Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2177036	01/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Waypoint Medical	1801 Hwy 18 E, Clear Lake, IA	

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
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 review of patient test reports, Abbott ID Now instructions for use, and confirmed by the laboratory director, the laboratory failed to follow manufacturer's instructions by indicating the incorrect COVID-19 test method on two of out nine patient test reports from 10/23/2020 - 1/14/2021. The findings include: 1. On 1/6 /2021, patient identifier A had COVID-19 testing performed using the Abbott ID Now test system. 2. On 1/12/2021, patient identifier B had COVID-19 testing performed using the Abbott ID Now test system. 3. The test reports for both patients had "PCR", indicating the laboratory performed the COVID-19 testing using a polymerase chain reaction test system. 4. The Abbott ID Now instructions for use under "Principles of the Procedure" do not state that the test is a polymerase chain reaction test system.