

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2082447	(X3) Date Survey Completed 03/31/2026
Name of Provider or Supplier Interventional Pain Management Services	Street Address, City, State 2730 S St Peters Pkwy, Suite 200, Saint Peters, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Carolina UDT Multi-Control quality control (QC) package insert, observation of the Carolina UDT Multi-Control QC vials, patient results and interview with the technical supervisor (TS), the laboratory failed to document open and expiration dates on opiate urine drug screen QC. Findings: 1. Review of the Carolina UDT Multi-Control QC package insert states "Once opened vials of control are stable for 30 days when stored tightly capped at 2-8 degrees celsius". 2. Observation of opened Carolina UDT Multi-Control QC vials Level 1 Lot # E2507 and Level 2 Lot # E2507 showed no open and expiration dates on QC vials. 3. The laboratory performs approximately 4800 opiate urine drug screen tests annually. 4. Interview with the TS on March 31, 2026 at 10:00 AM confirmed the laboratory failed to document open and expiration dates on opiate urine drug screen QC.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the Carolina Medica Easy RA toxicology screening analyzer quality control (QC), patient results and interview with the technical supervisor (TS), the laboratory failed to provide documentation of two control materials of different concentrations each day of patient testing for urine screening creatinine for one of thirteen testing days in 2026. Findings: 1. Review of Caroline Medica Easy RA QC showed the laboratory could not provide acceptable level 1 QC for creatinine on February 21, 2026. 2. The laboratory performs approximately 100 creatinine tests each day of patient testing. 3. Interview with the TS on March 31, 2026 at 10:30 AM, confirmed the laboratory failed to provide documentation of two control materials of different concentrations each day of patient testing for creatinine.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:

Based on review of QC procedures, review of the Carolina Medica Easy RA toxicology screening analyzer quality control (QC) records for one of two analytes, review of laboratory's established range for level 1 QC, review of level 1 QC in the Carolina Medica Easy RA, patient results, and interview with the technical supervisor (TS), the laboratory failed to appropriately document how criteria was established for acceptability of control materials providing quantitative results for the analyte creatinine. Findings: 1. Review of "SOP #UDT002a" procedure states "The following statistical parameters must be established for all creatinine control levels for each procedure of frequent analysis. 1. Mean 2. Standard deviation. monthly statistics must lie within two standard deviation indexes of the group". 2. Review of the Carolina Medica Easy RA toxicology screening analyzer QC records revealed Thermo Scientific chemistry controls in use. The laboratory could not show how they established, documented, and defined statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC for the analyte creatinine. 3. Review of the laboratory established range for creatinine level 1 QC 6.72 ng/ml-7.14 ng/ml. 4. Review of Carolina Medica Easy RA creatinine level 1 QC in the instrument is 6.6 ng/ml-7.34 ng/ml. 5. The laboratory performed 4800 creatinine tests annually. 6. Interview with the TS on March 31, 2026 at 10:00 AM confirmed the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results for the analyte creatinine.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the "Carolina UDT Multi-Control" package insert, observation of the Carolina Medica Easy RA toxicology screening analyzer quality control (QC) for one of two analytes, patient results and interview with the technical supervisor (TS), the laboratory failed to ensure QC was acceptable before reporting patients results for the analyte opiates. Findings: 1. Review of the "Carolina UDT Multi-Control" package insert revealed: opiates level 1 225 ng/ml opiates level 2 375 ng/ml cutoff 300 ng/ml 2. Observation of the Carolina Medica Easy RA toxicology screening analyzer revealed the analyzer reported positive and negative QC results. The laboratory could not find the opiate cutoff or opiate QC levels in the Carolina Medica Easy RA toxicology screening analyzer to ensure they were within acceptable limits. 3. The laboratory performs approximately 4800 opiate urine drug screen tests annually. 4. Interview with the TS on March 31, 2026 at 10:30 AM confirmed the laboratory failed to ensure QC was acceptable before reporting patient results for opiates.