Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2228255	10/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Psh Hampden Medical Center Poct	2200 Good Hope Rd, Enola, PA	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Abbott istat analyzer validation records and interview with technical consultant (TC) #1, the laboratory failed to demonstrate and document the performance specifications of precision and accuracy for chemistry analytes performed on the Abbott istat Chem 8+ Cartridges used from 10/01/2021 to 10/21/2021. Findings Include: 1. On the day of survey, 10/21/2021, review of the Abbott istat Chem 8+ Cartridge validation records revealed, the validation performed on 08/31/2021 did not include performance specifications for precision and accuracy. 2. From 10/01/2021 to 10/21/2021, 53 patients were analyzed on the Abbot istat. 3. TC #1 confirmed the finding above on 10/21/2021 around 09:55 a.m.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure and interview with Technical Consultant (TC)#1, the laboratory failed to establish a procedure to evaluate biannual relationship between 7 of 7 Abbott Istat analyzers using the chem8+ cartridges from 10/1/2021 to 10/21/2021 Findings include; 1. On the day of survey 10/21/2021, the laboratory could not provide a procedure to evaluate the biannual relationship between 7 of 7 Abbott Istat analyzers from 10/01/2021 to 10/21/2021. 2. The TC#1 confirmed the finding above on 10/21/2021 at 10:05 a.m.