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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>44D2326995       | <b>(X3) Date Survey Completed</b><br><br>02/18/2026 |
| <b>Name of Provider or Supplier</b><br><br>Perry County Community Hospital                                                 | <b>Street Address, City, State</b><br><br>2718 Squirrel Hollow Drive, Linden, TN |                                                     |
| 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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| D0000              | During an initial survey completed on 02/18/26, the laboratory was found OUT OF COMPLIANCE with the following condition: 493.1210 Condition: Routine chemistry.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| D3031              | <p>RETENTION REQUIREMENTS<br/>CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of the laboratory's December 2025 quality control (QC) records and staff interview, the laboratory failed to maintain chemistry QC records that in a manner that reflected the correct lot numbers and expiration dates of the controls used in December 2025 for the Beckman Coulter Access 2 B-Type Natriuretic Peptide (BNP) and high sensitivity Troponin I (hs-TnI) assays. The findings include: 1. A review of the laboratory's December 2025 QC records for the Beckman Coulter Access 2 instrument for the BNP and hsTnI analytes revealed the following: The lot numbers and expiration dates were recorded as 1003143 (Cardiac Level 3) and 1003145 (Cardiac Level 1B), with an expiration date of 07/31/2025. The QC audit log showed changes to the laboratory's QC files to the current lot number, expiration date, and ranges on 01/23/26. The December 2025 QC was reviewed on 01/29/2026. 2. The Regional Laboratory Supervisor stated during an interview on 02/18/26 at approximately 4:00 p.m. that the QC data for the previous QC lot was not printed prior to changing the QC lot numbers and expiration dates, which resulted in the incorrect lot number and expiration date recorded in the December 2025 QC records. This confirmed the survey findings.</p> |
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| <p><b>D5016</b></p> | <p>ROUTINE CHEMISTRY<br/>CFR(s): 493.1210</p> <p>If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on laboratory observation, a review of the manufacturer's package insert, a review of patient test reports, and staff interviews, the normal range on the final patient test report for the i-STAT hs-TnI did not match the normal range stated in the manufacturer's instructions used as part of laboratory procedures from the time patient testing began on 09/29/25 to the survey date on 02/18/26 (Refer to D5807).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <p><b>D5401</b></p> | <p>PROCEDURE MANUAL<br/>CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:<br/>CITATION ONE: Based on laboratory observation, a review of the laboratory procedure manual, test validation records, and a lack of documentation, and a staff interview, the laboratory failed to follow the established procedure for implementing new test methods for 10 of 14 non-waived test systems implemented in 2025. The findings include: 1. Laboratory observation on 02/17/26 at 8:30 a.m. revealed the following non-waived test systems that were used for patient testing: Beckman Coulter Access 2 used for performing B-Type Natriuretic Peptide (BNP), Ferritin, Folate, Free Thyroxine (FT4), Human Chorionic Gonadotropin- Quantitative (hCG-Quan), Prolactin, Progesterone, Prostate Specific Antigen (PSA), Testosterone, high sensitivity Troponin I (hs-TnI), Total Thyroxine (TT4), Thyroid Stimulating Hormone (TSH), Vitamin B12, and Vitamin D. Beckman Coulter DxC 700 AU used for performing Acetaminophen, Albumin, Ethanol (ETOH), Alkaline Phosphatase (AlkPhos), Alanine Transaminase (ALT), Amylase, Aspartate Aminotransferase (AST), Blood Urea Nitrogen (BUN), Calcium, Creatine Kinase (CK), Cholesterol, Chloride (Cl-), Carbon Dioxide (CO2), Creatinine, C-Reactive Protein (CRP), Direct Bilirubin (DBil), Digoxin, Iron, Gamma-glutamyl Transferase (GGT), Glucose, Glycated Hemoglobin (Hgb A1c), High-density Lipoprotein Cholesterol (HDL), Potassium (K+), Lactic Acid, Lipase, Sodium (Na+), Magnesium, Phosphorus, Phenytoin (PTN), Salicylate, Total Bilirubin, Total Protein, Transferrin, Triglyceride, Uric Acid and Vancomycin assays. Beckman Coulter DxH 690T used for performing Complete Blood Count with automated White Blood Cell differential (CBC w/Diff) and Reticulocyte Count. A microscope used for performing patient testing for wet prep, urine microscopy, and manual blood cell identification. The Med-Tox instrument was used for performing urine drug of abuse screening. The Biorex K-check used for serum qualitative ketone analysis. The OSOM serum mononucleosis test kit. The Sysmex CA 600 used for Prothrombin Time (PT), activated Partial Thromboplastin Time (aPTT), and D-Dimer. The Diesse MiniCube used for Erythrocyte Sedimentation Rate (ESR). The Siemens Clinitek Advantus for dipstick</p> |

