

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0645082	(X3) Date Survey Completed 08/30/2022
Name of Provider or Supplier St Johns Biomedical Laboratories Inc	Street Address, City, State 165 Southpark Blvd Ste A, Saint Augustine, FL	
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
D0000	A desk review survey of the laboratory's proficiency test results was performed on August 30, 2022 for St. John Biomedical Laboratories Inc. St. Johns Biomedical Laboratories, Inc., is not in compliance with the Code of Federal Regulations (CFR), Part 493, Laboratory Requirements.
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: Based on review of the laboratory's proficiency testing records for 2022, the laboratory did not have successful performance in proficiency testing for analytes in the subspecialty of endocrinology and the specialty of hematology. Refer to D2107 and D2130. Findings include: Review of the American Association of Bioanalysts</p>

	<p>(AAB) proficiency testing records and the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports, on August 30, 2022 on or about 10:00 AM, showed that the laboratory had unsatisfactory testing scores in two consecutive testing events for the analytes, free T4 (free thyroxine), T3 (triiodothyronine), T4 (total thyroxine) in the subspecialty of endocrinology and the analyte, fibrinogen, in the specialty of hematology. .</p>
<p>D2107</p>	<p>ENDOCRINOLOGY CFR(s): 493.843(f)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports and the laboratory's proficiency testing records, the laboratory did not have successful performance in proficiency testing for analytes in the specialty of routine chemistry. Findings include: On April 20, 2022 on or about 10:00 AM the American Association of Bioanalysts (AAB) proficiency testing records and the CMS 153 and 155 reports were reviewed. The review showed that the laboratory failed to achieve satisfactory performance for the analytes, free T4, T3, and total T4, as shown below. Event #1, 2022 free T4-40% T3-20% total T4-60% Event #2, 2022 free T4-40% T3-0% total T4-20%</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports and the laboratory's proficiency testing records, the laboratory did not have successful performance in proficiency testing for an analyte in the specialty of hematology. Findings include: On August 30, 2022 on or about 10:00 AM the American Association of Bioanalysts (AAB) proficiency testing records and the CMS 153 and 155 reports were reviewed. The review showed that the laboratory failed to achieve satisfactory performance for the analyte, fibrinogen, as shown below. Event #1, 2022 fibrinogen-60% Event #2, 2022 fibrinogen-60%</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on the review of the laboratory's proficiency testing records, the laboratory</p>

director failed to ensure that the laboratory maintained a satisfactory score in proficiency testing for analytes found in the subspecialty of endocrinology and the specialty of hematology. Findings include: On August 30, 2022, on or about 10:00 AM, the American Association of Bioanalysts (AAB) proficiency records and the Centers for Medicare & Medicaid Service (CMS) 153 and 155 reports were reviewed. The review showed that the laboratory had unsatisfactory testing scores for two consecutive testing events for the analyte, fibrinogen, in the specialty of hematology and for two consecutive testing events in the subspecialty of endocrinology for the analytes, free T4, T3, and total T4. The laboratory director is responsible for ensuring that the laboratory maintains successful participation in proficiency testing. Refer to D2107 and D2130.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:
Based on the review of the laboratory's proficiency testing scores, the laboratory director failed to ensure that the laboratory performed proficiency testing in such a manner as to achieve and maintain successful participation in proficiency testing for analyte(s) found in the subspecialty of endocrinology and for an analyte in the specialty of hematology. Findings Include: The review of the American Association of Bioanalysts (AAB) proficiency testing records and the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports on August 30, 2022, on or about 10:00 AM showed that the laboratory received unsatisfactory proficiency testing scores for two consecutive testing events for the analytes shown below. Event #1, 2022 free T4-40% T3-20% total T4-60% fibrinogen-60% Event #2, 2022 free T4-40% T3-0% total T4-20% fibrinogen-60%