Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0374190	11/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Saginaw County Health Department	1600 N Michigan Avenue, Saginaw, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to follow the manufacturer's instructions for specimen collection for one of one tests reviewed. Findings: 1. Upon entering the facility at approximately 08:30 AM on November 30, 2021, a sign in the lobby was observed stating the following "Please do not collect COVID-19 testing samples in the lobby. Please go to your vehicle or step outside to self collect the sample." 2. During the entrance interview at approximately 09:00 AM on November 30, 2021, the Technical Supervisor (TS) confirmed that the laboratory performed BD SARS-CoV-2 and Panther Fusion SARS-CoV-2 assays. 3. Review of the United States Food & Drug Administration website for In Vitro Diagnostics Emergency Use Authorizations (EUA) - Molecular Diagnostics Tests for SARS-CoV-2 revealed that neither assay system was listed with the attribute for home collection. 4. Review of the Instructions for Use (IFU) for the SARS-CoV-2 Assay (Panther Fusion System) in the "Intended Use" section revealed "The Panther Fusion SARS-CoV-2 assay is a real-time RT-PCR in vitro diagnostic test intended for the qualitative detection of RNA from SARS-CoV-2 isolated and purified from nasopharyngeal(NP) and oropharyngeal (OP) swab specimens, nasopharyngeal washes/aspirates or nasal aspirates, and bronchoalveolar lavage specimens (collected by a healthcare provider) and anterior nasal (nasal) and mid-turbinate nasal swab specimens (collected under observation of or by a healthcare provider) from individuals who meet COVID-19 clinical and/or epidemiological criteria, as well as NP and OP swab specimens (collected by a healthcare provider) and nasal and mid-turbinate nasal swab specimens

	(collected under observation of or by a healthcare provider) from any individual, including from individuals without symptoms or other reasons to suspect COVID-19." 5. Review of the IFU for BD SARS-CoV-2 Reagents for BD Max (Trademark) System in the "Intended Use" section revealed "The BD SARS-CoV-2 Reagents for BD MAX (Trademark) System is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, anterior nasal, mid-turbinate, and oropharyngeal swab specimens, nasopharyngeal wash/aspirate or nasal aspirates obtained from individuals suspected of COVID-19 by their healthcare provider or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least weekly and with no more than 168 hours between serially collected specimens." 6. At approximately 12:30 PM on November 30, 2021, the laboratory director (LD) and TS confirmed that laboratory personnel were not collecting the SARS- CoV-2 samples. The LD and TS confirmed that patients were provided with instructions for collection but not observed collecting the samples for SARS-CoV-2 testing in their vehicle or outside the laboratory.