| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 17D2129537 | 03/07/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Labette Health Independence Hopd Laboratory | 510 N Peter Pan Road, Independence, 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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| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of performance verification documentation for the lipase assay LIPL on the Siemens Dimension EXL 200 and interview with the general supervisor (GS) #2, the laboratory failed to verify the lipase reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient results. Findings: 1. Review of the performance verification documentation of the lipase assay LIPL on the Siemens Dimension EXL 200 revealed no verification of normal values for the laboratory's patient population. Patient testing began on 4/14/23. 2. Lipase test volume from 4/14/23 to date of survey was 548 patient test results. 4. Interview with GS #2on 3/7/24 at 3:15 p.m. confirmed, the laboratory failed to verify the lipase reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient results. |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test |

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| | results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of test lists, 16 analytes performed by more than one method or analyzer, lack of comparison records and interview with GS #1, the laboratory failed to evaluate and define the relationship between test results using different methodology/analyzers for 16 of 16 analytes. Findings: 1. Review of test lists revealed the analytes sodium (Na), potassium (K), chloride (Cl), carbon dioxide (CO2), calcium (Ca), glucose, creatinine, and blood urea nitrogen (BUN) were performed on both the Dimension EXL 200 and the on two Siemens EPOC analyzers: serial numbers 27103 and 27107. The analytes pH, pCO2, pO2, HCO3, and O2 saturation are performed on two Siemens EPOC analyzers. The analytes troponin, and beta natriuretic peptide (BNP) were performed on both the Dimension EXL 200 and the Quidel Triage Meter Pro. The Dimension EXL 200 is the primary testing method with Triage is the secondary test method for Troponin and BNP. The Dimension EXL 200 is the primary testing method and the EPOC is the secondary test method for Na, K. Cl, CO2, Cl Ca, glucose, creatinine, and BUN. The two Siemens EPOC analyzers both perform pH, pCO2, pO2, HCO3, and O2 saturation. 2. The surveyor requested documentation of the semiannual comparison studies for the 16 analytes listed in item #1. No comparison study documentation for 16 of 16 analytes were provided at the time of survey for 2023 and to date of survey 2024. 3. Patient results reported under the secondary method from 1/1/23 to 3/7/24 were: a. Na, K. Cl, CO2, Cl Ca, Glucose, Creatinine, BUN- 87 patients, 783 results, b. Troponin-51 patient results. c. BNP-29 patient results. 4. Patient results reported under two of two Siemens EPOC analyzers from 1/1/23 to 3/7/24 were: a. pH, pCO2, pO2, HCO3, and O2 saturation- 297 patients, 1,485 results. 5. Interview with GS #2 on 3/7/24 at 1:50 p.m. confirmed, the laboratory failed to evaluate and define the relationship between test results using different methodology/analyzers for 16 of 16 analytes. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>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 postanalytic systems specified in 493.1291.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the Individualized Quality Control Plan (IQCP) for the two Siemens EPOC chemistry analyzers S/N 27103 and 27107, EPOC quality control (QC) records for 2023, lack of documentation for the failure to perform QC as required, the "Annual Assessment of IQCP" for the two Siemens EPOC chemistry analyzers for 2023, and interview with GS #1, the laboratory failed to re-evaluate the IQCP after the QC interval was not met and implement correct actions (CA) as needed. Findings: 1. Review of the IQCP for the Siemens EPOC chemistry analyzer revealed QC was to be performed monthly, with each new lot, and with each new shipment on both analyzers. Monthly QC interval is considered to be not more than 31 days. 2. Review of the EPOC QC for the year 2023 revealed QC for April was performed on 4/1/23 on both analyzers. QC for May was performed on 5/27/23 on both analyzers. a. No documentation of the failed QC interval or CA were noted on the May QC log. The document was reviewed by both GS #1 and GS #2. 3. Review of |

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| | the "Annual Assessment of IQCP" for the two Siemens EPOC chemistry analyzers for 2023 revealed: a. A check marked box for "Quality Control performed appropriately and reviewed monthly." The corresponding "Corrective Actions Taken" box has no entries. b. The question "Have test process failures been identified?" is answered "No." c. The annual review is signed by GS #1 as the laboratory director designee on 2 /28/24. 4. Request was made for CA documents to address QC interval failures. No documentation was provided at the time of survey. 5. From 5/1/23 to 5/27/23 11 patients and 55 results were reported. 6. Interview with GS #1 on 3/7/22 at 12 p.m. confirmed, the laboratory failed to re-evaluate the IQCP after the QC interval was not met and implement CA as needed. |