urinalysis. The Abbott i-STAT used for performing arterial blood gas pH, partial pressure of oxygen (pO<sub>2</sub>), partial pressure of carbon dioxide (pCO<sub>2</sub>), venous pH, lactate, hs-TnI, and chemistry analytes (Glucose, BUN, creatinine, ionized calcium, Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, and CO<sub>2</sub>). The Cardinal test kit used for performing qualitative serum pregnancy test. 2. The laboratory procedure titled "Test Correlations" revealed the following: "Test Verification/Correlation provides guidelines for the verifying the performance specifications of the procedure for patient testing, as outlined In the CLIA '88 guidelines. This includes: Verification of accuracy, Precision, Reportable Range, Reference range, Analytical Measurement Range (AMR), Critically Reportable Range (CRR)." "Validation data for new methods introduced in the laboratory will demonstrate that the method will yield a reliable result on patient specimens." "Copies of the manufacturer's method literature will be reviewed and retained." "All data will be reviewed by the Medical Director and the signed procedure will be put into use." 3. A review of the Diesse MiniCube manufacturer's operator's manual revealed that the AMR for the instrument was 1-140 mm/hr for the 4mL tube and 1-100 mm/hr for the pediatric tube. 4. A review of the laboratory's validation records revealed the following: For the analytes performed on the Beckman Coulter Access 2, a reference range study had not been completed. For the analytes performed on the Beckman Coulter DxC 700 AU, a reference range study had not been completed. For the analytes performed on the Beckman Coulter DxH 690T, the raw data for the AMR for the CBC w/Diff analytes had not been evaluated to determine if the analytes passed; a reference range study for the CBC w/Diff analytes and the reticulocyte count had not been performed, and the available data had not been reviewed by the Laboratory Medical Director. The AMR for the ESR performed on the Diesse MiniCube had not been validated. The normal range for Siemens Advantus dipstick urinalysis instrument had not been validated. For the Abbott i-STAT instrument, the AMR, accuracy and precision had not been evaluated for acceptability for the pH, pO<sub>2</sub>, and pCO<sub>2</sub> analytes; the AMR had not been evaluated for acceptability for the lactic acid analyte; the AMR for the routine chemistry analytes (Glucose, BUN, creatinine, ionized calcium, Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, and CO<sub>2</sub>) had not been evaluated to determine acceptability. A reference range study had not been completed for the lactic acid and general chemistry analytes. A reference range study had not been completed for the hs-TnI. The laboratory Medical Director had not reviewed or approved the available validation records. No validations had been performed for the wet prep, urine microscopic, or manual differential. A reference /normal range study had not been completed for the qualitative serum hCG test. 5. A review of the laboratory's procedure manual revealed no procedure for the Siemens Clinitek Advantus, and no procedures for the Cholesterol, Creatinine, Glucose, Magnesium, Phenytoin, Total Protein, and HDL performed on the Beckman Coulter DxC AU 700. 6. A review of a patient activity report revealed the following dates when patient testing began for each test system: Beckman Coulter Access 2: 11/6/25 (patient AM000596) Beckman Coulter DxC 700 AU: 11/06/25 (patient AM000896) Beckman Coulter DxH 690T: 09/29/25 (patient AM000128) Diesse Mini-Cube: 10/6/25 (patient AM000530) Siemens Clinitek Advantus: 09/29/25 (patient AM000128) iSTAT: 09/29/25 (patient AM000128) Urine Microscopy: 09/30/25 (patient AM000156) Wet Prep: No wet preps had been performed Manual Blood Cell Identification: 10/03/25 (patient AM000242) Qualitative serum hCG: 11/20/25 (patient AM001208) 7. The Regional Laboratory Supervisor confirmed the survey findings during an interview on 02/18/26 at 5:00 p.m. Word Key: mm/hr=Millimeters per hour CITATION TWO: Based on laboratory observation, a review of the laboratory procedure manual, a review of the laboratory's quality control records, and staff interview, the laboratory failed to follow the procedure for maintaining QC target means and standard deviation for 8 of 44 control files reviewed. The findings include:

