Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0688964	11/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Acadiana Family Practice Lab, Inc	717 Curtis Drive, Rayne, 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 Certification survey was performed on November 29, 2022 at Acadiana Family Practice Lab, INC, CLIA ID # 19D0688964. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 review of the laboratory's policies, documents, and interview with personnel, the laboratory failed to ensure complete detailed written instructions for providers to maintain integrity of samples were established. Findings: 1. In interview on November 29, 2022 at 10:40 am, Testing Personnel 1 stated the laboratory receives samples from local home health agencies. 2. Review of the laboratory's policies and documents revealed the laboratory did not have detailed written instructions for providers that included the following: a) Patient preparation. b) Specimen collection. c) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. d) Specimen storage and preservation. e) Conditions for specimen transportation. f) Specimen processing. g) Specimen acceptability and rejection. h) Specimen referral. 3. In further interview on November 29, 2022 at 10:47 am, Testing Personnel 1 stated the laboratory provides a list of tests offered to providers. Testing Personnel 1 confirmed the document provided did not include detailed written instructions for providers.
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 observation by surveyor, review of the laboratory's policies, review of quality control (QC) records, manufacturer's instructions, and interview with personnel, the laboratory failed to establish a policy for establishment of ranges for QC material utilized for urine sediment testing. Findings: 1. Observation by surveyor on November 29, 2022 at 10:24 am during the laboratory tour revealed the laboratory utilizes Cliniqa Dipscopic controls for urine sediment testing. 2. Review of the laboratory's policies and quality control records revealed the laboratory did not have detailed written instructions for putting new lots of urinalysis QC into use. 3. Review of the manufacturer's instructions under "Limitations of Procedure" revealed "Each laboratory should establish their own acceptable ranges and tolerance limits based on their test system." 4. In interview on November 29, 2022 at 9:41 am, the Laboratory Director stated the laboratory utilizes the manufacturer's ranges for the QC utilized for urine sediment testing. The Laboratory Director confirmed the laboratory did not establish a policy for establishment of their own ranges for QC utilized for urine sediment testing.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5317.

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 observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.