Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0307350	01/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Perry County Medical Center	115 E Brooklyn St, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's procedure manual and testing personnel records, and interview with the laboratory director, the laboratory failed to follow testing personnel policy/procedures in 2019, 2020 and 2021. The findings include: 1. Observation of the laboratory on January 24, 2022 at approximately 8:30 am revealed the following moderately complex test systems in use for patient testing: A microscope used for performing wet prep and urine microscopy, rheumatoid factor test kit, Sysmex XN430 used for performing complete blood count (CBC), and an Ace Axcel instrument used for performing chemistry tests. 2. Review of the laboratory's Quality Assessment policy/procedure for assessment of testing personnel competency revealed that personnel will have documentation training for the tests they perform, initial competency after training, a six month competency assessment and then annual competency assessments thereafter. Competency will also be assessed any time a new test methodology or instrument is put into use, prior to reporting patient test results. Additionally, the policy included "The Competency Checklist will be comprised of the six required elements. These include: 1. Direct Observation of Patient Testing 2. Monitoring of Test Results 3. Review of Records 4. Review of Maintenance 5. Blind Testing 6. Problem Solving. 3. Review of the laboratory's personnel records revealed the following: No competency assessment for use of the new Sysmex SN-430 complete blood instrument before use for testing personnel numbers one and two. No documented training for wet prep and urine microscopy for testing personnel number two. No interim competency performed in 2019 for testing personnel number two. The six competency assessment elements

	were not addressed for each moderately complex test system as follows: Lead testing personnel: 2020 annual competency: Direct observation not performed for wet prep, urine microscopy, rheumatoid factor. Monitoring of test result and reporting not performed for wet prep, urine microscopy, rheumatoid factor. Direct observation of instrument maintenance not performed for Sysmex XN430 CBC. Assessment of blind testing not performed for Sysmex XN430 CBC, Ace Axcel chemistry, wet prep, urine microscopy, and rheumatoid factor. Assessment of problem solving skills not performed for wet prep, urine microscopy, rheumatoid factor, and Ace Axcel chemistry. 2021 annual competency: Direct observation not performed for wet prep, urine microscopy, rheumatoid factor, Sysmex XN430 CBC. Monitoring of test result and reporting not performed for wet prep, urine microscopy, rheumatoid factor, CBC. Review of worksheets, QC, PT & Maintenance Records not performed for rheumatoid factor. Direct observation of instrument maintenance not performed for Sysmex XN430 CBC. Assessment of blind testing not performed for Sysmex XN430 CBC, wet prep, and urine microscopy. Assessment of problem solving skills not performed for wet prep, urine microscopy, rheumatoid factor, and Sysmex XN430 CBC. Testing personnel number two: 2020 annual competency: Direct observation not performed for wet prep and urine microscopy. Monitoring of test result and reporting not performed for wet prep and rheumatoid factor. Review of worksheets, QC, PT & Maintenance Records not performed for rheumatoid factor. Direct observation of instrument maintenance not performed for Sysmex XN430 CBC. Assessment of blind testing not performed for Sysmex XN430 CBC, wet prep, ACE Axcel chemistry, rheumatoid factor and urine microscopy. Assessment of problem solving skills not performed for wet prep, urine microscopy, rheumatoid factor, and complete blood count. 2021 annual competency: Direct observation not performed for wet prep and rheumatoid factor. Monitoring of test result and reporting not performed for wet prep and rheumatoid factor. Review of worksheets, QC, PT & Maintenance Records not performed for rheumatoid factor. Assessment of blind testing not performed for complete blood count, wet prep, and urine microscopy. Assessment of problem solving skills not performed for wet prep, urine microscopy, and rheumatoid factor. 4. Interview with the laboratory director on January 24, 2022 at approximately 5:00 pm confirmed the laboratory failed to follow testing personnel policies/procedures for training and competency assessments in 2019, 2020, and 2021.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual and interview with the lead testing personnel, the laboratory director failed to approve the procedure for complete blood count (CBC) in 2020. The findings include: 1. Observation of the laboratory on January 24, 2022 at approximately 8:30 am revealed the Sysmex XN-430 on the counter in use for patient testing for CBC. 2. Review of the laboratory's procedure manual revealed a procedure for the Sysmex XN-430 CBC instrument with an effective date of 10-21-2020 that had not been approved by the laboratory director. 3. Interview with the lead testing personnel on January 24, 2022 at approximately 5:00 pm confirmed the procedure for CBC on the Sysmex XN-430 had not been approved for use by the laboratory director.

D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient test reports and quality control (QC) records, and staff interview, the laboratory failed to include a titered control for rheumatoid arthritis (RA) factor in 2020. 1. Review of patient #130522 revealed RA factor reported as "Positive- 1:8 dilution" on 05.20.2020. 2. Review of the laboratory's QC records for RA factor revealed a titered control of known reactivity was not performed on 05.20.2020. 3. Phone interview with the lead testing person on February 1, 2022 at approximately 2:30pm confirmed the laboratory did not include a titered control on date when patient testing included titered results. The lead testing person confirmed the survey findings.