

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0394842	(X3) Date Survey Completed 01/13/2020
Name of Provider or Supplier Two Rivers Clinic-Amg Inc	Street Address, City, State 2219 Garfield St, Two Rivers, WI	
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
D5413	<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 surveyor review of SensoScientific logs and interview with the general supervisor, the laboratory did not monitor and document temperatures to ensure proper storage of reagents in the main laboratory refrigerator on 10 of 73 days from September 2019 through November 23, 2019. Findings include: 1. Record review of the "SensoScientific Current Status and Battery Status Monitoring" log from September 2019 through November 23, 2019 revealed the testing personnel did not monitor and document temperature recordings daily: September 2019: Four of twenty-four days had no recorded documentation of temperatures October 2019: Four of twenty-seven days had no recorded documentation of temperatures November 2019: Two of twenty-two days had no recorded documentation of temperatures. 2. Interview with the general supervisor on January 13, 2020 at 2:15 PM confirmed the laboratory did not monitor and document temperatures on 10 of 73 days from September 2019 to November 23, 2019 in the main laboratory refrigerator to ensure proper storage of reagents.</p>
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p>

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on surveyor review of SensoScientific logs and reports, observation of the main laboratory refrigerator and interview with testing personnel and the general supervisor, the laboratory did not document and review the effectiveness of corrective actions taken to resolve unacceptable temperatures in the main laboratory refrigerator from September through December 2019. Findings include: 1. Record review of the "SensoScientific Current Status and Battery Status Monitoring" log from September 2019 through November 2019 revealed the testing personnel manually recorded temperatures in the main laboratory refrigerator until November 23, 2019. Further review revealed the main laboratory refrigerator was out of range, 2-8 C (degrees Celsius), 37 of 63 days temperatures were manually recorded: September: seventeen of twenty days showed unacceptable temperatures ranging from 9-12 C. October: ten of twenty-three days showed unacceptable temperatures ranging from 9-11 C. November: ten of twenty days showed unacceptable temperatures ranging from 8.5-11.5 C. Review of the logs for the three months show the laboratory documented corrective action for unacceptable temperatures on only three days in November. 2. Review of the December 2019 SensoScientific "Alarm History and Corrective Action Report" showed thirty-five unacceptable temperatures in the main laboratory refrigerator. The laboratory documented corrective action for seventeen of these events. 3. Review of the December 2019 SensoScientific "Advanced Report" showed one day with an average temperature of 0.6 C and four days with the average temperature above 8.0 C for the main laboratory refrigerator. 4. Observation of the main laboratory refrigerator on January 13, 2020 at 12:15 PM revealed the refrigerator contained reagents for the Siemens Xpand chemistry analyzer. The reagent boxes were labeled with the manufacturer's temperature range of 2-8 C. 4. Interview with Staff A on January 13, 2020 at 12:17 PM confirmed laboratory staff were not routinely documenting corrective actions taken for manually recorded unacceptable temperature readings on the main laboratory refrigerator. Further interview confirmed the main laboratory refrigerator contained the Siemens Xpand reagents. 5. Interview with the general supervisor on January 13, 2020 at 2:15 PM confirmed the laboratory did not review the effectiveness of corrective actions taken to resolve unacceptable temperatures in the main laboratory refrigerator.