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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 26D2006713 | (X3) Date Survey Completed 02/02/2021 |
| Name of Provider or Supplier Olympic Rehab Wellness And Pain Center | Street Address, City, State 10420 Old Olive Street Rd Ste 305, Saint Louis, MO | |
| 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 |
|---------------------------|---|
| D5411 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of Thermo Scientific manufacturer's package insert, quality control (QC) and interview with testing personnel (TP) #1, the laboratory failed to follow manufacturer's instructions for specimen handling. Findings: 1. Review of the Thermo Scientific package insert for the analyte amphetamine stated "urine specimens may be stored at 2 degrees Celsius to 8 degrees Celsius for five working days". 2. Review of October QC showed on October 8, 2020 twelve patient's urine specimens were collected, refrigerated and October 14, 2020 six days later testing was completed and the patient's results were reported. 3. Review of October QC showed on October 15, 2020 six patient's urine specimens were collected, refrigerated and on October 21,2020 six days later testing was completed and the patient's results were reported. 4. Interview with TP #1 on February 2, 2021 at 10:30 AM confirmed the laboratory failed to follow manufacturer's instructions for specimen handling of urine specimen's being tested for amphetamine.</p> |