

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D1019114	(X3) Date Survey Completed 08/10/2022
Name of Provider or Supplier Southeast Medical Clinic	Street Address, City, State 641 West Willoughby Ave, Suite 201, Juneau, AK	
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: Based on an off-site desk review of CMS CASPER 155 Report, the laboratory's 2021 and 2022 American Proficiency Institute (API) proficiency testing (PT) records, and an email with the laboratory director on August 9, 2022 it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for Total Bilirubin (TBili) in two (2) out of three (3) chemistry testing events. See 2096</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</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.

This STANDARD is not met as evidenced by:

Based on an off-site desk review of CMS CASPER 155 Report, the laboratory's 2021 and 2022 American Proficiency Institute (API) proficiency testing (PT) records, and an email with the laboratory director on August 9, 2022 it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for Total Bilirubin (TBili) in two (2) out of three (3) chemistry testing events. Findings include: 1. Desk review of the laboratory's 2021 and 2022 API PT records revealed TBili scores of less than eighty percent for the following Chemistry events: a. 2021-3 - score of 60% b. 2022-2 - score of 40% 2. In an email with the laboratory director on 8/9/2022, it was confirmed that the laboratory was unsuccessful in the PT events listed above.