Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0363220	06/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Eastland Womens Clinic	15921 E Eight Mile Road, Eastpointe, 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
D0000	. The Department of Licensing and Regulatory Affairs has evaluated this facility during an announced recertification survey. It was determined the laboratory is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003) and Immediate Jeopardy was identified. The following Conditions were not met: 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant 493.1250 Condition: Analytic Systems
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 lack of documentation and interview with the Office Manager (OM) and Testing Personnel #1 (TP1), the individual testing proficiency testing samples and the Laboratory Director failed to attest to the routine integration of samples into the patient workload for 1 (1st event 2022) of 4 endocrinology serum Beta-Human Chorionic Gonadotropin (BhCG) testing. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed a lack of the signed attestation statement sheet for 1 (1st event 2022) of 4 events reviewed. 2. An interview on 6/27/2023 at 11:28 am, the OM and TP1 confirmed the signed attestation statement sheet was not available on the day of the survey. .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic

	systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interview with the Office Manager (OM) and Testing Personnel (TP) #1, the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to establish a test procedure for the Rh testing. Refer to D5401. 2. The laboratory failed to perform and document the traceable thermometer calibration checks. Refer to D5431. 3. The laboratory failed to perform control procedures each day of patient testing for the immunohematology Rh testing. Refer to D5445. 4. The laboratory failed to document corrective action for improper temperature of the Magic Chef refrigerator used for the storage of testing material and controls. Refer to D5785.
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 record review and interview with the Office Manager (OM) and Testing Personnel #1 (TP1), the laboratory failed to establish a test procedure for the Rh testing not being required if the patient is less than 12 weeks gestation for 9 (September 2022 - June 2023) of 9 months since the testing was implemented. Findings include: 1. A review of the laboratory's policies and procedures revealed a lack of a policy for the Rh testing of patients less than 12 weeks of gestation for 9 of 9 months since the new criteria was implemented. 2. An interview on 6/27/2023 at 2:41 pm, the OM and TP1 confirmed the laboratory had not established a test procedure for this new Rh testing criteria.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on observation, lack of documentation, and interview with the Office Manager (OM) and Testing Personnel #1 (TP1), the laboratory failed to perform and document the traceable thermometer calibration checks as required by the manufacturer before the expiration for 1 (Traceable Excursion Trac) of 1 thermometer in use in the laboratory Magic Chef refrigerator. Findings include: 1. During a tour of the

	laboratory on 6/27/2023 at 9:56 am, the surveyor observed a traceable thermometer in the Magic Chef refrigerator in use past the expiration date of 6/08/2023. 2. Review of the laboratory records revealed a lack of documentation pertaining to calibration and /or replacement of the thermometer by the expiration date of 6/08/2023. 3. A interview on 6/27/2023 at 9:56 am, the OM and TP1 confirmed the traceable thermometer was not calibrated and/or replaced.
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 record review and interview with the Office Manager (OM) and Testing Personnel #1 (TP1), the laboratory failed to perform control procedures each day of patient testing for the immunohematology Rh testing for 5 (March-June 2022 and June 2023) of 16 months of testing. Findings include: 1. A record review of the "Eastland Women's Clinic Rh Log" revealed for 5 (March-June 2022 and June 2023) of 16 months of testing the daily quality control was not performed or documented and patient specimens were tested and reported on the following dates: a. March 2022 - 2, 3, 25, and 26. b. April 2022 - 9,13,15,16, 20, 22, 23, 27, and 29. c. May 2022-entire month of testing d. June 2022 - 2 ,9, and 13. e. June 2023 - 9, 10, 14, 20, 22, and 23. 2. A review of the laboratory's "Rh Factor Testing Policy" revealed that "Prior to performing patient testing, quality control activities must be performed to verify proper function of all necessary equipment." Additionally, Step 2 stated "Both positive and negative control tests are performed daily." 3. An interview on 6/27/2023 at 12:00 pm, with the OM and TP1 revealed they were not aware that daily quality control procedures were not being performed and documented as the policy states.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM) and Testing Personnel #1 (TP1), the laboratory failed to document corrective action for improper temperature of the Magic Chef refrigerator used for the storage of the Anti-D Blend, Rhogam injections, and the positive/negative serum controls for the endocrinology testing for 10 (April - December 2022) of 16 months. Findings include: 1. A record review of the "Daily Temperature Log" revealed for 10 of 16 months reviewed the temperature for the Magic Chef refrigerator was either above or below the stated

