Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0373059	02/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Harbor Beach Community Hospital	210 S 1st Street, Harbor Beach, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results 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. This CONDITION is not met as evidenced by: . Based on record review and interview with Testing Personnel #2 (TP2), the laboratory failed to report all SARS-CoV-2 test results every day of patient testing for 95 patients tested since the laboratory started testing for SARS-CoV-2 antibodies in March 2020. Findings include: 1. The surveyor requested documentation showing the laboratory was sending all SARS-CoV-2 results to the health department and documentation for patients tested using the Beckman Coulter COVIGG SARS-CoV-2 antibody assay on the Access 2 analyzer were not available on 2/1/22 at 1:22 pm. 2. An interview on 2/1/22 at 1:33 pm with the TP2 revealed the laboratory started testing in October 2021 and had not been reporting results from the Beckman Coulter COVIGG SARS-CoV-2 antibody assay to the health department. 3. A review of the laboratory's test records revealed 95 patients had been tested using the SARS-CoV-2 antibody assay and had not been reported to the health department.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f)

	(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor (GS), the laboratory failed to have a policy to ensure the use of fresh recipient serum or plasma samples less than 3 days old for all pretransfusion testing if the recipient has been pregnant or transfused within the previous 3 months or the patient's history is not available for 2 (February 2020 to February 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's policies and procedures revealed a lack of requirements for the age of specimens used in pretransfusion testing for recipients that have been pregnant or transfused within the previous 3 months or the patient's history. 2. An interview on 2/1/22 at 1:02 pm with the GS revealed the laboratory does not have a policy regarding the age of specimens used in pretransfusion testing.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor (GS), the laboratory failed to perform and document visual inspections of blood units immediately before issue for 2 (February 2020 to February 2022) of 2 years. Findings include: 1. A review of the laboratory's "Issue of products from the Blood Bank" policy revealed a lack of visual inspection of blood units immediately before issue. 2. A review of the laboratory's records revealed a lack of documentation showing visual inspections of blood units issued between February 2020 and February 2022 immediately before issue. 3. An interview on 2/1/22 at 12:47 am with the GS confirmed the laboratory did not perform and document visual inspections of blood units immediately before issue.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to ensure Testing Personnel #2 performing the duties of a Technical Consultant, met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure the personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to ensure personnel performing the TC duty of performing personnel competency assessments was qualified for 1 (Testing Personnel (TP) #5) of 5 personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel competency records revealed TP #2 had performed competency assessments for TP #5 as follows: a. 110/20/2021 - competency for the Beckman Coulter Access 2, Au480 and the DxH520 b. 11/01/2021 - competency for the ABL80 Flex blood gas analyzer 2. A review of the qualifications for TP #2 revealed they did

	not meet the qualification requirements to perform Technical Consultant responsibilities. 3. An interview on 2/01/2022 at 1:41 pm and document review on 02 /02/2022 at 1:25 pm, confirmed TP #2 did not meet the qualification requirements to be a Technical Consultant.