Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0373059	10/02/2023
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with the General Supervisor (GS), the laboratory failed to verify the accuracy for the chemistry urine creatinine testing at least twice annually for 19 (February 2022 to September 2023) of 19 months of testing. Findings include: 1. A review of the laboratory's records revealed a lack of verification of accuracy for 19 months for the chemistry urine creatinine testing. 2. An interview on 10/02/2023 at 9:48 am, the GS confirmed the laboratory had not performed verification of accuracy for the chemistry urine creatinine testing.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to perform and document control procedures for its Wright Stain used in peripheral blood smears for 2 (October 2021 to October 20230 of 2 years reviewed. Findings include: 1. A review of the laboratory's "Manual Differential" procedure

	revealed a section stating, "Before evaluating the leukocytes on the stained blood smear, the tech shall first determine that the blood smear is well made, the distribution of the cells is uniform, and the staining of the cells is satisfactory." 2. The surveyor requested documentation of documentation of the control procedures performed for wright stain quality each date of testing on 10/2/23 at 12:04 pm and it was not made available 3. An interview on 10/2/23 at 12:06 pm with the General Supervisor confirmed the laboratory had not documented its control procedures performed for wright stain quality each date of testing.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with the General Supervisor (GS), the laboratory failed to verify the 6-month competency assessments for the Xpert Express Cepheid testing for 7 (February to September 2023) of 7 months of testing. Findings include: 1. A review revealed the Xpert Express Cepheid testing was put into use in February 2023. 2. A review of the competency assessments for 4 testing personnel revealed a lack of documentation for the 6-month competency assessment for the following Cepheid tests: a. CoV-2 b. Influenza A (Flu A) c. Influenza B (Flu B) c. Respiratory Syncytial Virus (RSV) 3. A review of the "Competency of Testing Personnel" policy states under "Purpose of Policy: As a resource so the lab testing personnel know that they will be monitored for competency upon being introduced to a new system, at six months, and annually." 4. An interview on 10/02/2023 at 12:31 pm, the GS confirmed the 6-month competency assessment was never performed and documented.