

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D1082776	<b>(X3) Date Survey Completed</b> 01/22/2020
<b>Name of Provider or Supplier</b> Women's Health Center Of Saginaw	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on procedure manual review, record review, and interview with Testing Personnel (TP) 1, the laboratory failed to perform and document the daily function checks for the room temperature for the immunohematology Rh group testing for 6 days (April 12, June 25, and September 20 in 2018 and May 29, July 10, and September 18 in 2019) of 24 months reviewed. 1. Procedure manual review revealed the laboratory did not have a policy and/or procedure for performing, documenting, and troubleshooting room temperature readings for the immunohematology Rh Group testing. 2. Record review of the "Blood - Urinalysis Tracking Sheet" revealed the TP were documenting the room temperature on the log in the upper right hand corner. There was no permanent place to record the reading and no normal range recorded on the tracking sheet. 3. Record review revealed 6 days in the 24 months reviewed, the TP failed to document the room temperature on the tracking sheet on the following days of testing patient samples as follows: a. 4/12/2018 b. 6/25/2018 c. 9/20/2018 d. 5/29/2019 e. 7/10/2019 f. 9/18/2019 4. During the interview on 1/22/2020 at approximately 10:00 a.m., TP1 confirmed the laboratory did not have a policy and/or procedure for the function check for the room temperature readings.</p>
<b>D5781</b>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken</p>

when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel (TP) 1, the laboratory failed to document corrective action taken when the room temperature readings fell outside the established ranges for 9 (July to September 2018 and April to September 2019) of 24 months reviewed. Findings include: 1. Record review of the "Blood-Urinalysis Tracking Sheet" revealed for 9 (July to September 2018 and April to September 2019) of 24 months reviewed the room temperature readings were above the manufacturer's stated range of 68 to 75.2 degrees Fahrenheit on the following days: a. July 2018 - 2, 7, 17, and 26 b. August 2018 - 3, 7, 9, 21, and 28 c. September 18, 2018 d. April 17, 2019 to September 19, 2019 2. When queried on 1/22/2020 at approximately 10:00 a.m., TP1 acknowledged the temperatures were out of range and no corrective action was performed and documented. 3. During the interview on 1/22/2020 at approximately 10:00 a.m., TP1 confirmed corrective action was not performed and documented for the out of range room temperature readings.

**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 interview with Testing Personnel (TP) 1, the laboratory failed to provide the educational requirements for 1 (TP4) of 4 testing personnel performing moderately complex immunohematology Rh group 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 record review and interview with Testing Personnel (TP) 1, the laboratory failed to ensure all testing personnel met the educational requirements at 493.1423 for 1 (TP4) of 4 TP. Findings include: 1. Record review of testing personnel credentials revealed a lack of documentation of the educational requirements for performing moderately complex immunohematology Rh group testing was not met. 2. During the interview on 1/22/2020 at 9:50 a.m., TP1 confirmed the above findings. 3. The laboratory was given 7 additional days to supply the necessary educational documents. The documents were not received.