

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1083610	(X3) Date Survey Completed 02/11/2020
Name of Provider or Supplier Patient First - Pasadena	Street Address, City, State 8105 Ritchie Highway, Pasadena, MD	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) and quality control (QC) record review and interview with the technical consultant (TC), the laboratory did not run 2 levels of QC each day of patient testing and failed to establish an Individual Quality Control Plan (IQCP) for performing testing on the Abbot i-STAT chemistry analyzer. Findings: 1. The laboratory performs chemistry testing on the Abbot i-STAT chemistry analyzer using the CHEM8+ cartridge. QC record review showed that QC was performed once a week. 2. During an interview on 2/11/20 at 10:30 AM, the TC stated that they did not have an IQCP in place to reduce the amount of QC required when performing testing on the Abbott i-STAT.</p>