

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 02D0641048 | (X3) Date Survey Completed 11/26/2025 |
| Name of Provider or Supplier Providence Seward Medical Center | Street Address, City, State 417 1st Ave, Seward, 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 |
|---------------------------|---|
| D0000 | The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 condition: successful participation [proficiency testing] |
| 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 the laboratory's 2025 American Proficiency Institute (API) proficiency testing (PT) records and a telephone interview with the</p> |

| | |
|---------------------|--|
| | <p>general supervisor on 11/10/2025, it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the analyte High Sensitivity C-Reactive Protein (hs-CRP) and the subspecialty of General Immunology in two (2) out of three (3) General Immunology testing events resulting in unsuccessful PT Performance. See D2084, D2085</p> |
| <p>D2084</p> | <p>GENERAL IMMUNOLOGY CFR(s): 493.837(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on an off-site desk review of the laboratory's 2025 American Proficiency Institute (API) proficiency testing (PT) records and a telephone interview with the general supervisor on 11/10/2025, it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the analyte High Sensitivity C-Reactive Protein (hs-CRP) in two (2) out of three (3) General Immunology testing events resulting in unsuccessful PT Performance. Findings include: 1. Desk review of the laboratory's 2025 API PT records revealed hs-CRP scores of less than eighty (80) percent for the following General Immunology events: a. 2025 1st event - score of 0% b. 2025 2nd event - score of 0% 2. In an email and telephone interview with the general supervisor on 11/10/25, it was confirmed that the laboratory was unsuccessful in the PT events listed above.</p> |
| <p>D2085</p> | <p>GENERAL IMMUNOLOGY CFR(s): 493.837(g)</p> <p>(g) Failure to achieve an overall testing event score of satisfactory performance for 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 an off-site desk review of the laboratory's 2025 American Proficiency Institute (API) proficiency testing (PT) records and a telephone interview with the general supervisor on 11/10/2025, it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses the subspecialty of General Immunology in two (2) out of three (3) General Immunology testing events resulting in unsuccessful PT Performance. Finding include: 1. Desk review of the laboratory's 2025 API PT records revealed overall General Immunology scores of less than eighty (80) percent for the following testing events: a. 2025 1st event - score of 50% b. 2025 2nd event - score of 50% 2. In an email and telephone interview with the general supervisor on 11/10/25, it was confirmed that the laboratory was unsuccessful in the PT events listed above.</p> |