Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0307350	10/23/2018
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CMS 209), the laboratory's proficiency testing attestation statements for 2016, 2017, and 2018, and interview with testing personnel number one, the laboratory failed to rotate proficiency testing (PT) in 2016, 2017, and 2018. The findings include: 1. Review of the CMS 209 revealed two testing personnel. 2. Review of the laboratory's proficiency testing attestation statements for 2016, 2017, and 2018 revealed the following: Chemistry PT: Testing personnel number one performed 5 of 6 events (2016-event 3, 2017-event 1 and 2, 2018-event 2 and 3). Immunology PT: Testing personnel number one performed 5 of 6 events (2017-event 1, 2, and 3, 2018-event 1 and 2). Hematology PT: Testing personnel number one performed 6 of 6 events (2016-event 3, 2017-event 1, 2, and 3, 2018-event 1 and 2) Microscopy PT: Testing personnel number two performed 6 of 6 events (2016 event 3, 2017 events 1, 2, and 3, 2018 event 1 and 2) 3. Interview with testing personnel one on October 23, 2018 at 1:05 pm confirmed that two testing personnel routinely perform patient testing in all specialties and the laboratory failed to ensure PT was rotated among all personnel who routinely perform patient testing in 2016, 2017 and 2018.
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 review of the laboratory's quality assessment policy and interview with testing personnel number one, the laboratory's policy for testing personnel competency was not in compliance with the personnel requirements in subpart M in 2018. The findings include: 1. Review of the laboratory's quality assessment policy under the section titled "Personnel Training and Qualifications" revealed that methods of assessing competency were not included in the policy. The required six elements as specified in subpart M are: Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, process, and testing; monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and Assessment of problem solving skills. 2. Interview with testing personnel number one on October 23, 2018 at 4:30 pm confirmed the laboratory's policy for assessing testing personnel competency was not in compliance with the personnel requirements in subpart M when it failed to include methods of assessing competency in 2018.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of patient number nine test report, the laboratory's quality control limits for the complete blood count (CBC) instrument and the manufacturer package insert limits, the monthly quality assessment for February 2017, and interview with testing personnel number one, the laboratory's quality assessment process failed to detect and correct problems with quality control limits for lot numbers 078500 and 088500 in 2017. The findings include: 1. Review of patient number nine test report revealed patient testing for CBC on February 7, 2017. 2. Review of the laboratory's quality control limits in the laboratory's information system and the manufacturer package insert revealed the following: Lot 078500 Limit in use Correct limit Red Blood Cell 3.5 - 4.5 3.79 - 4.29 Lot 088500 Limit in use Correct Limit Platelet 223 - 523 313 - 433 3. Review of the February 2017 monthly quality assessment form signed by the laboratory director on March 5, 2017 revealed no corrective action documented for the use of incorrect quality control limits. 4. Interview with testing personnel number one on October 23, 2018 at 4:30 pm confirmed the laboratory used incorrect quality control limits in their laboratory information system for red blood cell for lot number 078500 and platelet for lot number 088500 in 2017. There was no corrective action documented for the incorrect quality control limits and the laboratory's quality assessment process failed to detect and correct incorrect quality control limits in 2017.

D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer operator's manual for the ACE Axcel chemistry instrument and interview with testing personnel number one, the laboratory failed to perform quality control as specified by the manufacturer when it did not perform quality control (QC) after calibration in 2018. 1. Review of the manufacturer operator's manual for the ACE Axcel chemistry instrument revealed the following under the section titled "When and How to Run Controls": "Controls are also run when new bottles of reagent are loaded or recalibration of the test is performed." 2. Interview with testing personnel number one on October 23, 2018 at 5:00 pm confirmed the laboratory failed to perform QC as specified by the manufacturer for the ACE Axcel chemistry instrument when it did not perform quality control after calibration in 2018.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the validation studies for the ACE Axcel chemistry instrument, and interview with testing personnel number one, the laboratory director failed to ensure validation studies performed for the ACE Axcel chemistry instrument were adequate in 2018. 1. Observation of the laboratory on October 23, 2018 at 8:30 am revealed the ACE Axcel chemistry instrument (serial #16110348) in use for patient testing. 2. Review of the validation studies performed June 13, 2018 for the ACE Axcel chemistry instrument revealed no review signatures of the laboratory director. 3. Interview with testing personnel number one on October 23, 2018 at 4:30 pm confirmed the laboratory director failed to ensure validation studies performed for the ACE Axcel chemistry instrument were adequate in 2018.