Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0482866	06/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Phynet, Inc	307 West Upshur, Gladewater, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on review of 2018 and 2019 documentation for the Hitachi CLA-1 immunology analyzer and staff interview, the laboratory failed to verify the accuracy of allergen-specific immunoglobulin E (IgE) testing at least twice annually. Findings: 1. In the course of the survey, test documentation for the Hitachi CLA-1 analyzer was reviewed. Included were test results for a split-sample accuracy verification performed by Allos Reference Laboratory and Hugman-Kent Clinic dated 06-26-2018. No other split-sample results for 2018 or 2019 were found. 2. In an interview at the site on 06-11-2019, testing person 2 (CMS form 209) stated that there had been "some confusion" regarding accuracy verification the previous year, and that no additonal results were available for 2018 or 2019. .
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: . Based on review of the manufacturer's instructions for the Hitachi CLA-1 analyzer and staff interview, the laboratory failed to perform testing according to those

	instructions. Findings: 1. The user's manual for the Hitachi CLA-1 states: "It is recomended that the CLA-1 should be left on when not in use. If it is necessary to turn the instrument OFF for more than 1 hour, ALLOW THE UNIT TO WARM UP FOR AT LEAST 6 HOURS BEFORE USE." (instructions in all caps as shown. Source: Hitachi CLA-1 user's manual, page 15, item 4.) 2. In an interview at the site on 06-11-2019, testing person 2 stated that the instrument was ordinarily used to analyze batched samples one or two weekdays a month, and that it was left powered down when not in use. She further stated that, when put in use, the analyzer was allowed to warm up "no more than an hour or so" before testing began, and was not aware of the manufacturer's recommendation for a 6-hour warm up. .
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on review of patient reports for allergen-specific IgE testing using the Hitachi CLA-1 analyzer, confirmed by staff interview, the laboratory failed to include the address of the location where the test was performed. Findings: 1. In the course of the survey, an example of a patient test report containing results for allergen-specific IgE testing was requested. The reports offered showed the patient's name and identifying number and a scan of the thermal printer tape with the test results and interpretive information. No performing laboratory address was included. 2. In an interview at the site on 06-11-2019, testing person 2 confirmed that the report observed was typical of that offered by the laboratory. .
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on review of testing personnel education and training documentation, confirmed by staff interview, the laboratory technical consultant failed to document evaluation of the competency of all testing personnel as required. Findings: 1. Personnel documentation for testing personnel was reviewed. No competency verification documents were included. 2. In an interview at the site on 06-11-2019, testing person 1 stated she was not aware of any annual competency evaluations being performed at the facility. .