

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0641048	(X3) Date Survey Completed 04/16/2021
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 laboratory is in substantial compliance with the CMS Interim Final Rule (CMS-3401-IFC) on Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE) effective August 25, 2020. No deficiencies were cited.
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on quality control review of Medtox Urine Drug Screen tests and General Supervisor interview, the laboratory did not test, at a minimum two levels of external quality control (QC) material to monitor the accuracy and precision of the Medtox Urine Drug Screen tests in from September 2020 to survey date. Findings include: 1. QC records for the Profile-V MedtoxScan Drugs of Abuse test system showed external controls were performed weekly as indicated in the manufacturer's package insert. 2. The laboratory performs approximately 125 urine drugs screens annually. 3. The general supervisor confirmed these findings on 4/16/2021 at 14:30 pm.</p>