Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2121716	05/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
La Pain Doctor	3220 S I-10 Service Rd W, Metairie, LA	

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
D0000	A Validation survey was performed at LA Pain Doctor-CLIA ID # 19D2121716 on May 14, 2019. LA Pain Doctor was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1210 CONDITION: Routine Chemistry 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing; Laboratory Director 42 CFR 493.1447 CONDITION: Laboratories performing high complexity testing, Technical Supervisor
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing in the specialty of Chemistry. Findings: 1. The laboratory failed to ensure turbid urine samples for Urine Drug Screens (UDS) were centrifuged prior to testing per manufacturer requirements. Refer to D5311 I. 2. The laboratory failed to reject four (4) of thirty-two (32) urine drug screen samples per laboratory policy. Refer to D5311 II. 3. The laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples. Refer to D5317. 4. The laboratory failed to ensure the established policies and procedures reflected what was in current practice. Refer to D5407. 5. The laboratory failed to have complete performance studies for urine pH. Refer to D5421. 6. The laboratory failed to ensure maintenance for the Medica EasyRA was performed and documented per manufacturer requirements in 2018. Refer to D5429 I. 7. The laboratory failed to ensure monthly maintenance for the Medica EasyRA was performed and documented for one (1) of five (5) months reviewed in 2019. Refer to D5429 II. 8. The laboratory failed to ensure personnel initials were documented on the minimum maximum

	refrigerator temperature logs for 2018. Refer to D5433. 9. The laboratory failed to establish their own means and ranges for Quality Control (QC) for pH as required by the manufacturer. Refer to D5469. 10. The laboratory failed to report urine drug screen results as required by the manufacturer. Refer to D5805.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to assess competency for the General Supervisor. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 4 serves as the General Supervisor. 2. Review of personnel records for Personnel 4 revealed competency assessments for duties as General Supervisor were performed in 2018 and 2019 by the Technical Supervisor. 3. In interview on May 14, 2019 at 9:56 am, Personnel 3 stated she performed the identified General Supervisor competency assessments, not the Laboratory Director.
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: I. Based on observation, record review, and interview with personnel, the laboratory failed to ensure turbid urine samples for Urine Drug Screens (UDS) were centrifuged prior to testing per manufacturer requirements. Findings: 1. Observation by surveyor during laboratory tour on May 14, 2019 revealed the laboratory utilizes the Medica EasyRA for UDS and pH testing. Surveyor further observed the laboratory did not have a centrifuge. 2. Review of the Thermo Scientific DRI assay inserts revealed "An effort should be made to keep pipetted samples free of gross debris. It is recommended that highly turbid specimens be centrifuged before analysis." 3. Review of the laboratory's assay procedures revealed "Specimens with gross turbidity should be sent to the reference lab for testing." 4. In interview on May 14, 2019 at 10:43 am, Personnel 3 stated the laboratory does not centrifuge urine samples. Personnel 3 confirmed the laboratory does not send grossly turbid samples to a reference laboratory. 5. Observation of urine samples in the laboratory's refrigerator revealed the following turbid samples tested on May 9, 2019: Patient 06601 Patient 07624 Patient 05788 Patient 02157 Patient 05195 Patient 01855 6. In interview on May 14, 2019, Personnel 3 confirmed the identified patients were tested without centrifugation of the turbid urine sample. II. Based on record review and interview with personnel, the laboratory failed to reject four (4) of thirty-two (32) urine drug screen samples per