1. Laboratory observation on 02/18/26 at 01:10 p.m. revealed the following control lots used for performing QC on the Beckman Coulter DxC AU 700 and the Beckman Coulter Access 2 instruments: Biorad Liquichek Immunoassay Plus Control lots 1003951 and 1003953, Biorad Immunology Control lots 85771 and 85773, and Biorad Liquid Assayed Multiquel lots 46041 and 46043. 2. A review of the laboratory procedure titled "Quality Control Plan" revealed that "Biorad assayed controls have provided ranges on package insert. The package insert notes that the ranges are based on a 3SD span, unless otherwise noted. A 2SD range will need to be calculated and used as the target range." "Means and ranges will be update in analyzer and any LIS system that quality control is monitored within." 3. A review of the laboratory's quality control records revealed the following: Immunoassay Plus Lot 1003951 (Start date of 01/23/26) Prolactin: Package insert target mean = 7.83, laboratory target mean = 9.05 Liquichek Immunology Control Lot 85771 (Start date of 10/31/25) C-Reactive Protein: Package insert target mean = .839, laboratory target mean = .70. Multiquel Lot 46041 Amylase: Package insert target mean = 32.4, laboratory target mean used = 40 (Start date of 11/14/25) Creatinine: Package insert target mean = .766, laboratory target mean used = .82 (Start date of 11/04/25) Digoxin: Package insert calculated 1SD = .09, laboratory 1SD used = .11. (Start date of 11/04/25) Lactate: Package insert calculated 1SD = .05, laboratory 1SD used = .08. (Start date of 11/05/25 Phosphorus: Package insert target mean = 1.86, laboratory target mean used = 1.84 (Start date of 11/05/25) Total Protein: Package insert target mean = 3.65, laboratory target mean used = 3.72 (Start date of 01/16/26) Multiquel Lot 46043 Amylase: Package insert target mean = 225, laboratory target mean used = 243 (Start date of 11/14/25) Phosphorus: Package insert target mean = 7.74, laboratory target mean used = 8.03 (Start date of 12/25/25) Phosphorus: Package insert calculated 1SD = .20, laboratory 1SD used = .28 Total Protein: Package insert target mean = 6.31, laboratory target mean used = 6.49 (Start date of 01/16/26) Total protein: Package insert calculated 1SD = .16, laboratory 1SD used = .25 4. The Regional Laboratory Supervisor confirmed the survey finding via electronic mail communication received on 02/25/26 at 4:20 p.m. Word key: SD=Standard Deviation LIS=Laboratory Information System

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

(d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on laboratory observation, a review of the laboratory procedure manual, lack of documentation, and staff interview, the laboratory failed to conduct a risk assessment for the implementation of the Individualized Quality Control Plans (IQCPs) for the MedTox Urine Drug Screen, the OSOM Mononucleosis, or the Cardinal qualitative human chorionic gonadotropin (hCG) test methods (three of six systems with an IQCP) with patient testing beginning on 09/29/25. The findings include: 1. Laboratory observation on 02/17/26 at 8:30 a.m. revealed the MedTox Urine Drug Screen,

OSOM Mononucleosis test, and the Cardinal qualitative serum hCG used for patient testing. During the tour, the Regional Laboratory Supervisor stated that the laboratory opened with minimal testing, including the kit testing, the i-STAT test system, microscopic tests, and CBC w/Diff testing on 09/29/25. 2. A review of the laboratory procedure manual revealed that the laboratory had developed an IQCP for the MedTox Urine Drug Screen, the serum OSOM Mononucleosis test, and the Cardinal qualitative serum hCG test. 3. The laboratory failed to provide evidence of a risk assessment conducted for the implementation of the IQCPs for the MedTox Urine Drug Screen, the OSOM Mononucleosis, or the Cardinal qualitative hCG test systems. 4. The Regional Laboratory Supervisor confirmed the survey findings during an interview on 02/18/26 at 5:00 p.m.

**D5807**

TEST REPORT  
CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:  
Based on laboratory observation, a review of the manufacturer's package insert, a review of patient test reports, and staff interviews, the normal range on the final patient test report for the i-STAT hs-TnI did not match the normal range stated in the manufacturer's instructions used as part of laboratory procedures from the time patient testing began on 09/29/25 to the survey date on 02/18/26 with approximately 104 patients reported. The findings include: 1. Laboratory observation on 01/20/26 at 8:40 a.m. revealed the Abbott i-STAT instrument used as a backup method for performing patient testing for hs-TnI. 2. A review of the manufacturer's package insert for the Abbott i-STAT hs-TnI revealed the 99th percentile of the upper reference limit (normal range) as follows: Female 13 ng/L, Male 28 ng/L, Overall 21 ng/L. 3. A review of the final patient test report for patient AM000918 (female) reported on 02/10/26, revealed a normal/reference range of 2.9 - 27 ng/L. 4. The Regional Laboratory Supervisor confirmed the survey findings during an interview on 02/18/26 at approximately 4:00 p.m. 5. The Regional Laboratory Supervisor stated via electronic mail communication on 02/25/26 at 4:12 p.m. that approximately 104 patients had been reported using the i-STAT hs-TnI since patient testing began. Word Key ng /L=Nanograms/Liter