Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1053583	01/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Verley Gordon Md Pa	5711 N La Homa Rd Ste B, Mission, 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
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 laboratory's submitted Form CMS 209, review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 and 2017, and confirmed in staff interview, it was revealed the laboratory failed to have documentation of rotating proficiency testing among all testing personnel. The findings were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 3 testing personnel. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 (events 1,2, and 3) and 2017 (events 1, 2, and 3) revealed testing personnel #2 as listed on Form CMS 209 performed proficiency testing for each of the 3 events in 2017. 3. The laboratory was asked to provide documentation of the other three testing personnel participating in proficiency testing. No documentation was provided. 4. An interview with testing personnel #1 and #2 on 01/24/2018 at 1530 hours at the nurse's station confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, review of the manufacturer's instructions for the AcT diff 2 hematology analyzer, review of the laboratory's environmental records, and confirmed in interview of facility personnel, the laboratory failed to define an acceptable temperature range for the laboratory. The findings were: 1. Direct observation made in the laboratory during the initial tour of the laboratory on 01/24 /2018 at 1410 hours revealed that the laboratory had an environmental log posted on the refrigerator. The log revealed that the laboratory defined the room temperature as 60 degrees Fahrenheit to 83 degrees Fahrenheit. 2. Review of the manufacturer's instructions for the AcT diff 2 hematology analyzer (PN 4237495A) under, "Cell Controls" revealed the operating temperature for the analyzer is, "20 to 25 degrees Celsius" or 68 to 77 degrees Fahrenheit. 3. The laboratory was asked to provide documentation of defining an acceptable room temperature range according to the manufacturer's instructions. No documentation was provided. 4. An interview with testing personnel #2 on 01/24/2018 at 1700 hours at the nurse's station confirmed the findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies, quality control records, and confirmed in interview, the laboratory's quality assurance program failed to detect problems in analytic systems. The findings were: 1. Review of the laboratory's policy, "Quality Assurance," approved by the laboratory director on 09/07/2007, stated, "We will evaluate all errors made by the laboratory and will determine if changes must be made in our policy and procedure to prevent similar errors in the future ..." 2. Review of the laboratory's quality control records from January 2016 to November 2017 revealed the laboratory failed to review quality control over time for the following timeframes: July 2016 to October 2016 July 2017 to November 2017 3. The laboratory was asked to provide documentation of performing quality assurance review that addressed the error as stated in the laboratory's policy. No documentation was provided. 4. An interview with testing personnel #1 and #1 on 01/24/2018 at 1700 hours at the nurse's station confirmed the findings.