Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D1093221	07/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bridgeport Express Care	1370 Johnson Avenue, Bridgeport, WV	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based upon a review of Proficiency Testing (PT) records and an interview with Testing Personnel 1 (TP1), the Laboratory Director (LD) had not signed the attestation statements for two 2019 PT events. Findings: 1. A review of PT records revealed that the AAFP 2019 Testing event A and AAFP 2019 Testing event B had attestation statements signed by the testing personnel, but not signed by the LD. 2. A review of the documents for the testing events established the LD had signed the raw data, submitted answers, and scored results for both PT events. 3. An interview with TP1, on 7/23/19 at approximately 1000 AM, determined that the LD had not signed the attestation statements but had reviewed all the raw data, submitted answers, and scored results for the PT events.
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 a tour of the laboratory and interview with Testing Personnel 1 (TP1), the laboratory failed to accurately monitor the conditions essential for proper storage of reagents and test system operation. Findings: 1. The room temperature and humidity were being monitored and documented from a thermometer that is not an approved NIST calibrated/traceable thermometer. 2. The procedure manual states the room temperature is to be monitored and documented. The environmental temperature range is established on the reagents for the AcTDiff analyzer and stated in the procedure manual. 3. An interview with TP1, on 7/23/19 at approximately 1100 AM, confirmed that the environmental temperature was being monitored with a thermometer that is not an approved NIST calibrated/traceable thermometer.