA) and hemoglobin A1C(A1C). b) The test results for pt#7 were entered into the medical record for pt#12 on 4-28-2025. The medical record for pt#12 contained the note "wrong patient" on 5-7-2025. The results for pt#7 were manually entered into the chart for pt#7 on 5-07-2025 by SP-3 (Technical Supervisor). (Refer to D5309) 2. In interview with Technical Supervisor (SP-03) on 8-05-2025 (Day 2) at 09:07 am, SP-03 confirmed the phlebotomist used the wrong medical record number (MRN) to order tests for pt #7. SP-03 confirmed they had "suppressed" the test results in "Orchard" to prevent the wrong information being transferred into "EPIC" system for pt#12. 3. In interview on 8-05-2025(Day 2) at 10:48 am SP#10 (phlebotomist) does not recall any incident regarding "wrong patient drawn or missing information on tubes" but if an error was made, the supervisor would inform them. 4. Review of PolicyStat ID: 16305354 on pages 1 and 2 of 3, titled, " Phlebotomy-Outpatient Identification" review/ approved on 07/2024 under Procedures (3-6) requires the following: 3. Laboratorian verify the orders match the paper order and/or Released Stored Orders (RSO). 4. Laboratorians will generate labels for samples being collected. 5. Prior to drawing the patient, the laboratorian will

ask the patient to state their first and last name and date of birth (DOB). 6. After sample collection, phlebotomist will label sample(s) in the presence of the patient followed by the patient looking at each sample collected for accuracy. Procedure guidelines also included that "any identification errors noted prior to sample collection must be corrected before collecting the patient sample" and "any errors with sample labeling must be corrected prior to patient leaving the presence of their own samples."

5. Policy titled, "MLS-Detection of Analytical and Clerical Errors " PolicyStat ID: 16305250 signed and dated by the Laboratory Director on 7-2024 under Procedure stated the following guidelines: A. Computer Entry (Clerical Errors) 1. A bar code is utilized ...pulling up patients and the test needs results in the LIS to prevent clerical errors. 2. Analytical analyzers are interfaced with LIS to reduce transcription errors. 3. Results are matched to the accession number, patient name, and MRN number. B. Results Review (guidelines #1, 6, 8) 1. Any result that fails one of the rules requires a team member to review and manually release results. 2. All results are reviewed by a qualified team member before the result is verified and those who have completed the competency assessment for the assay. 3. Any errors discovered are brought to the attention of the technical supervisor. 6. Review of PolicyStat ID: 17940116 on page 2 of 6 titled, "Incident and Employee Injury Event Reporting (Patients, Visitors, and employees) review/ approved on 04/2025 stated "Follow up review and communications related to investigation are documented in MIDAS and kept confidential". 7. The error log for 4-08-2025 through survey date did not indicate any errors reported for dates 4-28-2025 and 5-07-2025 involving PT #7 and PT #12. 8. Total test volume for chemistry is 395,498.