

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2307745	(X3) Date Survey Completed 09/04/2025
Name of Provider or Supplier Saint Peter's Cancer Center	Street Address, City, State 215 Easton Avenue, New Brunswick, NJ	
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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A) Based on surveyor review of the Procedure Manual (PM), and interview with the Technical Consultant (TC), the laboratory did not follow its procedure for "Quality Management Plan" for verifying new lots of Quality Control (QC) material for use on the PixCell Hemoscreen analyzer from 11/6/24 to 9/4/25. The findings include: 1. The PM stated "new lot of quality control is run in parallel with the current lot of quality control." 2. There were no QC verification records available for review for QC lots PIX 250805, 250405 and 241205. 3. The TC confirmed on 9/4/25 at 12:20 pm, the laboratory did not follow its procedure for verifying new lots of QC. B) Based on surveyor review of the PM and interview with the TC, the laboratory did not establish a detailed Quality Control Verification (QCV) procedure for verifying new lots of QC used for Hematology tests from 11/6/24 to 9/4/25. The findings include: 1. The laboratory did not establish a detailed procedure for performing QCV on new lots of QC material that included the frequency, acceptability and rejection criteria. 2. The TC confirmed on 9/4/25 at 12:10 pm, the laboratory did not establish a detailed QCV procedure.</p>