

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2142995	(X3) Date Survey Completed 12/07/2022
Name of Provider or Supplier Port Health Services	Street Address, City, State 2602 Courtier Drive, Greenville, NC	
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
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory verification of performance records, review of United States Federal Drug Administration (FDA) medical device database and interview with laboratory director (LD) 12/7/22, the laboratory failed to verify the precision and specimen stability for the Fentanyl (FENT) testing performed on the Diatron Pictus 700 since testing began in September of 2020, approximately 26 months. 1. The laboratory failed to include variances to verify the precision of the FENT testing. Findings: Review of laboratory performance verification records for FENT revealed the testing for precision was completed on one day, within one run and by one operator. Interview with LD at approximately 12:00 p.m. confirmed the performance verification for FENT testing failed to include variances. 2. The laboratory failed to verify specimen stability for the FENT testing. Findings: Review of FDA medical device database revealed the Thermo Scientific DRI FENT reagent is not approved for use on the Diatron Pictus 700 analyzer. Review of laboratory performance verification records revealed no documentation for specimen stability verification.</p>