	laboratory policy. Findings: 1. In interview on May 14, 2019 at 9:25 am, Personnel 4 stated urine samples from clinics located in Laplace, Harvey, and New Orleans East are received in the laboratory. Personnel 4 further stated collectors contracted with their facility travel to the different locations for collection and sample transport. Personnel 4 stated samples from Laplace are brought to the laboratory the same day of collection. Personnel 4 further stated New Orleans East samples are brought and stored in the Harvey location's refrigerator the same day of collection. Personnel 4 stated samples from Harvey are transported to the laboratory approximately twice a week. Personnel 4 stated samples are stored in the laboratory's refrigerator until testing performed. 2. Review of the laboratory's "On Site Procedures" under "Specimen Requirements & Handling" revealed: "Freshly voided urine collected in a sterile container. Store in the refrigerator if not tested immediately for 5 days at 2-8 degrees C. Samples if not tested within the 5 days period are to be stored in a freezer unit at -20 degrees C and must be assayed within 2 weeks." 3. Review of the laboratory's "Specimen Unsatisfactory for Analysis" policy under "Common Reasons for Rejection" section revealed "prolonged transportation of the specimen to the laboratory without following the proper handling requirements." 4. Review of the Thermo Scientific DRI assay inserts revealed "Testing of fresh urine specimens is suggested. Specimens that do not receive an initial test within 7 days of arrival in the laboratory should be placed into secure refrigeration units." 5. Review of the Thermo Scientific CEDIA Buprenorphine assay insert revealed " Cap samples immediately after collection, store at 2-8 degrees C and assay within 7 days after collection. If the assay can't be performed within 7 days, or if the sample is to be shipped, cap the sample, and keep it frozen. Store sample at -20 degrees C and assay within 2 weeks." 6. In interview on May 14, 2019 at 10:10 am, Personnel 4 stated urine samples are tested within seven (7) days of collection. 7. Review of urine drug screen patient reports from November 15, 2018 revealed the following four (4) of thirty-two (32) patients exceeded the laboratory's sample acceptability policy: Samples received in laboratory: November 15, 2018 Patient 06813: Collected October 30, 2018 2:05 pm , Tested November 15, 2018 11:21 pm (Exceeded lab policy by eleven (11) days) Patient 06802: Collected November 7, 2018 10:00 am, Tested November 15, 2018 10: 45 am (Exceeded lab policy by three (3) days) Patient 06008: Collected November 8, 2018 9:25 am, Tested November 15, 2018 10:51 am (Exceeded lab policy by two (2) days) Patient 06086: Collected November 8, 2018 8:50 am, Tested November 15, 2018 10:48 am (Exceeded lab policy by two (2) days) 8. In further interview on May 14, 2019, Personnel 4 confirmed the identified patients test date exceeded the laboratory's policy.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples. Findings: 1. In interview on May 14, 2019 at 9:25 am, Personnel 4 stated urine samples from clinics located in Laplace, Harvey, and New Orleans East are received in the laboratory. Personnel 4 further stated collectors contracted with their facility travel to the different locations for collection and sample transport. 2. In

	further interview on May 14, 2019, Personnel 3 stated the laboratory does not provide a client service manual to the other clinics. 3. Review of the laboratory's policy and procedure manual revealed the laboratory did not have detailed instructions for providers that include the following: (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. 4. In further interview on May 14, 2019, Personnel 3 confirmed the laboratory does not have written instructions related to sample collection, labeling, handling, and transport for providers.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the established policies and procedures reflected what was in current practice. Findings: 1. Review of the laboratory's policy and procedure manual revealed the following policies: a) "Toxicology Quality Control" policy revealed "Two levels of controls are performed once per 24 hours." b) "Specimen Unsatisfactory for Analysis" policy revealed "Any specimen with Oxidant Positive or pH outside of 3.0-11.0 range will be rejected. The drug analytes will not be tested and It is recommended to recollect those specimens." 2. In interview on May 14, 2019 at 9:05 am, Personnel 3 stated the laboratory tests and reports pH for validity. Personnel 3 further stated the physician decides what further action is needed if results fall outside of acceptable range. 3. In interview on May 14, 2019 at 9:28 am, Personnel 4 stated the laboratory performs quality control every day of patient testing, not once per twenty four (24) hours.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance studies for urine pH. Findings: 1. Observation by surveyor during the laboratory tour on May 14, 2019 revealed the laboratory performs pH testing for validity of urine drug screens (UDS). 2. Review of the laboratory's performance specification studies revealed the laboratory did not include the following: a) Complete Precision: to include day to day, acceptability criteria, and Laboratory Director's approval b) Reference Range: studies or clinical reference to

