Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2205048	06/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bayou Pain And Spine	1810 Lindberg Drive, Suite 3500, Slidell, 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	An Initial survey was performed at Bayou Pain and Spine, CLIA # 19D2205048, on June 12, 2023. Bayou Pain and Spine was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing; Technical Consultant
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, procedures, and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have written performance specification procedures that specified the analytes and cut-offs (reference values) to be verified by the laboratory. 2. In interview on June 12, 2023 at 11: 00 am, the laboratory's Testing Personnel confirmed the laboratory's "IR500 Validation Protocol" was generalized and included analytes the laboratory do not test for and cut-off values not validated or used by the laboratory.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have the following written procedures: a) Calibration verification to include, but not limited to, number, type, concentration of materials, and frequency of performance 47757 b) Quality Control - Criteria and instructions for performing a patient assessment after failed quality control. c) Verification of instrument performance - Detailed instructions for verification of instrument performance after an instrument is taken out of use for any period of time. 2. In interview on June 12, 2023 at 2:40 p.m., the Testing Personnel confirmed the laboratory did not have the policies identified above.
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 review of the laboratory's policy and procedure manual and interview with laboratory personnel, the laboratory failed to ensure laboratory policies and procedures were approved and signed by the laboratory director. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory director did not sign the polices and procedures in use. 2. In interview on June 12, 2023 at 4:50 p. m., the Testing Personnel confirmed the laboratory director did not sign the laboratory's policies and procedures.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
Based on review of temperature logs and interview with personnel, the laboratory failed to document corrective actions performed when the freezer temperature was not maintained within the laboratory's acceptable range for ninety-eight (98) of ninety-eight (98) days reviewed. Findings: 1. Review of the laboratory's temperature logs from November 2022 through March 2023 revealed the laboratory utilized a freezer (Freezer #1) with an acceptable temperature range defined as less than or equal to -20 degrees Celsius. 2. Further review of the laboratory's temperature logs revealed the freezer temperature was documented as outside of the laboratory's acceptable temperature range on the following days: November 7, 2022: 18 degrees Celsius November 8, 2022: 18 degrees Celsius November 9, 2022: 16 degrees Celsius November 10, 2022: 18 degrees Celsius November 11, 2022: 18 degrees Celsius November 14, 2022: 15 degrees Celsius November 15, 2022: 19 degrees Celsius November 16, 2022: 19 degrees Celsius November 17, 2022: 16 degrees Celsius November 18, 2022: 19 degrees Celsius November 21, 2022: 19 degrees Celsius November 22, 2022: 19 degrees Celsius November 23, 2022: 19 degrees Celsius November 28, 2022: 19 degrees Celsius November 29, 2022: 19 degrees Celsius November 30, 2022: 18 degrees Celsius December 1, 2023: -18 degrees Celsius December 2, 2023: -18 degrees Celsius December 5, 2023: -18 degrees Celsius December 6, 2023: -18 degrees Celsius December 7, 2023: -18 degrees Celsius December 8, 2023: -17 degrees Celsius December 9, 2023: -18 degrees Celsius December 12, 2022: -18 degrees Celsius December 13, 2022: -18 degrees Celsius December 14, 2022: 18 degrees Celsius December 15, 2022: 18 degrees Celsius December 16, 2022: 18 degrees Celsius December 19, 2022: 16 degrees Celsius December 20, 2022: 17 degrees Celsius December 21, 2022: 18 degrees Celsius December 22, 2022: 18 degrees Celsius December 23, 2022: 17 degrees Celsius December 27, 2022: -17 degrees Celsius December 28, 2022: -17 degrees Celsius December 29, 2022: -17 degrees Celsius December 30, 2022: -17 degrees Celsius January 3, 2023: 17 degrees Celsius January 4, 2023: 17 degrees Celsius January 5, 2023: 17 degrees Celsius January 6, 2023: 17 degrees Celsius January 9, 2023: 17 degrees Celsius January 10, 2023: 18 degrees Celsius January 11, 2023: 18 degrees Celsius January 12, 2023: 18 degrees Celsius January 13, 2023: 17 degrees Celsius January 16, 2023: 17 degrees Celsius January 17, 2023: 17 degrees Celsius January 18, 2023: 17 degrees Celsius January 19, 2023: 17 degrees Celsius January 20, 2023: 18 degrees Celsius January 23, 2023: 17 degrees Celsius January 24, 2023: 18 degrees Celsius January 25, 2023: 17 degrees Celsius January 26, 2023: 17 degrees Celsius January 27, 2023: 16 degrees Celsius January 30, 2023: 17 degrees Celsius January 31, 2023: 17 degrees Celsius February 1, 2023: 17 degrees Celsius February 2, 2023: 17 degrees Celsius February 3, 2023: 17 degrees Celsius February 6, 2023: 17 degrees Celsius February 7, 2023: 17 degrees Celsius February 8, 2023: 17 degrees Celsius February 9, 2023: 17 degrees Celsius February 10, 2023: 18 degrees Celsius February 13, 2023: 17 degrees Celsius February 14, 2023: 18 degrees Celsius February 15, 2023: 18 degrees Celsius February 16, 2023: 17 degrees Celsius February 17, 2023: 17 degrees Celsius February 20, 2023: 18 degrees Celsius February 22, 2023: 19 degrees Celsius February 23, 2023: 17 degrees Celsius February 24, 2023: 18 degrees Celsius February 27, 2023: 16 degrees Celsius February 28, 2023: 17 degrees Celsius March 1, 2023: 17 degrees Celsius March 2, 2023: 17 degrees Celsius March 3, 2023: 17 degrees Celsius March 6, 2023: 17 degrees Celsius March 7, 2023: 17 degrees Celsius March 8, 2023: 17 degrees Celsius March 9, 2023: 17 degrees Celsius March 10, 2023: 18 degrees Celsius March 13, 2023: 17 degrees Celsius March 14, 2023: 18 degrees Celsius March 15, 2023: 18 degrees Celsius March 16, 2023: 17 degrees Celsius March 17, 2023: 17 degrees Celsius March 20, 2023: 18 degrees Celsius March 21, 2023: 17 degrees Celsius March 22, 2023: 17 degrees Celsius March 23,

