

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0550092	(X3) Date Survey Completed 07/17/2024
Name of Provider or Supplier St John's Physician Partners	Street Address, City, State 2001 Santa Monica Blvd, Ste 560w, Santa Monica, CA	
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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the survey conducted on July 17, 2024, at approximately 12:40 p.m., review of the laboratory's policy and procedure, American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, and interviews with the technical consultant (TC) and testing personnel (TP), it was determined that the laboratory failed to attain at least 80% of the acceptable score in routine chemistry for Chloride analyte. The findings included: 1. Based on review of PT records for the third event of 2023 (Q3-2023), AAB-MLE reported an unsatisfactory score report as follow: Chloride PT Q3-2023 Overall score: 20% Specimen Reported Expected 11 *121 104.0 - 114.0 12 95 86.0 - 95.0 13 *110 98.0 - 109.0 14 *107 95.0 - 105.0 15 *103 92.0 - 101.0 2. The TC and TP affirmed on July 17, 2024, at approximately 12:40 p.m. that the laboratory obtained PT scores in statement #1. 3. According to the laboratory testing declaration submitted on the day of the survey, the laboratory performed approximately 90,600 routine chemistry test samples, including Chloride, during the time the laboratory had unsatisfactory proficiency testing results. Thus, the reliability and quality of Chemistry patient results reported cannot be assured.</p>
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems</p>

identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on the surveyor's interviews with the technical consultant (TC) and testing personnel (TP), review of the laboratory's policies and procedures, and record review of pre-analytic, analytic, and postanalytic phases of testing on July 17, 2024, at approximately 12:30 p.m., the laboratory failed to establish a complete written policy and procedure for an ongoing quality assessment mechanism to monitor, assess, and, when indicated, correct problems identified in the laboratory's systems. Findings included: 1. Based on the surveyor's review of quality assessment records and interviews with the TC and TP at approximately 12:30 p.m. on July 17, 2024, the quality assessment policies and procedures found at the time of the survey were incomplete. 2. The TC and TP affirmed that the quality assessment (QA) procedure found at the time of the survey did not state any detailed procedure on how to monitor, assess, and correct patients' issues identified but provided documentation evidence that QA is performed monthly. 3. According to the laboratory testing declaration submitted on July 17, 2024, the laboratory performed approximately 167,600 tests annually that included Chemistry and Hematology specialties.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on the deficiencies cited, the Laboratory Director is herein cited for deficient practice in ensuring that systems for the preanalytic, analytic, and postanalytic phases of the laboratory were monitored and followed. Findings include: 1. The laboratory received unsatisfactory performance results for Chloride. See D2087 2. The laboratory failed to have a complete Quality Assessment policy and procedure. See D5391. 3. The Technical Consultant missed to conduct a corrective action report. See D6036

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on the survey conducted on July 17, 2024, interviews with the laboratory's technical consultant (TC) and testing personnel (TP), a review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, and a review of corrective action reports (CAR); the technical

consultant is herein cited for the deficient practice of overlooking the review of laboratory records. The findings include: 1. Based on the surveyor's review of PT and CAR, it was determined that the TC missed conducting an investigation for red blood cell (RBC) analyte that received an 80 percent score. 2. The TC and TP affirmed that CAR was missed to be recorded as documented on statement #1. 3. According to the submitted laboratory testing declaration on July 17, 2024, the laboratory performed 77,000 tests for Hematology that included RBC analyte.