

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2118506	(X3) Date Survey Completed 01/24/2022
Name of Provider or Supplier Roper Saint Francis Physicians Network	Street Address, City, State 8901 University Blvd, North Charleston, SC	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: During an onsite recertification survey performed on 01/24/2022, based on review of CASPER report 155D and graded reports from American Proficiency Institute (API), it was determined that the laboratory failed to successfully participate in proficiency testing for the specialty of chemistry, the analyte chloride (Cl), creatine, glucose, potassium (K), sodium (Na), and blood urea nitrogen (BUN), for two of three consecutive proficiency testing events reviewed (2021, Events 2 and 3). See D2087 and D2096. The laboratory also failed to successfully participate in proficiency testing</p>

for the specialty of hematology, the analyte hematocrit (Hct), and hemoglobin (Hgb) for two of three consecutive proficiency testing events reviewed (2021, Events 2 and 3).

D2087

ROUTINE CHEMISTRY
CFR(s): 493.841(a)

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.

This STANDARD is not met as evidenced by:

During the onsite recertification survey performed on 01/28/2022, based on review of CASPER report 155D and graded proficiency reports from API, it was determined that the laboratory failed to attain a satisfactory score of at least 80% for the specialty of chemistry, the analyte chloride (Cl), creatine, glucose, potassium (K), sodium (Na), and blood urea nitrogen (BUN), for two of three consecutive proficiency testing events reviewed (2021, Events 2 and 3). Findings include: 1. The CASPER 155D report revealed the following scores for your laboratory's: a. 2021, Event 2: Chemistry: 0%, Cl: 0%; creatine: 0%, glucose: 0%, K:0%, Na: 0%, and BUN: 0% b. 2021, Event 3: Chemistry: 10%, Cl: 40%; creatine: 0%, glucose: 0%, K: 0%, Na: 0% and BUN: 20% 2. The scores were confirmed by review of the graded API results. Scores less than 80% for these analytes indicate failure or unsatisfactory performance. A failure of the analytes for two consecutive or two out of three testing events is scored as unsuccessful. A failure of the analyte for three consecutive or three out of four/five events is scored as a repeat unsuccessful.

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

During the onsite recertification survey performed on 01/28/2022, based on review of CASPER report 155D and graded proficiency reports from API, it was determined that the laboratory failed to attain a satisfactory score of at least 80% for the specialty of chemistry, the analyte chloride (Cl), creatine, glucose, potassium (K), sodium (Na), and blood urea nitrogen (BUN), for two of three consecutive proficiency testing events reviewed (2021, Events 2 and 3). See D2087.

D2121

HEMATOLOGY
CFR(s): 493.851(a)

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.

This STANDARD is not met as evidenced by:

During an onsite recertification survey performed on 01/28/2022, based on review of the CASPER report 155D and laboratory proficiency testing records (graded copies

from API), it was determined that the laboratory failed to attain a score of at least 80 percent in proficiency testing for the specialty of hematology, the analyte hematocrit (Hct), and hemoglobin (Hgb) for two of three consecutive proficiency testing events reviewed (2021, Events 2 and 3). The findings include: 1. Review of CASPER report 155D revealed the following proficiency scores for your laboratory: a. 2021, Event 2: Hematology: 0%, Hct: 0%, Hgb: 0% b. 2021, Event 3: Hematology: 0%, Hct: 0%, Hgb: 0% 2. The scores were confirmed upon review of the graded API results. Scores less than 80% for these analytes indicate failure or unsatisfactory performance. A failure of the analytes for two consecutive or two out of three testing events is scored as unsuccessful. A failure of the analyte for three consecutive or three out of four/five events is scored as a repeat unsuccessful.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
During the onsite recertification survey performed on 01/28/2022, based on review of CASPER report 155D and graded API results, it was determined that the laboratory failed to achieve satisfactory performance for the specialty of hematology, the analyte hematocrit (Hct), and hemoglobin (Hgb) for two of three consecutive proficiency testing events reviewed (2021, Events 2 and 3). See D2121.