Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1075505	08/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Perry County Medical Center	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Casper Report 155 (CMS 155), the laboratory's proficiency testing records and interview with testing personnel number one, the laboratory failed to maintain satisfactory performance for the creatinine analyte for 2017 events one and three, resulting in the first unsuccessful occurrence.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e)

	(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Casper report 155 (CMS 155), the laboratory's proficiency testing records, the performance evaluation report for chemistry for 2018 event two, and interview with testing personnel number one, the laboratory failed to perform corrective action for the unsatisfactory glucose analyte and the unacceptable direct bilirubin analyte scores for 2018 chemistry event two. The findings include: 1. Review of the CMS 155 report revealed a score of 20% for the glucose analyte for 2018 event two. 2. Review of the laboratory's available proficiency testing records on the day of the survey revealed there was no performance evaluation report available for 2018 chemistry event two. 3. Review of the performance evaluation report obtained from the laboratory's proficiency testing provider revealed the following: "Evaluation Published: 6/27 /2018"; Sample numbers CH-06, CH-08, CH-09, CH-10 scored as unacceptable for the glucose analyte; CH-06 scored as unacceptable for the direct bilirubin analyte. 4. Interview with testing personnel number one on August 2, 2018 at 11:30 am confirmed the laboratory had not performed corrective action for the unsatisfactory glucose score of 20% or the unacceptable score for the direct bilirubin sample number CH-06 for proficiency testing 2018 event two for chemistry.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CMS 155, the laboratory's 2017 proficiency testing records, and interview with testing personnel number one, the laboratory failed to maintain satisfactory performance for creatinine analyte, resulting in the first unsuccessful occurrence. The findings include: 1. Review of the CMS 155 report revealed the following unsatisfactory scores for creatinine: 2017 event one = 40%, 2017 event three = 40%. 2. Review of the 2017 event one proficiency testing summary report revealed the following samples scored as unacceptable for the creatinine analyte: CH-02, CH-03, CH-04. 3. Review of the 2017 event three proficiency testing summary report revealed the following samples scored as unacceptable for the creatinine analyte: CH-11, CH-12, CH-15. 4. Interview with testing personnel number one on August 2, 2018 at 11:30 am confirmed the laboratory failed to maintain satisfactory performance for the creatinine analyte for 2017 events one and three, resulting in the first unsuccessful occurrence for the creatinine analyte.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230

	Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to verify the accuracy of calculated low-density lipoprotein (LDL) cholesterol (Refer to D5217) and failed to have an effective quality assurance plan that detected problems with quality control (Refer to D5291).
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 the laboratory's policy titled Quality Assessment, review of the laboratory's documents used for review of quality control, the daily quality control for creatinine, the quality control limits entered into the laboratory's system for maintaining quality control records and interview with testing personnel number two, the laboratory's Quality Assessment program was ineffective when it failed to detect multiple problems in quality control in 2017 and 2018. 1. Review of the laboratory's policy titled Quality Assessment revealed the following under the section for quality control: "IQAP and Summary reports are examined for any long-term QC problems and when noted, corrective action is taken." 2. Review of the documents used for quality control review revealed there were no documents showing technical consultant review of the daily quality control for chemistry tests performed on the Alfa Wasserman chemistry instrument or the Beckman Coulter AcT Diff 2 complete blood count instrument. 3. Review of the quality control for on August 31, 2017 revealed both levels of control were out of the laboratory's acceptable range. 4. Review of patient number five test report dated August 31, 2017 revealed creatinine patient testing was reported. 5. Review of the document titled Alfa Wassermann Group Coordinator Report, dated Aug, 2017, signed by the laboratory director on 9/13, revealed review of August 2017 chemistry quality control performed using only a data summary report with comparison against peer group. There were no documents showing technical consultant review of the August 2017 chemistry daily quality control using the laboratory's control data with comparison to the laboratory's expected ranges. 6. Review of the quality control package inserts for the Beckman Coulter AcT Diff 2 instrument and the ranges entered into the laboratory electronic system used for recording and monitoring quality control revealed the following: Lots 069900 (Low), 079900 (Normal), 089900 (High) - Current lot-placed into use on 6.15.2018 Level Low (Lot # 069900) Package Range insert range in Lab System White blood Cell 3.6 - 4.6 3.1 - 5.1 Red blood Cell 2.15 - 2.65 1.9 - 2.9 Hemoglobin 5.8 - 7.2 5.1 - 7.9 Hematocrit 15.7 - 21.2 13.0 - 23.8 Platelet 55 - 95 35 - 115 Level Normal (Lot # 079900) Package Range insert range in Lab System White blood Cell

