

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2183702	(X3) Date Survey Completed 08/30/2022
Name of Provider or Supplier Cpn, Inc DbA Atrium Health Urgent Care	Street Address, City, State 2041 South Blvd, Suite 100, Charlotte, 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
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 ISTAT analyzer performance verification records, review of ISTAT quality control (QC) and patient testing records and interview with technical consultant (TC) 8/30/22, the laboratory failed to ensure the precision of the ISTAT analyzer was verified and failed to ensure the laboratory director (LD) had reviewed and approved the performance verification before patient testing began in September of 2020. Approximately 28 patients were tested. 1. The laboratory failed to ensure the precision of the ISTAT analyzer was verified before patient testing began in September of 2020. Findings: Review of performance verification records revealed calibrator levels 1, 3 and 5 and QC levels 1 and 3 were performed once on 9/4/20 by one operator. The performance verification failed to demonstrate a verification of precision by including variances of day to day runs and multiple operators. Interview with TC at approximately 3:40 p.m. confirmed the verification of precision failed to include variances of day to day runs and multiple operators. She also confirmed approximately 28 patients were tested since testing began in September of 2020. 2. The laboratory failed to ensure the LD had reviewed and approved the performance verification of the ISTAT analyzer before patient testing began in September of 2020. Findings: Review of performance verification records revealed the LD did not sign his approval of the performance verification of the ISTAT analyzer until 8/24/21,</p>

approximately 1 year after testing began. Interview with TC at approximately 3:40 p. m. confirmed testing began in September of 2020.