Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0373059	(X3) Date Survey Completed 01/08/2020
Name of Provider or Supplier Harbor Beach Community Hospital	Street Address, City, State 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with Testing Personnel #4 (TP4), the laboratory failed to observe safety procedures for 1 (TP4) of 2 testing personnel observed. Findings include: 1. An observation by the surveyor on 1/8/20 at 11:07 am revealed TP4 handled specimens without wearing a lab coat. 2. A record review of the laboratory's established "General Safety Management" procedure. The section titled "Standard Precautions" states, "Lab coats and gloves will be worn while performing phlebotomy, manipulating specimens of any kind, and while cleaning bio-hazardous /chemical spills." 3. An interview on 1/8/20 at 11:07 am with TP4 confirmed a lab coat was not worn while handling specimens.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . A. Based on procedure review and interview with the General Supervisor (GS) and Testing Personnel #2 (TP2), the laboratory failed to establish and follow written

	procedures for the chemistry Biorex K-Check test for ketones for 2 (January 2018 to January 2020) of 2 years. Findings include: 1. Review of the "Laboratory Policies" manual revealed the laboratory did not have a procedure for the Biorex Labs K-Check test for serum and/or plasma ketone testing for the 2 of 2 years the product has been in use. 2. During the interview on 1/09/2020 at 2:30 pm with TP2 and at approximately 3: 30 pm with the GS, they confirmed the laboratory did not have a policy for the Biorex Labs K-check test. B. Based on record review and interviews, the laboratory failed to establish and follow written procedures for chemistry testing performed on the Beckman Coulter AU480 analyzer for 2 (January 2018 to January 2020) of 2 years. Findings include: 1. A record review of the Beckman Coulter AU480 user guide volumes 1 and 2, Beckman Coulter Assay Manual, and the laboratory's established policy and procedure manual revealed a lack of procedures to perform the following assays on the Beckman Coulter AU480 chemistry analyzer: a. Alanine aminotransferase (ALT) b. Albumin c. Alkaline phosphatase (ALP) d. Amylase e. Aspartate aminotransferase (AST) f. Bicarbonate g. Direct bilirubin h. Total bilirubin i. Calcium j. Chloride k. Total cholesterol l. High density lipoproteins (HDL cholesterol) m. Creatinine kinase n. Creatinine o. Lactate dehydrogenase p. Gamma glutamyl transferase (GGT) q. Glucose r. Magnesium s. Phosphorous t. Potassium u. Sodium v. Total protein w. Triglycerides x. Blood urea nitrogen (BUN) y. Uric acid z. Urine total protein aa. Ethyl alcohol 2. An interview on 1/8/20 at 1:11 pm with Testing Personnel #1 and Testing Personnel #4 revealed they did not know where the approved procedures for the tests listed above were located. 3. An interview on 1/8/19 at approximately 3:45 pm with the General Supervisor confirmed the procedures for the tests listed above were not available.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . A. Based on observation, record review, and interview with Testing Personnel #4 (TP4), the laboratory failed to label open control materials with the updated, open expiration date for chemistry and endocrinology testing for the bottles currently in use. Findings include: 1. An observation by the surveyor on 1/8/20 at 10:12 am revealed the following controls in use by the laboratory with open dates written on the bottles in the refrigerator and no updated expiration dates: a. MAS Chemistry ChemTrak Liquid Assayed controls levels 1 and 3, open date 1/2/20 b. MAS Liquimmune controls levels 1 and 3, open date 12/30/19 c. MAS Cardioimmune XL controls level 1, open date 12/30/19 2. A record review of the laboratory's established "Quality Control Testing" procedure revealed a section titled "Chemistry" stating, "MAS controls are stable until the printed expiration date when stored at -25 to -15 degrees Celsius. Once opened, vials of MAS QC material are stable for 7 days when stored, tightly capped, at 2 to 8 degrees Celsius. Liquid Immune controls are stable until the printed expiration dated when stored at -25 to -15 degrees Celsius. Once opened, vials of Liquid Immune QC material are stable for 30 days when stored tightly capped at 2 to 8 degrees Celsius. Cardioimmune XL control material is stable up to the printed expiration date when stored at -20 degrees Celsius or colder. Once

	opened, vials of Cardioimmune XL are stable for 15 days when stored tightly capped at 2 to 8 degrees Celsius." 3. An interview on 1/8/20 at 10:12 am with TP4 revealed the testing personnel did not know the new expiration dates of the controls in use and confirmed they were not on the vials.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. 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 maintenance on the Beckman Coulter AU480 chemistry analyzer for 1 (May-September 2019) of 8 quarters reviewed. Findings include: 1. A record review of the Beckman Coulter AU480 Maintenance Schedule log revealed a section titled "Quarterly Maintenance" that includes the following procedures: a. Clean the air filters b. Replace the Detergent Rolling Tube 2. A record review of the Beckman Coulter AU480 Maintenance Schedule revealed 5 months had lapsed between quarterly maintenance performed in April 2019 to when it was performed again in October 2019. 3. An interview on 1/8/20 at 10:48 am with the GS confirmed quarterly maintenance had not been documented during the duration listed above.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . A. Based on record review, manufacturer's package insert review, and interview with Testing Personnel #2 (TP2), the laboratory failed to perform quality control each day of testing for the chemistry Biorex Labs K-Check test for ketones for 1 (98843) of 1 patients audited for 2 years (January 2018 to January 2020). Findings include: 1. Record review for 1 of 1 patient charts audited revealed the laboratory did not run external positive and negative controls for patient 98843 tested on 1/04/2020. 2. Review of the manufacturer's package insert for the Biorex Labs K-Check revealed "Use known positive and negative controls as recommended by your Institutional guidelines." "At least a positive and negative control must be run each time a new bottle of K-check is opened." 3. When queried on 1/08/2020 at 2:30 pm, TP2 was not able to provide the surveyor with documentation for each day of patient testing the quality control results and testing results whenever a new bottle of K-Check is opened. 4. During the interview on 1/08/2020 at 2:30 pm with TP2 and at approximately 3:30 pm with the General Supervisor, they both confirmed that quality control for the moderately complex serum and/or plasma ketone testing had not been performed and documented from January 2018 to January 2020.

D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor (GS), the laboratory failed to ensure test results were accurately sent from the point of data entry to the final report for 1 (patient #8) of 10 patient charts audited. Findings include: 1. A record review revealed on 1/30/18, patient #8 had the following laboratory testing ordered: a. Complete Blood Count (CBC) with automatic differential b. Complete Metabolic Panel (CMP) c. Lipid Panel d. Prostate Specific Antigen (PSA) e. Urinalysis f. Vitamin B12 2. The surveyor requested the test report for the tests ordered for patient #8 on 1/8/20 at 2:08 pm and they were not made available. 3. An interview on 1/8/20 at 2:08 pm with the GS confirmed the results for patient #8 were not available.