Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1066063	12/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
American Women's Services	333 E Jimmie Leeds Road, Galloway Township, NJ	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: a) Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J. S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to obtain a NJCLL before the laboratory started patient testing. The Supervisor for the Clinical Laboratory Improvement Services (CLIS) confirmed on 12/20/22 that the laboratory did not obtain its NJCLL license before the laboratory started testing. b) Based on interview with the office manager, and an in-office interview with Supervisor for the CLIS both confirmed on 11/30/22 that Laboratory Director (LD) did not hold a license for bioanalytical laboratory director under New Jersey State Administrative Code: N.J.A.C. 8:44-2.3. The the LD listed on the CMS 209 form is not a qualified LD as stated above.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the lack of Competency Assessment (CA) records and interview with the Office Manager (OM), the laboratory failed to perform a CA on five out of fivew

	testing personnel for the calendar years 2020 and 2021. The OM confirmed on 12/20 /22 at 10:30 am that the CA was not performed as stated above.
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: Based on surveyor review of the Procedure Manual (PM), the lack of Quality Assurance records and interview with the Office Manager (OM), the laboratory failed to follow their procedure for"Quality Assurance Procedures" in the calendar years 2021 and 2022. The findings include: 1. The procedure "Quality Assurance Procedures" stated "Every three months the following items will be reviewed by the Lab Director": a) "Daily Laboratory Logs" b) "The Quality Control Log" c) "The Refrigerator Temperature log" d) "participation in a proficiency testing program" 2. There was no documented evidence the above mentioned procedure was performed in the calendar years 2021 and 2022 3. The OM confirmed on 12/20/22 at 11:38 am that the laboratory did not follow the PM.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Daily Laboratory Log (DLL) and interview with the Office Manager (OM), the laboratory failed to monitor and document Room temperature, Refrigerator temperature, and View box temperature where immunohematology tests are performed on the date of survey. The finding include: 1. Room temperature, Refrigerator temperature, and View box temperature were not documented on the DLL 7/11/22, 7/18/22, 12/17/22 2. The OM confirmed on 12/20 /22 at 11:35 am that Room temperature, Refrigerator, and View box temperature were not documented .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on surveyor observation of Capillary tubes and interview with the Office Manager (OM), the laboratory failed to discard expired Capillary tubes from 4/30/21 to the date of survey. The finding include: 1. Capillary Tubes used on the Adams Micro Hematocrit analyzer expired 4/30/2021. 2. Approximately 300 patients were tested with expired Capillary Tubes . 3. The OM confirmed on 12/20/22 at 10:30 am that the laboratory used expired Capillary Tubes.
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: Based on surveyor review of the Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to perform and document Immunohematolgy QC on each day of patient testing on the date of survey. The findings include: 1. The QC records reviewed showed that the lab did not perform positive and negative QC on the following dates: 7/9/22, 7/11/22,7/15/22, 7/16/22, 7 /18/22, 12/17/22 2. Approximately 70 patients where run and reported. 3. The OM confirmed on 12/20/22 at 11:30 am that positive and negative QC were not run every day of patient testing.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: a) Based on surveyor review of the Laboratory records and interview with the Office Mnager (OM)), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 10/08/19 to the date of survey. The findings include: 1. The LD failed to ensure that all PT results received were reviewed . Cross refer D6018 2. The LD failed to ensure that the QC program was maintained. Cross refer D6020. 3. The LD failed to maintained a QA plan. Cross refer D6021. 4. The LD failed to maintain all QC records: Cross refer D6072 b) Based interview with the Office Manager (OM) and in-office interview with the Supervisor for the Clinical Laboratory Improvement Services (CLIS) The laboratory failed have a a qualified Laboratory Director (LD) an the date of survey. Cross refer 3009
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Office Manager (OM) , the Laboratory Director (LD) failed to ensure that all PT results received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for Rhesus factor testing testing performed with the American Association of Bioanalysts (AAB) in the calendar years 2021 and 2022. The TC confirmed on 12/20/22 at 10:30 am that the AAB PT results were not reviewed.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of Quality Control (QC) records, Procedure manual (PM), and interview with the Office Manager (OM), the Laboratory Director (LD) failed to ensure that the QC program was maintained for laboratory services provided from 10 /08/19 to the date of the survey. The OM confirmed on 12/2/22 at 11:30 am the LD did not ensure a QC plan was maintained. .
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a lack of a Quality Assurance (QA) records and interview with the Office Manager (OM), the Laboratory Director failed to maintained a QA plan in the calendar year 2021 and 2022. The TP confirmed on 12/20/22 at 11:10 am that a QA plan had not been Maintained.
D6072	TESTING PERSONNEL RESPONSIBILITIES

	CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on the survey review of the Log of Control Blood (LOCB), and interview with the Office Manager (OM) the laboratory failed to maintain the LOCB for immunohematology controls on the date of survey. The finding include: 1. There was no documentation for Qualitry Control (QC) on the LOCB from 8/1/21 - 11/21/21: 2. The OM confirmed on 12/20/22 at 11:00 am that laboratory did not maintain all QC records.