	support range in use 3. Review of the laboratory's patient final test report revealed "pH acceptable range = 4.5-8" 4. Review of the Thermo Scientific DRI pH-Detect package insert under "Expected Values" section revealed "The normal range of urine pH values of apparently healthy individuals have been determined to be 4.7 to 7.8." 5. In interview on May 14, 2019 at 12:04 pm, Personnel 3 stated the reference range for the pH came from the consultant that set up the instrument. Personnel 3 confirmed the laboratory did not have a reference range study or clinical reference for the laboratory's urine pH reference range. 6. In further interview on May 14, 2019, Personnel 3 confirmed the laboratory performed simple precision on June 21, 2017 for pH. 7. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs 4,581 pH tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to ensure maintenance for the Medica EasyRA was performed and documented per manufacturer requirements in 2018. Findings: 1. Review of the laboratory's Medica EasyRA maintenance logs for 2018 revealed the following replacement schedule: a) Probe: four (4) months b) Wash cup: six (6) months c) Waste pump line: six (6) months d) Diluent line: one (1) year 2. Further review of the laboratory's Medica EasyRA 2018 maintenance logs revealed the laboratory did not have documentation of replacement of the identified instrument components with the following due dates: a) Probe: due March 2018, July 2018, November 2018 b) Wash cup:due May 2018 and November 2018 c) Waste pump line: due May 2018 and November 2018 d) Diluent line: due November 2018 3. Review of the laboratory's "Toxicology Quality Control" policy under "Action logs and Maintenance logs" section revealed "All maintenance is performed by the manufacturer's instructions and logged in the maintenance log kept in the laboratory." 4. In interview on May 14, 2019 at 1:57 pm, Personnel 4 confirmed the laboratory did not have documentation of the identified instrument components were replaced in 2018. II. Based on record review and interview with personnel, the laboratory failed to ensure monthly maintenance for the Medica EasyRA was performed and documented for one (1) of five (5) months reviewed in 2019. Findings: 1. Review of the laboratory's Medica EasyRA maintenance logs for 2019 revealed the following monthly tasks: a) Bleach diluent and waste bottle b) Clean wash cup c) Clean air filter 2. Further review of the maintenance logs revealed the laboratory did not have documentation of the monthly tasks for April 2019. 3. Review of the laboratory's "Toxicology Quality Control" policy under "Action logs and Maintenance logs" section revealed "All maintenance is performed by the manufacturer's instructions and logged in the maintenance log kept in the laboratory." 4. In interview on May 14, 2019 at 1:57 pm, Personnel 4 confirmed the laboratory did not have documentation of monthly maintenance performance in April 2019.
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 record review and interview with personnel, the laboratory failed to ensure personnel initials were documented on the minimum maximum refrigerator temperature logs for 2018. Findings: 1. Review of the laboratory's temperature logs for 2018 and January through May 14, 2019 revealed a "Minimum Maximum Refrigerator Temperature Log" that included the following headers: a) Date b) Minimum c) Maximum d) Tech 2. Further review of the laboratory's "Minimum Maximum Refrigerator Temperature Log" for 2018 revealed the personnel ("Tech") who recorded the temperatures were not documented for the following twenty one (21) dates: May 3, 2018 May 29, 2018 June 5, 2018 July 11, 2018 July 16, 2018 July 18, 2018 July 24, 2018 July 25, 2018 July 31, 2018 August 6, 2018 August 8, 2018 August 13, 2018 August 20, 2018 August 21, 2018 August 27, 2018 August 28, 2018 September 10, 2018 September 11, 2018 September 12, 2018 September 19, 2018 September 24, 2018 3. In interview on May 14, 2019, Personnel 4 confirmed the identified dates did not include the initials of the personnel who recorded the refrigerator temperatures.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish their own means and ranges for Quality Control (QC) for pH as required by the manufacturer. Findings: 1. Observation by surveyor during laboratory tour on May 14, 2019 revealed the laboratory utilizes the Medica EasyRA for testing of urine pH. 2. Review of the Thermo Scientific DRI pH-Detect assay insert under the "Quality Control and Calibration" section revealed "Ensure that control results are within established ranges as determined by your laboratory." 3. Review of the laboratory's "Toxicology Quality Control" policy revealed "All levels of Quality Control are assayed controls. New lots will be evaluated for performance before put