	range of 35-46 degrees Fahrenheit with no corrective action documented on the following days: Temperatures above 46 degrees Fahrenheit a. April 2022 - 30. b. May 2022 - 4, 6, 7, 11, 13, 14, 18, 20, 21, 25, 27, and 28. c. June 2022 - 1, 3, 4, 8, 10, 11, 15, 17, 18, 22, 24, 25, and 29. d. July 2022 - 1, 2, 6, 8, 9, 13, 15, 16, 20, 22, 23, 27, 29, and 30. e. August 2022 - 3, 5, 6, 10, 12, 13, 17, 19, 20, 24, 26, 27, and 30. f. September 2022 - 6, 7, 9, 10, 14, 16, 17, 19, 21, 22, 23, 24, 28, and 30. g. October 2022 - 1, 5, 6, 7, and 12. Temperature below 35 degrees Fahrenheit a. November 2022 - 11, 14, 15, 16, 17, 18, 19, 21, 22, 23, 25, 26, 28, 29, and 30. b. December 2022 -1, 2, 3, 4, 5, 6, 7, 9, 10, 17, 21, 22, 29, and 30. 2. A interview on 6/27/2023 at 1:32 pm, the OM and TP1 confirmed that no corrective action was documented for the refrigerator temperatures out of the stated range.
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 record review and interviews, the Laboratory Director failed to meet the qualification requirement of 493.1405. 1. Record review of the Laboratory Directors credentials (Bachelor of Science in Biology 5/14/2011, Master of Science in Medical Science 12/16/2014, Doctor of Osteopathic Medicine 5/3/2019, American Board of Family Medicine 2022). 2. When queried on 6/27/2023 at 10:22 am with the Office Manager and Testing Personnel #1 and on a phone conversation with the Laboratory Director at 3:38 pm, a lack of documentation for 20 Continuing Education Units (CEU), lack of experience and/or supervisory experience in the specialty area, the Laboratory Director did not meet the qualifications. B. Based on record review, observation, and interviews, the Laboratory Director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The Laboratory Director failed to ensure the proficiency testing proficiency testing reports were reviewed by the testing personnel (Refer to D6018). 2. The Laboratory Director failed to ensure the quality control program established was maintained (Refer to D6020). 3. The Laboratory Director failed to ensure for 2 (Technical Consultant #1 [TC1] and #2 [TC2]) of 2 Technical Consultants as listed on the CMS-209 had met the qualification requirements at 493.141 (Refer to D6035).
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 record review and interview with the Office Manager (OM) and Testing

	Personnel #1 (TP1), the Laboratory Director failed to ensure 1) proficiency testing reports were reviewed by the testing personnel for 8 (events 1-3 in 2022 and events 1-2 in 2023 for Rh and events 1-3 in 2022 for endocrinology) of 9 events reviewed and 2) the original paperwork from the proficiency testing program was maintained for 1 (event 1 2022) of 3 events for the Endocrinology testing. Findings include: 1. A review of the laboratory's final American Proficiency Institute (API) proficiency testing documents revealed a lack of review of results by the testing personnel listed on the attestation statement sheet for the following testing events: Rh testing - Immunology/Immunohematology a. 2022 i. events 1 - 3 b. 2023 i. events 1-2 Endocrinology (beta-human chorionic gonadotropin) - Chemistry-Core a. 2022 i. events 1-3 2. A review of the laboratory's final American Proficiency Institute (API) proficiency testing documents revealed a lack the original paperwork from the proficiency testing program for 1 (event 1 2022) of 3 events reviewed in 2022. 3. An interview on 6/27/2023 at 11:28 am, the OM and TP1 confirmed the events listed above were not reviewed by the TP listed on the attestation statement sheet and the original paperwork from the proficiency testing program was not maintained.
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 record review, observation, and interviews, the Laboratory Director failed to ensure the quality control program established was maintained. Refer to D5445.
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 interview with the Office Manager and Testing Personnel #1, the Laboratory Director failed to ensure Technical Consultant #1 and #2 as listed on the CMS 209 had met the qualification requirements at 493.1411. Refer to 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 and interview with the Office Manager (OM) and Testing Personnel #1 (TP1), the Laboratory Director failed to ensure for 2 (Technical Consultant #1 [TC1] and #2 [TC2]) of 2 Technical Consultants as listed on the CMS-209 had met the qualification requirements at 493.141. Findings include: 1. A review of the laboratory's personnel files revealed a lack of documentation showing the Technical Consultant's Bachelor of Science degree had been in a chemical, physical or biological science of medical technology. 2. The surveyor requested additional documentation to show the Technical Consultant's had met the qualification requirements on 6/27/2023 at 10:22 am and 10:28 am and it was not made available.