

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2058115	(X3) Date Survey Completed 02/08/2022
Name of Provider or Supplier Geisinger Pottsville Oncology	Street Address, City, State 1 E Norwegian Plaza, Pottsville, 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	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Abbott istat analyzer validation records and interview with Technical consultants (TC), the laboratory failed to establish criteria for acceptable performance specifications of precision and accuracy for the Abbott istat Chem 8+ Cartridges Validation used in routine chemistry specimens from October 1, 2021 to February 8, 2022. Findings Include: 1. On the day of survey, 02/08/2023 at 11:25 am, review of the Istat System Validation records revealed, the validation performed on 04/21/2021 did not include criteria for acceptable precision and accuracy. 2. From 10/01/2021 to 02/08/2022, 236 patients were analyzed on the Abbot istat. 3. TC confirmed the finding above on 02/08/2022 around 12:15 p.m.</p>