Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1037004	02/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pain Management Institute	10181 Lincoln Hwy, Frankfort, IL	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation and interviews with testing personnel (TP) #1 the technical consultant (TC); the laboratory failed to ensure specimen integrity was maintained throughout the testing process by failing to follow the laboratory's specimen storage requirements. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "PMI 100 - Laboratory Policy and Procedure Manual", which stated on page 3 under the heading of "Specimen Handling": " - If not analyzed immediately, specimens can be stored refrigerated for up to one week. - After 7 days, all specimens (if kept by facility) should be frozen. Within two months, all frozen samples should be analyzed and then discarded, or sent out for analysis." 2. During tour of the laboratory facility on 2-27-2019, at 11:00 am, processed specimens were found stored at room temperature in the laboratory. 3. Interview with TP#1, at 11:00 am, confirmed once a specimen has been processed they are stored at room temperature in the laboratory. 4. On survey date 2-27-2019, at 1:00 pm, the TC confirmed the laboratory was not following the specimen handling procedure as outlined in the laboratory policy and procedure manual.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3)

	Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical consultant (TC); the laboratory's specimen handling procedure failed to meet the specimen acceptability requirements set by the manufacturer for urine toxicology testing on the Medica EasyRA analyzer. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "PMI 100 - Laboratory Policy and Procedure Manual", which stated on page 3 under the heading of "Specimen Handling": "- If not analyzed immediately, specimens can be stored refrigerated for up to one week." 2. Review of the manufacturer's reagent inserts for MEDICA Amphetamine-qualitative (AMP), Barbiturate-qualitative (BAR), Opiate-qualitative (OPI), Oxycodone Enzyme Immunoassay (OXY), and Benzodiazepine enzyme immunoassay (BZO) all state the following: "if the sample cannot be analyzed immediately, it may be stored refrigerated for up to 3 days." 3. On survey date 2-27-2019, at 1:00 pm, the TC confirmed the laboratory's policy for specimen acceptability is not in line with the manufacturer's specimen acceptability criteria.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical consultant (TC); the laboratory failed to follow the laboratory's quality control procedure for 2 of 5 patient test dates reviewed. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "PMI 100 - Laboratory Policy and Procedure Manual", which stated on page 5 under the heading of "Quality Control Frequency Requirements": "A minimum of two levels of quality controls will be run with a batch. The negative control will have an expected value below the assay cut-off. The expected value of the positive control will be above the cut-off. Minimum frequency of control testing will be: - Each day of patient testing - After each calibration - After major or preventative maintenance - When troubleshooting QC or instrument issues - When patient results are questionable" 2. Review of quality control records for 2 of 5 patient testing dates found the Medica EasyRA was re-calibrated after quality control (QC) failures but 2 levels of quality control materials were not re-ran as outlined in the laboratory procedure. Test Date QC Analyte Failure Failed Control 2-14-2019 Oxycodone UDT A-2 (Positive) 2-21-2019 Barbiturate UDT B-2 (Positive) 3. Review of the patient testing log identified 14 patients tested on the two dates (2-14-2019 and 2-21-2019) when 2 levels of quality control were not ran after

	calibration, as indicated in the laboratory's policy and procedure manual. 4. On survey date 2-27-2019, at 1:00 pm, the TC confirmed the laboratory failed to follow the laboratory's quality control procedure.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical consultant (TC); the laboratory failed to include interpretation information for urine toxicology testing performed on the Medica EasyRA analyzer for 5 of 5 patient test reports reviewed. Findings Include: 1. Review of the reagent inserts for the analytes tested on the Medica EasyRA analyzer all indicated the following: Amphetamine-qualitative (AMP), Barbiturate qualitative (BAR), Opiate-qualitative (OPI), Oxycodone Enzyme Immunoassay (OXY), and Benzodiazepine enzyme immunoassay (BZO) "The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/mass spectrometry (GC/MS) or Liquid Chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgement should be exercised to any drug of abuse test result, particularly when the preliminary test result is positive." 2. Review of 5 of 5 patient test reports found the reports failed to provide the above interpretation information. Test Date Patient Identification 11-21-2018 P1 12-20-2018 P2 01-21-2019 P3 02-14-2019 P4 02-21-2019 P5 3. On survey date 2-27-2019, at 1:00 pm, the TC confirmed the laboratory failed to include the manufacturer's interpretation information on the patient test reports for urine toxicology testing performed on the Medica EasyRA analyzer.