

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0363220	(X3) Date Survey Completed 01/24/2022
Name of Provider or Supplier Eastland Womens Clinic	Street Address, City, State 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Liaison (LL), the laboratory failed to test the American Proficiency Institute (API) samples like a patient sample and record on the daily Rh Log and the serum pregnancy log for 2 (January 2020 to January 2022) of 2 years reviewed. Findings include: 1. Review of the API proficiency testing final reports revealed a lack of documentation on the Rh log and serum pregnancy log to show that testing and results of the proficiency testing samples are treated like a patient. 2. When queried on 1/24/2022 at 10:35 am, the LL stated "she was unaware that the proficiency testing samples needed to be recorded on the daily Rh and serum pregnancy logs." 3. An interview on 1/24/2022 at 10:35 am, the LL confirmed the API proficiency testing samples were not recorded on the daily Rh and serum pregnancy logs like routine patient samples for 2 of 2 years.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:
. Based on observation and interview with the Laboratory Liaison (LL), the laboratory failed to label the Anti-D Blend ALBA clone reagent with the open date for 1 (1/22 /2022) of 2 days of testing. Findings include: 1. During a tour of the laboratory on 1/24 /2022 at 9:28 am, the LL took 2 bottles of Anti-D Blend ALBA clone reagents from the refrigerator. The surveyor observed 1 of the 2 bottles did not have an open date recorded on the bottle. 2. When queried on 1/24/2022 at 9:32 am, the LL stated "the bottle was opened on Saturday and the date was not recorded on the bottle." 3. An interview on 1/24/2022 at 9:32 am, the LL confirmed 1 of the 2 bottles of Anti-D Blend ALBA clone reagent bottles was opened that past Saturday and the open date was not recorded on the bottle.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
. Based on observation and interview with the Laboratory Liaison (LL), the laboratory failed to perform and document thermometer calibrations for 1 (Serial number (S/N) 10031746) of 1 thermometers before the expiration date. Findings include: 1. During a tour of the laboratory on 1/24/2022 at 9:28 am, the surveyor observed a Traceable Excursion thermometer in use in the refrigerator with an expiration date of 2/02/2019. 2. When queried on 1/24/2022 at 9:34 am, the LL was unaware the thermometer had an expiration date recorded on the back side of the thermometer. 3. An interview on 1 /24/2022 at 9:34 am, the LL confirmed the laboratory failed to perform and document thermometer calibration for the expired thermometer or replace it. ***Repeat Deficiency from 6/20/2017 survey***

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 Laboratory Liaison (LL), the Laboratory Director failed to ensure proficiency testing reports were reviewed by the appropriate testing staff for 6 (Events 1, 2, and 3 in 2020 and 2021) of 6 events for the chemistry endocrinology and immunohematology testing reviewed. Findings include: 1. A review of the American Proficiency Institute (API) proficiency testing records revealed a lack of review by the appropriate staff for 6 (events 1, 2, and 3) of 6 events

reviewed for 2020 and 2021. 2. An interview on 1/24/2022 at 10:35 am, the LL confirmed the appropriate testing staff did not review the final proficiency testing reports in 2020 and 2021.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
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 Laboratory Liaison (LL), the laboratory failed to ensure Testing Personnel #1 performing the duties of a Technical Consultant, met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure the personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified. 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 Laboratory Liaison (LL), the laboratory failed to ensure personnel performing the Technical Consultant (TC) duty of performing competency assessments was qualified for 1 (Testing Personnel (TP) #2) of 2 personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel competency records revealed TP #1 had performed competency assessments for TP #2 on the following dates: a. 9/10/2020 - initial b. 8/4/2021 - annual 2. A review of TP #1 qualifications revealed they did not meet the requirements to perform TC responsibilities. 3. An interview on 1/24/2022 at 10:18 am with the LL confirmed that TP #1 had been performing the competency assessments on TP #2 and they did not meet the qualification requirements to be a TC.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Laboratory Liaison (LL), the Technical Consultant failed to evaluate and document competency assessments at least semiannually in the first year of testing for 2 (Testing Personnel (TP) #1 and #2) of 2 testing personnel listed on the CMS-209 form. Findings include: 1. A review of personnel records revealed the following competency assessments: a. TP #1 - 2/20/2020 training, 3/19/2020 initial assessment, and 2/21/2021 annual assessment b. TP #2 - 9/10/2020 initial assessment and 8/4/2021 annual assessment 2. The surveyor requested documentation of the semiannual competency assessment for TP #1 and #2 and it was not made available as follows: a. TP #1 - 6 month assessment due 9/2020 b/ TP#2 - 6 month assessment due 3/2021 3. An interview on 1/24/2022 at 10:15 and 10:18 am, TP#1 confirmed the 6 month competency assessments were not performed and documented.