

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  06D2142212	<b>(X3) Date Survey Completed</b>  09/21/2018
<b>Name of Provider or Supplier</b>  Commonspirit Primary Care & Sports	<b>Street Address, City, State</b>  255 S Routt St, Lakewood, CO	
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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of test records and staff interview, the laboratory failed to retain written patient blood lactate test records for at least 2 years since testing began in June 2018. Findings include: a. The laboratory tests blood lactate levels using a Nova Biomedical Lactate Plus analyzer. b. On 9-21-18 around 10 a.m., the laboratory director stated that testing personnel write the lactate test result onto a sheet of paper and shred the paper after entering the test result into the electronic patient record. c. On 9-21-18 around 10 a.m., the laboratory director confirmed the laboratory did not retain written test records at least two years as required by the federal CLIA regulation.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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>

This STANDARD is not met as evidenced by:

Based on a review of the operator's manual, maintenance records and staff interview, the laboratory failed to ensure the room temperature and humidity in the laboratory met the operating conditions of the manufacturer of the Lactate Plus analyzer since testing began on 6-15-18. Findings include: a. The laboratory tests blood lactate levels using a Nova Biomedical Lactate Plus analyzer. b. The operator's manual of the lactate meter stated the testing environment in the laboratory must be 41-113 Fahrenheit (5-45Centigrade) and have 10-90% relative humidity. c. No records existed to show the environmental conditions in the laboratory had been monitored each day of patient testing. d. No system was found in the laboratory for monitoring the environmental conditions. e. On 9-21-18 around 10:30 a.m., the technical consultant stated they recently realized the environmental conditions of the laboratory needed to be monitored for the lactate testing, and confirmed the laboratory had not ensured the testing environment as required by the manufacturer and federal CLIA regulation.