

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D1075505	<b>(X3) Date Survey Completed</b> 09/08/2021
<b>Name of Provider or Supplier</b> Perry County Medical Center	<b>Street Address, City, State</b> 7723 Clearview Church Lane, Lyles, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5024</b>	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to follow manufacturer instructions for entry of mean normal patient value used in calculation of International Normalized Ratio (INR) (Refer to D5411) and failed to verify the performance specifications of the current coagulation instrument in use for patient testing for Prothrombin Time (PT) and INR (Refer to D5421), resulting in IMMEDIATE JEOPARDY.</p>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient normal mean study, manufacturer thromboplastin package insert, manufacturer procedure manual, review of patient test reports, and interview with testing person number one, the laboratory failed to follow manufacturer instructions for entering the patient normal mean value in the Helena Cascade M-4 instrument, resulting in incorrect calculation of patient International Normalized Ratio (INR) values and resulting in immediate jeopardy.</p>

The findings include: 1. Observation of the laboratory on September 8, 2021 at approximately 10:45 am revealed the Helena Cascade M-4 instrument in use for patient testing for Prothrombin time and INR. The current lot number of thromboplastin in use was 1-21-5249. The patient normal mean setting in the instrument was 13.5. 2. Review of the patient normal mean study conducted on the current lot of thromboplastin revealed a value of 13.76. 3. Review of the manufacturer thromboplastin package insert revealed that ""Normal range" is re-established with each new lot of reagent." 4. Review of the manufacturer procedure manual revealed the following: "INR-Normal Mean Value: If using INR conversion, you must enter a normal mean PT value for your laboratory here." 5. Review of patient test reports revealed eight patient INRs were reported incorrectly since beginning the use of lot 1-21-5249 on August 2, 2021 for patient accession numbers 143280, 143407, 143493, 144037, 144120, 144178, 144744, and 144763. 6. Interview with testing person number one on September 8, 2021 at approximately 11:15 am confirmed the patient normal mean setting in the instrument was incorrect for the current lot of thromboplastin, resulting in incorrect INR calculations beginning August 2, 2021 until current date with eight patients reported.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
Based on observation of the specimen collection area and interview with testing person number three, the laboratory failed to ensure expired reagents were not used for patient wet prep testing in 2021. The findings include: 1. Observation of the area used for collection of patient specimens for vaginal wet prep on September 8, 2021 at approximately 9:15 am revealed normal saline (Lot number 1905108) in use for transport and testing of specimens for vaginal wet prep testing with an expiration date of 2021-05-22. 2. Interview on September 8, 2021 at approximately 9:15 am with testing person number three confirmed the expired saline was in use for patient testing for vaginal wet prep testing.

**D5421**

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE  
CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory, review of previous survey notes, request for performance verification studies, and interview with testing person number one, the laboratory failed to perform performance verification studies for the current Helena

Cascade M-4 instrument in use for patient testing for Prothrombin Time (PT) and International Normalized Ratio (INR), resulting in immediate jeopardy. 1. Observation of the laboratory on September 8, 2021 at approximately 8:30 am revealed the Helena Cascade M-4 instrument, serial number 411834501, in use for patient testing for PT/INR. 2. Review of notes from the previous survey conducted on August 2, 2018 revealed a different instrument serial number from the one currently in use. 3. Request on September 8, 2021 at approximately 8:30 am for performance verification studies for the Helena Cascade M-4 instrument currently in use revealed no documents were present. 4. Interview with testing person number one on September 8, 2021 at approximately 9:15 am confirmed no performance verification documents were available for the current instrument in use for performing PT/INR patient testing. The laboratory was unable to provide the date the instrument was placed into use.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Citation Number One Based on review of final patient test reports, manufacturer procedure manuals, and interview with testing person number three, the laboratory failed to use correct units of measure for red blood cell (RBC) and International Normalized Ratio (INR) in 2019, 2020, and 2021 for six of six patient RBC results and twelve of twelve patient INR results. The findings include: 1. Review of final patient test reports for RBC and INR revealed the following units of measure on the final patient test report: RBC =  $10^3/uL$  (six of six patients reviewed; accession numbers 121218, 131177, 135287, 136972, 143959, and 144892). Patient report dates range from 08.12.19 to current date of 09.08.21. INR = % (twelve of twelve patients reviewed; accession numbers 118140, 129754, 134798, 140925, 144178, 143280, 144763, 143407, 144037, 143493, 144744, 144120). Patient report dates ranged from 05.23.2019 to 09.03.2021. 2. Review of the manufacturer procedure manuals for the Sysmex XN-430 and the Helena Cascade M-4 revealed the following: Units of measure for RBC =  $10^6/uL$  INR = No units of measure 3. Interview on September 8, 2021 at approximately 4:30 pm with testing person number three confirmed incorrect units of measure were used on the final patient test report for RBC and INR in 2019, 2020 and 2021. Citation Number Two Based on review of final patient test reports, and interview with testing person number three, the final patient test report failed to include units of measure for three of three wet preps and one of one urine microscopic in 2019, 2020, and 2021. The findings include: 1. Review of final patient test reports for urine microscopic and wet prep revealed the following: Wet Prep-No units of measure for Bacteria, Tricomoniosis, and Yeast for patient accession numbers 116523, 134178, 142714. Patient report dates range from 04.11.2019 to 07.15.2021. Urine microscopic-No units of measure for bacteria, amorphous, mucous, crystals, or casts for patient accession number 144892, reported on 09.08.2021. 2. Interview on

September 8, 2021 at approximately 4:30 pm with testing person number three confirmed the final patient test reports for wet prep and urine microscopic did not contain units of measure for all analytes reported in 2019, 2020 and 2021.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on review of laboratory personnel records and interview with the technical consultant, the technical consultant failed to perform annual competency assessments for testing personnel numbers one and two (two of two established testing personnel) in 2019. The findings include: 1. Review of laboratory personnel records revealed no annual competency assessments were available for testing personnel numbers one and two. 2. Interview with the technical consultant on September 8, 2021 at approximately 5 pm confirmed that annual competency assessments were not performed for testing personnel number one and two in 2019.