	2023: 17 degrees Celsius March 24, 2023: 18 degrees Celsius March 27, 2023: 17 degrees Celsius March 30, 2023: 16 degrees Celsius March 31, 2023: 17 degrees Celsius 3. In interview on June 12, 2023 at 3:13 p.m., the Testing Personnel confirmed the laboratory did not take corrective actions on the dates identified above.
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 by surveyors, review of manufacturer's instructions, review of patient final test reports, and interview with personnel, the laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Findings: 1. Observation by surveyors during the laboratory tour on June 12, 2023 at 10:19 am revealed the laboratory utilized the Synermed IR 500 for UDS testing with Lin-Zhi International, INC (LZI) reagents. 2. Review of the LZI package insert under "Intended Use" section revealed "This assay provides only a preliminary analytical result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas or Liquid Chromatography/Mass Spectrometry (GC /MS or LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgement should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive." 3. Review of random selection of three (3) final patient test reports revealed the laboratory did include the identified preliminary result comment. 4. In interview on June 12, 2023 at 5:00 pm the laboratory's Testing Personnel confirmed the laboratory did not report the urine drug screen results as preliminary as required by the manufacturer.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 2. The Laboratory Director failed to ensure patient final test reports included required pertinent information. Refer to D6026. 3. The Laboratory Director failed to ensure the

	Technical Consultant met state of Louisiana licensure requirements for moderate complexity testing. Refer to D6029. 4. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective action by the laboratory was taken when temperatures were not maintained within the laboratory's acceptable range. Refer to D5785
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final test reports included required pertinent information. Refer to D5805.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the Laboratory Director failed to ensure the Technical Consultant met state of Louisiana licensure requirements for moderate complexity testing. Refer to D6035.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) 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 laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish complete policies and procedures. Refer to D5403. 3. The laboratory failed to ensure laboratory policies and procedures were approved and signed by the laboratory director. Refer to D5407.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The laboratory failed to ensure the Technical Consultant met the state of Louisiana licensure requirement. Refer to D6035
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for

	example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the laboratory failed to ensure the Technical Consultant met the state of Louisiana licensure requirement. Findings: 1. Review of the Technical Consultant's personnel records revealed he did not have a laboratory license issued by the Louisiana State Board of Medical Examiners (LSBME). 2. In interview on June 12, 2023 at 10:57 am, the laboratory's Compliance Group Personnel 1 stated she thought licensure did not apply to physician office laboratories. The Compliance Group Personnel 1 confirmed the laboratory's Technical Consultant did not have a laboratory license issued by LSBME.