	7.7 - 9.1 7.0 - 9.8 Red blood Cell 3.78 - 4.28 3.5 - 4.5 Hemoglobin 11.1 - 12.9 10.2 - 13.8 Hematocrit 31 - 37 28 - 40 Level High (Lot # 089900) PackageRange Range insert range in Lab System White blood Cell 16.9 - 19.3 15.7 - 20.5 Red blood Cell 4.93 - 5.53 4.6 - 5.8 Hemoglobin 16.2 - 18.0 15.3 - 18.9 Hematocrit 44.7 - 52.7 40.7 - 56.7 Platelet 320 - 440 260 - 500 Lots 067900 (Low), 077900 (Normal), 087900 (High) Placed into use on 9.25.17 Level Low (Lot # 067900) Package Range insert range in Lab System White blood Cell 3.6 - 4.6 3.1 - 5.1 Red blood Cell 2.07 - 2.57 1.8 - 2.8 Hemoglobin 5.5 - 6.9 4.8 - 7.6 Hematocrit 15.1 - 20.5 12.3 - 23.1 Platelet 58 - 98 38 - 118 Level Normal (Lot 077900) Package Range insert range in Lab System White blood Cell 8.4 - 9.8 7.7 - 10.5 Red blood Cell 3.82 - 4.32 3.6 - 4.6 Hemoglobin 11.3 - 13.1 10.4 - 14.0 Hematocrit 31.5 - 37.5 28.5 - 40.5 Level High (Lot 087900) Package Range insert range in Lab System White blood Cell 17.8 - 20.2 16.6 - 21.4 Red blood Cell 4.96 - 5.56 4.7 - 5.9 Hemoglobin 16.2 - 18.0 15.3 - 18.9 Hematocrit 44.9 - 52.9 40.9 - 56.9 Platelet 323 - 443 263 - 503 7. Review of reports used for review of chemistry quality control for the months of December 2016, February 2017, October 2017, and May 2018 revealed the use of the laboratory's cumulative data with comparison to their peer group. There were no documents present showing technical consultant review of the laboratory's daily quality control and how it performed against the laboratory's acceptable ranges. 8. Review of reports used for review of CBC quality control for the months of March and April 2017 revealed the use of only laboratory cumulative data with comparison to peer group. There were no documents present showing technical consultant review of the laboratory's daily quality control and how it performed against the laboratory's acceptable ranges. 9. Interview with testing personnel number two on August 2, 2018 at 5:00 pm confirmed the laboratory's current quality assessment review process was ineffective when quality control problems were not identified and corrective action was not documented in 2017 and 2018.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy for proficiency testing, the laboratory's proficiency testing performance evaluation reports, and interview with testing personnel number one, the laboratory director failed to ensure an approved corrective action plan was followed for unacceptable proficiency testing scores in 2017. The findings include: 1. Review of the laboratory's proficiency testing performance evaluation report for hematology 2017 event one revealed unacceptable score for prothrombin time for sample COA-12. Report signed by the laboratory director, no corrective action for unacceptable score documented. 2. Review of the laboratory's proficiency testing performance evaluation report for chemistry 2017 event one revealed unacceptable score for sodium for sample number CH-03. Report signed by the laboratory director, no corrective action for unacceptable score documented. 3. Review of the laboratory's proficiency testing policy revealed the following statement: "If any PT test sample result is graded as "Unacceptable" or "Fail," take action to

	identify and correct the problem, even if the overall event received a passing grade." 4. Interview with testing personnel number one on August 2, 2018 at 11:00am confirmed the laboratory director failed to ensure the corrective action plan for proficiency testing was followed when corrective action was not performed for the unacceptable scores for the prothrombin time analyte for 2017 event one for hematology, and for the sodium analyte for 2017 event one.