Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0904148	06/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Grundy County Primary Care Center	10120 Sr 56, Coalmont, 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
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the 2019 American Association of Family Physicians (AAFP) PT manual, 2018-2019 proficiency testing (PT) records, quality assurance (QA) plan & assessments and interview with the lab's QA nurse coordinator, the lab director failed to ensure the PT of the regulated analyte, Hemoglobin, was reported in 2018 AAFP PT Events A, B, & C (Refer to D6016) and failed to ensure the QA plan & assessments monthly identified the missing regulated analyte, Hemoglobin, during the 2018 AAFP PT Events A, B, & C.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of the 2018-2019 AAFP PT manual & assessments, PT records, and an interview with the QA nurse coordinator, the the laboratory director failed to

	ensure the regulated analyte, Hemoglobin, was not enrolled/reported during all 3 hematology events (A, B, & C) in 2018. Findings include: 1. Review of the 2019 AAFP PT manual, page 22, for CLIA Regulated Analytes stated: the requirement for the laboratory "must be enrolled" for "Hematology" including regulated analyte, Hemoglobin (excluding HemaCue). 2. Review of the 2018-2019 AAFP PT assessments for CMS Performance Summary, Regulated Analytes, for 3 of 3 events (A, B, & C) revealed no enrollment/reporting for Hemoglobin during 2018. 3. Review of 2018-2019 PT records revealed the regulated analyte for hematology, Hemoglobin, was not reported in 3 of 3 2018 AAFP PT events. 4. In an interview, on June 6, 2019, at 10:00am, the QA nurse coordinator confirmed the laboratory director failed to ensure the hematology regulated analyte, Hemoglobin, was enrolled/reported during the 3 of 3 2018 AAFP PT events.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the Laboratory's Quality Assurance & Assessments (QA) Plan, review of the Director's monthly QA for the 2018 proficiency testing (PT) program for hematology regulated analytes and an interview with the QA nurse coordinator, determined the Laboratory Director did not ensure quality of laboratory services were maintained for the 2018 year time period per QA plan. The findings include: 1. A review of the QA Plan stated: "The Lab Director will ensure that Quality Control and Quality Assurance Plans are established and maintained by review to assure the quality of the laboratory services and identify failures as they occur. 2. The documentation of Director review for Quality Controls or Qualtiy Assessments for 2018 did not ensure the hematology regulated analyte, Hemoglobin, was enrolled /reported for the 2018 AAFP PT events A, B, & C. 3. An interview with the QA nurse coordinator at approximately 11:00 a.m. June 6, 2019 confirmed the Director review of the quality quality assessment records to ensure the quality of the laboratory services were maintained for the 2018 year time period