Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0957447	08/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
West Texas Pediatrics	5215 96th Street, Lubbock, TX	

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
D0000	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, Medical Laboratory Evaluation. The facility was found to be out of compliance with the conditions of the CLIA program. The conditions not met were: D2016 - 42 C.F.R. 493.803 Condition: Successful participation in a proficiency testing program D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 CMS Casper 153 & 155 proficiency testing reports and the

	Medical Laboratory Evaluation proficiency testing records for the 1st and 2nd testing events in 2020, the laboratory failed to successfully participate in proficiency testing for Hematology (See D2123 and D2130).
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on desk review of proficiency testing, the laboratory failed to participate in two consecutive testing events resulting in a test score of 0% in WBC Diff (White Blood Cell Differential), WBC (White Blood Cell Count), RBC (Red Blood Cell Count), HCT (Hematocrit), HGB (Hemoglobin), and Platelets (PLT) in the specialty of Hematology for the 1st and 2nd Events, respectively in 2020. Findings follow. Review of the CMS Casper Report 153 showed the facility received 2 out of 3 consecutive failures with scores of 0 in the report. Review of the CMS Casper Report 155 showed scores of 0 in WBC Diff, WBC, RBC, HCT, HGB, and PLT for the 1st and 2nd events of 2020. Review of the Medical Laboratory Evaluation Proficiency Testing Evaluation for the 2020 MLE-M1 (1st) and MLE-M2 (2nd) Events, respectively, show scores of 0% for WBC Diff, WBC, RBC, HGB, HCT, and PLT under the specialty of Hematology with the comment Failure to Participate.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of proficiency testing records, the laboratory failed to achieve satisfactory performance for the same analyte in two consecutive events resulting in unsuccesssful performance with a test score of 0% in WBC Diff (White Blood Cell Differential), WBC (White Blood Cell Count), RBC (Red Blood Cell Count), HCT (Hematocrit), HGB (Hemoglobin), and Platelets (PLT) in the specialty of Hematology for the 1st and 2nd Events, respectively in 2020. Findings follow. Review of the CMS Casper Report 153 showed the facility received 2 out of 3 consecutive failures with scores of 0 in the report. Review of the CMS Casper Report 155 showed scores of 0 in WBC Diff, WBC, RBC, HCT, HGB and PLT for the 1st and 2nd events of 2020. Review of the Medical Laboratory Evaluation Proficiency Testing Evaluation for the 2020 MLE-M1 (1st) and MLE-M2 (2nd) Events, respectively, show scores of 0% for WBC Diff, WBC, RBC, HGB, HCT, and PLT under the specialty of Hematology for the two consecutive testing events.

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 CMS Casper 153 & 155 proficiency testing reports and the Medical Laboratory Evaluation proficiency testing records for the 1st and 2nd testing events in 2020, the Laboratory Director failed to provide direction and management for the laboratory testing performed (see D6017).
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the CMS Casper 153 & 155 proficiency testing reports and the Medical Laboratory Evaluation proficiency testing records for the 1st and 2nd testing events in 2020, the Laboratory Director failed to ensure the laboratory participated in proficiency testing for Hematology (See D2130).