

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2151311	(X3) Date Survey Completed 02/05/2021
Name of Provider or Supplier Spearhead Medical Inc	Street Address, City, State 5812 Hollywood Blvd, Hollywood, 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
D0000	An onsite complaint visit, complaint #2020018683, conducted on 02/04-05/21 at Spearhead Medical. The allegations were not substantiated
D1002	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to report SARS-COV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) test results for rapid nucleic acid detection of Coronavirus 2019 Disease (COVID-19) from 10/13/2020 to 11/19/2020 (positive and negative) and from 11/20/2020 to 02/04/2021 (negative) at such time and frequency as prescribed. Findings include: -Procedure Manual review revealed that the laboratory failed to have a policy to report all COVID-19 tested cases to the Florida Department of Health (FDH). -Patient log review revealed that the laboratory started performing patient testing on 10/13/2020 with the Abbot rapid point of Care ID NOW test for the rapid detection of nucleic acid of COVID-19. -The laboratory failed to report to the FDH all 478 results (positive and negative) from 10/13/2020 to 11/19/2020 and negative results from 11/20/2020 to 02/04/2021. During an interview on 02/04/2021 at 1:30 pm, the owner, confirmed that the laboratory failed to report to the FDH all cases from 10/13/2020 to 11/19/2020 and negative cases from 11/20/2020 to 02/04/2021</p>