Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0388738	03/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ascension Medical Group At Sheboygan	1703 N Taylor Dr, Sheboygan, WI	

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**
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Individualized Quality Control Plan (IQCP) and control and patient test records, and interview with a technical supervisor, Staff A, the laboratory did not meet their stated Quality Control (QC) requirements for testing external quality control every thirty days for the serum human chorionic gonadotropin (HCG) analyte for three of twenty-four months in 2019 and 2020. Findings include: 1. Review of the laboratory's IQCP for serum HCG testing showed external QC is required every thirty days and with each new lot or shipment of test kits. 2. Review of QC records showed the laboratory performed QC testing on: a. June 12, 2019 and July 19, 2019, with thirty day QC due July 12, 2019. b. January 13, 2020 and February 18, 2020, with thirty day QC due February 13, 2020. c. April 20, 2020 and May 28, 2020, with thirty day QC due May 20, 2020. 3. Review of patient testing records showed: a. Patient 1 tested on July 14, 2019 and Patient 2, 3, and 4 tested July 18, 2019, with no QC run within thirty days prior to patient testing. b. Patient 5 tested on February 17, 2020, with no QC run within thirty days prior to patient testing. c. Patient 6 and 7 tested on May 27, 2020, with no QC run within thirty days prior to patient testing. 4.

	Interview with Staff A, on March 5, 2021 at 1:25 PM, confirmed the laboratory did not meet their QC requirements for serum HCG testing for three of twenty-four months in 2019 and 2020.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on surveyor review of personnel records and interview with a technical supervisor, Staff A, one of one new testing personnel do not have credentials available showing they meet the qualification requirements for high complexity testing personnel. Findings include: 1. One of one new testing personnel do not have credentials showing they meet the qualification requirements for high complexity testing. See 6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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 or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such

	training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on surveyor review of personnel records, interview with a technical supervisor, Staff A, and email correspondence with Staff A, one of one new testing personnel do not have documented evidence showing they meet the minimum qualification requirements to perform high complexity testing. Findings include: 1. Review of personnel records showed the laboratory did not have sufficient documentation to show Staff B meets the minimum qualification requirements to perform high complexity testing. 2. Interview with Staff A on March 5, 2021 at 11:00 AM, confirmed Staff B performs high complexity testing. 3. Email correspondence from Staff A on March 10, 2021 at 9:26 AM confirmed the laboratory had no documentation showing Staff B meets the minimum qualification requirements to perform high complexity testing personnel.