

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0382436	(X3) Date Survey Completed 11/23/2021
Name of Provider or Supplier Bayside Village	Street Address, City, State 832 Sicotte Street, Lanse, MI	
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 purpose of this unannounced survey was for complaint #MI00123543. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003).
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 with the testing personnel, the laboratory failed to follow the CareStart COVID-19 Antigen test manufacturer's instructions for specimen collection for one of one testing observation. Findings include: 1. A review of the laboratory's "CareStart COVID-19 Antigen" package insert revealed a section titled "Specimen Collection" stating, "Acceptable specimen type for testing with the CareStart COVID -19 Antigen is a direct nasopharyngeal swab specimen or a swab in BD universal transport media. It is essential that correct specimen collection and preparation methods are followed. Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, specimen collection requires specific training and guidance due to the importance of specimen quality to obtain accurate test results." 2. The surveyor observed testing personnel take a nasopharyngeal swab from the kit box, unwrap the swab, and insert the swab into the patient's nose and swabbed the anterior nares on 11/23/21 at 10:49 am. 3. An interview on 11/23/21 at 10:49 am with the testing personnel confirmed the specimen collected was nasal specimen and not a nasopharyngeal specimen.</p>