Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2147621	01/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pain Institute Of Southern Arizona (Pisa), Pc	4881 E Grant Rd, Ste 201, Tucson, AZ	

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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of patient test requisitions and interview with the facility personnel, the laboratory's test requisition failed to identify the specific tests performed by the laboratory. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Toxicology, with an approximate annual test volume of 429,153. The laboratory began patient testing in July 2019. The laboratory performs a urine drug screen on the ImmTox analyzer and performs a confirmation test, if warranted, on the Agilent LC-MS 6460 analyzer. 2. Each test requisition reviewed during the survey conducted on January 4, 2022 included one of three different test types, New Patient UDT Order, Presumptive Urine Drug Screen or Definitive Order UDT Moderate Risk. 3. The test requisitions presented for review during the survey (A24948, A24873 and A24958) failed to list the specific analytes to be tested, instead only listed one of the test types indicated above. 4. No policy was presented for review during the survey to

	indicate which analytes were included with each test type listed on the test requisition. 5. The facility personnel confirmed that the specific analytes tested by the laboratory were not indicated on the test requisition for the patient testing referenced above, and no policy was established to identify the specific analytes tested in each test type.
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 the laboratory's Policy and Procedure manual and interview with the facility personnel, the laboratory failed to establish policies and procedures related to specimen storage and preservation. Findings include: 1. The laboratory performs urine toxicology testing, with an approximate annual test volume of 429,153. The laboratory began patient testing in July 2019. 2. No policy or procedure was presented for review to indicate acceptable specimen storage and preservation requirements for the urine specimens that are tested in the laboratory, specifically specimens that are refrigerated or frozen. 3. The facility personnel confirmed that the laboratory failed to establish policies and procedures for the storage and preservation of urine specimens as indicated above.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of maintenance and function check documentation for the pipettes utilized as peripheral equipment involved in patient testing under the sub-specialty of Toxicology and interview with the laboratory director, the laboratory failed to follow established policies and document pipette calibrations as required. Findings include: 1. The laboratory's established policy titled, '1.10 Equipment Maintenance' states, "An orderly preventative maintenance program is intended to increase system reliability and reduce downtime. Each instrument and piece of equipment (including pipettes, balances, etc.) must have a maintenance schedule and records of repair and maintenance performed, including date of repair, reason for repair, and remedial action taken if any. Maintenance records are kept near each instrument that is used for testing". 2. During the survey conducted on January 4, 2022, the laboratory failed to provide evidence that the pipettes used by the laboratory were routinely calibrated as

	required per laboratory policy. The laboratory began patient testing in July 2019. 3. The laboratory director confirmed that the pipettes were not calibrated as required since patient testing began.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are manually entered and electronically interfaced into the laboratory's information system (LIS). Findings include: 1. The laboratory performs toxicology testing on urine specimens on the ImmTox analyzer and the Agilent LC-MS 6460 analyzer, with an approximate annual test volume of 429,153. The laboratory began patient testing in July 2019. 2. The test results from the ImmTox analyzer are electronically interfaced into the Laboratory Information System (LIS), LabDaq. The test results obtained from the Agilent LC-MS analyzer are manually entered by laboratory personnel into the LIS. 3. No documentation was presented for review during the survey conducted on January 4, 2022 to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are electronically interfaced and manually entered into the LIS. 4. The facility personnel confirmed that the laboratory did not have a system in place to verify the accuracy of the patient test results that are electronically sent from the ImmTox analyzer to the LIS or manually entered into the LIS.