

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0663791	(X3) Date Survey Completed 04/20/2021
Name of Provider or Supplier South Peninsula Hospital	Street Address, City, State 4300 Bartlett St, Homer, 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.
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) results and technical supervisor interview, the laboratory failed to document the acceptability of PT results when these results were not evaluated or scored by the PT provider for all non-scored analytes in the 2020 Hematology and Microbiology surveys. Findings include: 1. The laboratory subscribes to the Wisconsin State Laboratory of Hygiene for proficiency testing. 2. In the 2020-1 Hematology survey, the following sample was not scored and did not have documented review for acceptability: a. 2020-HemeReg1: Cell Identification (XIE-7) 3. In the Microbiology surveys, the following samples were not scored and did not have documented review for acceptability: a. 2020-BactiReg1: Susceptibility (MC-5), BioFire FilmArray GI Panel (EP-1, EP-2), and BioFire FilmArray ME Panel (MEP-1, MEP-2, MEP-3, MEP-4, MEP-5) b. 2020-BactiReg2: Susceptibility (MC-14), BioFire FilmArray ME Panel (MEP-6, MEP-7, MEP-8, MEP-9, MEP-10) c. 2020-Bacti-Reg3: Susceptibility (MC-22, MC-23), BioFire FilmArray ME Panel (MEP-11, MEP-12, MEP-13, MEP-14, MEP-15) 4. The technical supervisor confirmed these finding on 4/20/2021 at 12:30 pm.</p>

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on interviews with the laboratory technical supervisor and review of the laboratory's verification of the Siemens EPOC, the laboratory failed to assess precision prior to testing patients. Findings include: 1. The verification for the Siemens EPOC was completed on 3/1/2020 and did not include documentation of precision for blood gas (pH, pCO₂, pO₂), Sodium, Potassium, Ionized Calcium, Chloride, Glucose, Lactate, Creatinine, and Hematocrit. 2. The laboratory performs approximately 320 blood gas analyses and 35 point of care chemistry panels annually. 3. The technical supervisor confirmed these findings on 4/20/2021 at 12:30 pm.