

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D1019382	<b>(X3) Date Survey Completed</b>  07/26/2022
<b>Name of Provider or Supplier</b>  James A Gibson Md Pc	<b>Street Address, City, State</b>  5784 Highland Rd, Waterford, 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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with the Technical Consultant (TC), the laboratory failed to calibrate and/or replace the expired thermometer in the Frigidaire refrigerator for 7 (12/07/2021 to 7/26/2022) of 7 months of operation. Findings include: 1. During a tour of the laboratory on 7/26/2022 at 9:00 am, the surveyor observed a Control Company thermometer in the Frigidaire refrigerator with an expiration date of 9/09/2018. 2. A record review of the "General Maintenance" policy in a section labeled "Thermometer check" step 3, "Verify accuracy of temperature readings annually by comparison to a NIST calibrated thermometer (or NIST traceable thermometer) or utilizing a certification services." 3. During the exit interview on 7/26/2022 at 1:45 pm, the TC confirmed the thermometer had expired and was not calibrated and/or replaced.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to ensure control materials were not used when they exceeded their expiration date for 3 (7/14/2022 low control, 7/15/2022 low and normal control, and 7/18/2022 low, normal, and high control) of approximately 127 testing dates reviewed. Findings include: 1. A review of the laboratory's "All Sample Summary Report" from January 2022 to July 26, 2022 revealed for 3 (7/14/2022 low control, 7/15/2022 low and normal control, and 7/18/2022 low, normal, and high control) of approximately 127 testing dates the controls flagged "\*" after the parameters. 2. A review of the laboratory's quality control testing records revealed an "EC" flag on the individual control reports indicating the quality control material was expired. 3. A record review of the "Quality Control and Assessment" policy lacks the directive of what to do when the quality control material has expired. 4. A review of the laboratory's quality control inserts revealed for lot number 22202-3K the quality control materials had an expiration date as follows: a. 22202-31 low control expired on 7/13/2022 b. 22202-32 normal control expired on 7/14/2022 c. 22202-33 high control expired on 7/15/2022 5. An interview on 7/26/2022 at 1:30 pm, the TC confirmed the laboratory did not ensure quality control materials were not used when the expiration date had been exceeded.

**D5781**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken 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 the Technical Consultant (TC), the laboratory failed to perform and document corrective action for out of range refrigerator and humidity readings for 7 (12/7/2021 to 7/26/2022) of 7 months of operation. Findings include: 1. A record review of the "Refrigerator & Freezer Temperature Log" and the "Temperature and General Maintenance" log revealed the following dates the refrigerator and humidity readings were outside the stated ranges and no corrective action was performed and documented as follows: A. Refrigerator - 2 to 8 degrees Celsius 1. 2/17-18/2022 had a reading of 9 degrees C 2. 2/23-24/2022 had a reading of 9 degrees C 3. 3/1-4/2022 had a reading of 12 degrees C 4. 3/7/2022 had a reading of 12 degrees C B. Humidity - 20-80% 1. 1/28/2022 had a reading of 16% 2. 1/31/2022 had a reading of 16.4% 3. 2/03/2022 had a reading of 19.4% 4. 2/07/2022 had a reading of 18.0% 5. 2/08/2022 had a reading of 18.3% 6. 2/11/2022 had a reading of 19.1% 7. 2/14/2022 had a reading of 15.3% 8. 2/15/2022 had a reading of 15.8% 9. 2/16/2022 had a reading of 17.0% 10. 2/18/2022 had a reading of 19.3% 11. 2/21/2022 had a reading of 19.6% 12. 2/28/2022 had a reading 18.8% 13. 3/01/2022 had a reading of 18.8% 14. 3/03/2022 had a reading of 19.6% 15. 3/04/2022 had a

reading of 18.5% 16. 3/09/2022 had a reading of 19.8% 2. A record review of the "General Maintenance" policy states under "Lab Conditions: Room temperature /humidity" step 4 "Document corrective action: If temperature deviates slightly, adjust thermostat accordingly. If temperature indicates the integrity of stored items may be in jeopardy, move contents to another monitored storage facility and have unit repaired." 3. A record review of the "General Maintenance" policy states under "Lab Conditions: Refrigerators/Freezers" step 3 "Record temperatures daily. If the temperature is outside of the acceptable range, note on the daily temperature log. Complete the following corrective actions: a. Check for the source of the problem \*Door left open or ajar \* Power turned off or unplugged \*Electrical power failure b. Adjust thermostat, if necessary c. Check temperature later during the same day \*If temperature has returned to acceptable range, record adjusted temperature on the daily temperature log. \*If temperature remains outside of the acceptable range, notify the supervisor. Call service, if necessary, and remove any temperature sensitive items." 4. During the exit interview on 7/26/2022 at 1:45 pm, the TC confirmed no corrective action was performed and documented for the out of range temperatures listed above.