Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0885687	11/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Womens Center Of Flint	5051 Villa Linde Parkway #29, Flint, 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, the laboratory failed to enroll in a proficiency testing program for the immunohematology testing for two (1st and 2nd) of three events in 2018. Findings include: 1. On November 29, 2018 at 11:00 AM, record review of the CMS database revealed the laboratory did not have records to show they were enrolled in a proficiency testing program for the immunohematology testing for the 2018 fiscal year. 2. On November 29, 2018 at 11:00 AM, record review revealed the laboratory did not enroll in a proficiency testing program until the 3rd event of 2018, however, the laboratory completed two offcycle events as follows: a. American Proficiency Institute - 1st event b. College of American Pathology - 2nd event 3. During the interview on November 29, 2018 at 11:00 AM, the office manager confirmed the facility enrolled with the American Association of Bioanalysts during the 3rd event of 2018.
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i)

	Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to authorize the release of their American Association of Bioanalysts (AAB) proficiency testing reports to the Health and Human Services (HHS) regulatory agency for one (2018) of two years reviewed. Findings include: 1. On November 29, 2018 at 10:40 AM, record review of the CMS database and the AAB proficiency testing reports revealed the facility did not authorize the release of their reports to the HHS regulatory agency in 2018. 2. During the interview on November 29, 2018 at 10:40 AM, the office manager confirmed the proficiency testing program was not given authority to release the laboratory scores to the regulatory agency.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory director/qualified technical consultant (TC) and testing personnel (TP) failed to attest to the routine integration of the immunohematology proficiency testing samples into the patient workload for four (1st-2nd in 2017 and 1st-2nd in 2018) of six events reviewed. Findings include: 1. On November 29, 2018 at 10:40 AM, record review of the final proficiency testing documents revealed the following: a. 1st and 2nd events 2017 - no laboratory directory /qualified TC and TP signed the attestation statement sheet b. 1st and 2nd events in 2018 - the designee was not qualified as a TC to sign the attestation statement sheet. 2. During the interview on November 29, 2018 at 10:40 AM, the office manager confirmed the attestation statement sheets were not signed by the laboratory director /qualified technical consultant or testing personnel.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to retain the immunohematology signed attestation statement sheet for one (3rd event 2017) of six events reviewed. Findings include: 1. On November 29, 2018 at 10:50 AM, record review of the final proficiency testing documents revealed for the 3rd event of 2017 the attestation statement sheet was not available for review. 2. On November 29, 2018 at 10:50 AM when queried, the office manager was unable to provide the surveyor the document requested. 3. During the interview on November 29, 2018 at 10:50 AM, the

	office manager confirmed the attestation statement sheet for the 3rd event of 2017 was not available to the surveyor.