Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0661201	08/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cypress Point Rehabilitation And Nursing	5580 Daniel Smith Road, Virginia Beach, VA	

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 unannounced Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (Complaint #VA00052875) was conducted at Pelican Health Virginia Beach on August 25, 2021 by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The inspector noted that the facility performs SARS-CoV-2 (COVID-19) antigen testing and was in compliance with the applicable COVID-19 reporting requirements. Based on a tour, review of documents and interviews, the inspector found the complainant's allegation of COVID-19 test discrepancies to be substantiated. Specific deficiency cited is as follows:
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Based on a review of specimen collection instructions, interviews, facility tour, review of temperature monitoring log sheets, eight (8) random referred COVID-19 reports, Food and Drug Administration's (FDA) Emergency Use Authorization (EUA), manufacturer's instructions for use (IFU), and lack of documentation, the facility failed to ensure the storage temperature for collected COVID-19 test specimens was maintained per the reference laboratory's instructions for three (3) of 3 months reviewed. Findings include: 1. Review of the facility's reference lab COVID-19 specimen collection kits revealed instructions titled: "COVID-19 Testing, Test Code 143OT, Protocol" that stated: "Once collected, specimens must be refrigerated and transported in a thermal cooler to maintain 2-8". The inspector noted that the specimen swab kit was labeled "Refrigerate Immediately". 2. Telephone interviews

	with reference laboratory outreach sales representatives on 8/25/21 revealed: Representative #1 stated at approximately 12:30 PM: "I believe storage temperature should be at refrigerated temperature 2-8 Celsius." The representative provided a second contact number of technical support representative for confirmation. Representative #2 stated at approximately 12:40 PM: "The specimens for our Quidel PCR test should be stored at 2 to 8 Celsius as soon as collected and until arrive at our testing facility." 3. A tour, at approximately 1 PM, of the facility's laboratory supply closet revealed PCR COVID-19 specimen swabs collected for send out were stored in a Haier dorm sized refrigerator/freezer. The inspector noted a thermometer was placed in the Haier freezer compartment. No thermometer was found in the Haier refrigerator compartment. 4. Review of the facility's Send Out temperature-monitoring logs from 6 /1/21 to 8/25/21 revealed daily temperatures were recorded in the range of 33-36 F. The inspector inquired if the recorded temperatures were for the freezer or refrigerator. The nursing director stated at approximately 1:15 PM: "We have been keeping the thermometer in the freezer area. They are recording the freezer temperatures. That is a mistake on our part." 5. Review of (8) randomly selected reference laboratory COVID-19 PCR reports (timeframe 7/20/21 to 8/19/21) revealed the test method with comment: "The Lyra Direct SARS-CoV-2 PCR Assay developed by Quidel and is authorized for diagnostic use under a March 2020 FDA Emergency Use Authorization for U.S. laboratories certified under CLIA to perform high complexity tests." 6. Review of the FDA EUA, revealed Quidel manufacturer's Lyra Direct SARS-CoV-2 Assay IFU statement: "Specimens should be transported and tested as soon as possible after collection. Specimens are stable up to 72-hours when stored at 2C to 8C." 7. An exit interview with the interim Administrator and Director of Nursing on 8/25/21 at approximately 3:00 PM confirmed the above findings.