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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D2193462 | (X3) Date Survey Completed 05/21/2021 |
| Name of Provider or Supplier Emergensea Llcdba Blue Med Consultants | Street Address, City, State 5450 S State Rd 7 Bay 39, Davie, 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 |
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| D0000 | An unannounced CLIA complaint survey (2021005899) was conducted at Emergensea DBA Blue Med Consultants on 05/20-21/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies: |
| D1001 | <p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review, observation, and interview the laboratory failed to follow the manufacturers' instructions (MI) for the RightSign COVID-19 IgG/IgM Rapid Test Cassette and the CareStart COVID-19 Antigen rapid diagnostic Test since January 2021. Findings Included: Review of the MI for the RightSign COVID-19 IgG/IgM Rapid Test Cassette revealed that the kit is to be stored at room temperature or refrigerated (2-30 degrees Celsius). Review of the MI for the CareStart COVID-19 Antigen rapid diagnostic Test revealed that the kit is to be stored between 1-30 degrees Celsius and that the tests should be disposed of as biohazardous waste. Observations taken at 2 out of 2 of the pop-up tent testing sites revealed no thermometer to monitor the temperature of the test kits and no biohazardous trash bags for the used kits. Temperature taken on 05/20/21 from 2:00 PM until 2:15 PM at pop-up tent testing site #2 with the agency issued thermometer and the temperature was 30.5 degrees Celsius. Interview on 05/21/21 at 11:00 AM the Medical Director confirmed that there was no thermometers or biohazard bags at the pop-up tent testing sites.</p> |
| D1002 | REPORTING OF SARS-CoV-2 TEST RESULTS |

During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:

Based on lack of records and interview the laboratory failed to report COVID-19 test results to the DOH (Department of Health) since March 11, 2021 for a total of 22,153 tests. Findings Included: Review of the laboratory COVID-19 testing revealed that testing began 11/27/2020. The first month, only positives were reported to the DOH. From January 2021 to March 11, 2021 the laboratory was reporting positives and negatives. After March 11, 2021 there was a system update and there were no other tests reported to the DOH. There was a total of 22,153 COVID-19 tests performed from March 11, 2021 to May 21, 2021. Interview on 05/21/2021 at 11:00 AM the Medical Director confirmed the aforementioned 22,153 COVID-19 tests have not been reported to the DOH.