

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0957447	(X3) Date Survey Completed 01/13/2020
Name of Provider or Supplier West Texas Pediatrics	Street Address, City, State 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
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based upon review of the CMS Enforcement letter E18-237 (dated February 13, 2019) , review of laboratory records and interview of facility personnel, the laboratory director failed to obtain the services of a qualified Technical Consultant (from outside the facility) to assist and review the laboratory's performance to be on the premises two days each week (minimum of 16 hours per week) during the duration of the condition level non-compliance as instructed in the enforcement letter received from CMS Dallas regional offices on February 13, 2019. The findings included: 1. Review of the CMS Enforcement letter E18-237 (dated February 13, 2019) found on page 2 under the heading Directed Plan of Correction: "The laboratory must obtain the services of a qualified Technical Consultant (from outside the facility) to assist and review the laboratory's performance. Any prospective candidate must hold a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and possess at least two years of laboratory training or experience or both in the designated specialty or subspecialty areas of services for which the technical consultant is responsible. The laboratory must submit the name and copies of credentials of the Technical consultant to the State survey Agency no</p>

later than February 28, 2019, and obtain that agency's approval prior to entering into any contractual arrangement with such individual. If there is a change in the Technical Consultant(s), the laboratory must inform the State Agency and CMS of the change in personnel, the effective date, the duration of the new contract, and official change in technical consultant(s). In addition, there must be a written report submitted by the consultant(S) to document efforts made toward compliance. During the duration of the condition level non-compliance, the technical consultant must be on the premises two days each week (minimum of 16 hours per week)." 2. Review of laboratory records found the laboratory obtained the services of a qualified Technical Consultant and submitted credentials to the State Agency for approval on July 24, 2019. The Technical consultant provided consultative services to the laboratory between July 19,2019 and December 4, 2019. 3. Review of invoices for payment of services for the Technical consultant provided consultative services to the laboratory between July 19,2019 and December 4, 2019 found the Technical Consultant documented 63.5 hours over 33 visits. July 19, 2019 - 1.5 hours July 20, 2019 - 1.5 hours July 21, 2019 - 1.5 hours July 22, 2019 - 1.5 hours July 23, 2019 - 4 hours July 26, 2019 - 1 hour July 28, 2019 - 2 hours July 31, 2019 - 2 hours August 2, 2019 - 0.25 hours August 8, 2019 - 0.75 hours August 9, 2019 - 4.25 hours August 12, 2019 - 2.0 hours August 14, 2019 - 1.25 hours August 23, 2019 - 0.25 hours August 30. 2019 - 3.75 hours September 1, 2019 - 3.0 hours September 2, 2019 - 5.0 hours September 3, 2019 - 1.0 hour September 5, 2019 - 1.5 hours September 6, 2019 - 1.0 hour September 9, 2019 - 1.0 hour September 11, 2019 - 0.5 hour September 13, 2019 - 1 hour September 14, 2019 - 1.5 hours September 16,2019 - 0.5 hour September 18, 2019 - 0.25 hour September 19,2019 - 0.5 hour October 4, 2019 - 1 hour October 11, 2019 - 3.25 hours October 23, 2019 - 0.25 hour October 29, 2019 - 1.50 hours November 6, 2019 - 1.25 hours November 13, 2019 - 0.75 hour 3. Interview of Testing person one on January 13, 2020 conducted at 3:40 PM confirmed that the laboratory did not have a Technical Consultant at the time of the survey.