	into use." 4. In interview on May 14, 2019 at 9:18 am, Personnel 4 stated the laboratory utilizes the manufacturer's QC ranges for pH. 5. Review of the laboratory's quality control records revealed the following lot numbers in current use: DRI pH-Detect pH 3.6 Control: Lot # 73162213 DRI pH-Detect pH 11.5 Control: Lot # 72978049
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 observation, record review, and interview with personnel, the laboratory failed to report urine drug screen results as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on May 14. 2019 revealed the laboratory utilizes the Medica Easy RA for Urine Drug Screens (UDS) for the following drugs: Buprenorphine, Benzodiazepines, Cocaine, Methadone, Opiates, Oxycodone, and Cannabinoids. 2. Review of the Thermo Scientific DRI assay package inserts under intended use revealed "This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical considerations and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used." 3. Review of random selection of patient final test reports for UDS revealed the laboratory included the following statements: "All drug test results are a preliminary screen result. For a confirmatory result send out for LCMS or GMS. The performance characteristics of these tests were determined by LA Pain Doctor. They have not been cleared and/or approved by the U. S. Food and Drug Administration." 4. In interview on May 14, 2019, Personnel 3 confirmed the laboratory did not include the full statement as listed in the manufacturer's package insert on UDS patient final test reports. 5. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs 32,607 UDS tests annually.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction. Findings: 1. The

	Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Refer to D6087. 2. The Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D6093. 3. The Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D6095. 4. The Laboratory Director failed to ensure the patient test reports included pertinent information required for interpretation. Refer to D6098. 5. The Laboratory Director failed to ensure policies and procedures were followed for assessing personnel competency. Refer to D6103. 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6106.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to establish pertinent performance characteristics for pH testing. Refer to D5421.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Findings: 1. The laboratory failed to ensure turbid urine samples for Urine Drug Screens (UDS) were centrifuged prior to testing per manufacturer requirements. Refer to D5311 I. 2. The laboratory failed to reject four (4) of thirty-two (32) urine drug screen samples per laboratory policy. Refer to D5311 II. 3. The laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples. Refer to D5317.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory

	Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D5469.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Findings: 1. The laboratory failed to ensure maintenance for the Medica EasyRA was performed and documented per manufacturer requirements in 2018. Refer to D5429 I. 2. The laboratory failed to ensure monthly maintenance for the Medica EasyRA was performed and documented for one (1) of five (5) months reviewed in 2019. Refer to D5429 II. 3. The laboratory failed to ensure personnel initials were documented on minimum maximum refrigerator temperature logs for 2018. Refer to D5433.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the patient test reports included pertinent information required for interpretation. Refer to D5805.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were followed for assessing personnel competency. Refer to D5209.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to

	all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5407.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Supervisor failed to provide technical oversight for high complexity testing. Findings: 1. The Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Refer to D6112. 2. The Technical Supervisor failed to ensure the laboratory established reference (normal) values for pH testing. Refer to D6115. 3. The Technical Supervisor failed to ensure that a quality control program was established to assure the quality of pH testing. Refer to D6117.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to ensure turbid urine samples for Urine Drug Screens (UDS) were centrifuged prior to testing per manufacturer requirements. Refer to D5311 I. 2. The laboratory failed to reject four (4) of thirty-two (32) urine drug screen samples per laboratory policy. Refer to D5311 II. 3. The laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples. Refer to D5317. 4. The laboratory failed to ensure the established policies and procedures reflected what was in current practice. Refer to D5407. 5. The laboratory failed to ensure maintenance for the Medica EasyRA was performed and documented per manufacturer requirements in 2018. Refer to D5429 I. 6. The laboratory failed to ensure monthly maintenance for the Medica EasyRA was performed and documented for one (1) of five (5) months reviewed in 2019. Refer to D5429 II. 7. The laboratory failed to ensure personnel initials were documented on minimum maximum refrigerator temperature logs for 2018. Refer to D5433.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)

	The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Supervisor failed to ensure the laboratory established complete performance studies for urine pH. Refer to D5421.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to ensure that a quality control program was established to assure the quality of pH testing. Refer to D5469.