Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 23D1082776	**(X3) Date Survey Completed** 12/20/2023
Name of Provider or Supplier Women's Health Center Of Saginaw	**Street Address, City, State** 3141 S Cabaret Trail Suite 100, 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**
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to enroll in an approved proficiency testing program for its regulated Immunohematology ABO group and D (Rho) typing for 1 (event Q1 2023) of 5 events from event Q2 2022 to event Q3 2023. Findings include: 1. A record review revealed for 1 (event Q1 2023) of 5 events reviewed, the laboratory had specimens sent over from their sister lab after the deadline date (2/25/2023) for testing on 4/05 /2023. The laboratory self-graded (100%). 2. When queried on 12/13/2023 for the delay in signing up for a proficiency testing program for the 2023 year, TP1 stated the main office overlooked signing them up. 3. An interview with TP1 on 12/13/2023 at 12:30 pm revealed the laboratory was not enrolled in a proficiency testing program until event Q2 2023.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I

	of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: . Based on record review of the CMS database and the AAB-Medical Laboratory Evaluation proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS-approved proficiency testing program for the overall Immunohematology ABO group and D (Rho) typing testing and failure to return proficiency testing results within the time frame. Findings include: 1. Review of the CMS database and the AAB-Medical Laboratory Evaluation proficiency testing reports showed overall unsatisfactory performance for the Immunohematology ABO group and D (Rho) typing testing. Refer to D2154 and cross reference D2000. 2. Review of the CMS database and the AAB-Medical Laboratory Evaluation proficiency testing reports revealed the laboratory failed to return the proficiency testing reports to the program within the time frame designated. Refer to D2159.
D2154	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: . Based on record review of the CMS database and the AAB-Medical Laboratory Evaluation proficiency testing reports, the laboratory failed to participate in a testing event for the overall specialty of Immunohematology ABO group and D (Rho) typing for 2 (event Q1 and Q3 in 2023) of 5 testing events reviewed. Findings include: 1. A review of the CMS database and the AAB-Medical Laboratory Evaluation proficiency testing reports revealed the laboratory failed to participate in 2 out of 5 testing events for the overall specialty Immunohematology ABO group and D (Rho) typing. Cross reference D2000. Immunohematology Specialty - D (Rho) typing PT Event Score 3rd event 2023 0% 1st event 2023 0%
D2159	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

	This STANDARD is not met as evidenced by: . Based on record review of the CMS database and the AAB-Medical Laboratory Evaluation proficiency testing reports, the laboratory failed to return the ABO group and D (Rho) typing proficiency testing results to the provider prior to the deadline date for 1 (event Q3 2023) of 5 testing events reviewed. Findings include: 1. A review of the CMS database and the AAB-Medical Laboratory Evaluation proficiency testing reports revealed the laboratory failed to return event Q3 of 2023 results prior to the deadline date. 2. When queried, the laboratory provided records showing the testing of the event was performed after the deadline date. 3. An interview on 12/13/2023 at 12: 30 pm, testing personnel #1 confirmed the testing was completed after the deadline date so the laboratory received a "0" score.
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 lack of documentation, the Technical Consultant was not qualified to perform duties for the laboratory's routine Immunohematology testing (refer 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, lack of documentation, and interview with Testing Personnel (TP) #1, the laboratory failed to ensure personnel performing the Technical Consultant duty of testing personnel competency assessments was qualified for 2 (TP#1 and a supervisor) of 2 personnel performing competency assessments. Findings include: 1. A review of the laboratory's personnel competency records revealed for 2 of 2 personnel performing competency assessments were not qualified as a Technical Consultant as follows: a. TP#1 tested by her supervisor not listed on the CMS-209. b. TP#2 tested by TP#1. 2. The surveyor requested the qualifications of TP#1 and TP#2 to serve as the Technical Consultant on 12/13/2023 at 12:30 pm and the documentation was not made available. 3. An interview on 12/13/2023 at 12:30 pm, testing personnel #1 confirmed that TP1 and TP2 do not have the qualifications to perform the duties of a Technical Consultant.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to ensure testing personnel met the qualification requirements at 493.1423. Findings include: 1. The laboratory failed to ensure testing personnel were qualified prior to performing moderately complex testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

	This STANDARD is not met as evidenced by: . Based on observation, record review, and a lack of documentation, the laboratory failed to ensure testing personnel were qualified for 1 (Testing Personnel (TP) #3) of 3 testing personnel listed on the CMS-209 form. Findings include: 1. During a tour of the laboratory on 12/13/2023 at 9:05 am, the surveyor observed testing personnel #3 collecting a blood sample from a patient. 2. A review of the laboratory's personnel records revealed a lack of qualification documentation for TP #3 performing moderate complexity testing. 3. The surveyor requested qualification documentation for TP #3 showing they were qualified to perform moderate complexity testing on 12/13/2023 at 11:33 am and it was not made available.