Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2116186	12/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Accurix Laboratory Inc	3030 Senna Drive Suite A, Matthews, NC	

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
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 procedures and interview with the TS (technical supervisor), GS (general supervisor), and TP (testing personnel) #2 on 12/16 /21, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The procedure manual did not include a step-by-step procedure for reporting SARS-CoV-2 test results to public health authorities. During interview at approximately 11:40 a.m., the TS (technical supervisor) and TP (testing personnel) #2 stated that the laboratory reports results electronically to state public health authorities. During interview at approximately 12:20 p.m., the GS (general

	supervisor) stated that the laboratory does not have a written policy for how SARS-CoV-2 test results are reported. 2. The procedure manual did not include instructions for plate set-up and result interpretation for the SARS-CoV-2 RT-PCR test. During interview at approximately 1:50 p.m., the GS stated that interpretation of results is performed by an off-site TP. She verified that the laboratory did not have a written procedure describing how plates are set up and how results are interpreted. 3. The laboratory's "Sample Reception and Accessioning" procedure states on page 3 "11. Perform Specimen Validity Testing on all samples utilizing the AU680. Use the refractometer and pH meter to verify any results that are outside the range of acceptability. ... 6.2 Sample Rejection Criteria ... 1. A sample will be rejected if it meets one or more of the following criteria: ... i. Sample fails Specimen Validity Testing ...". During interview at approximately 3:10 p.m., the TS and TP #2 stated that specimens are not rejected based on validity testing. They stated the laboratory does not have a refractometer or pH meter.
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 review of validation records for the Apex Lab Solutions SARS-CoV-2 RT-PCR test and interview with the TS (technical supervisor) 12/16/21, the laboratory director failed to ensure that verification procedures were adequate to determine all performance characteristics of the method. Review of Apex Lab Solutions SARS-CoV-2 RT-PCR validation records revealed the validation consisted of the following documents: Simple Precision Summary, Simple Accuracy Summary, Alternate Method Comparison Summary, Stability Summary, and Interference Summary. Review of validation records revealed only the Stability Summary was signed and dated by the laboratory director. The records did not include a detailed description of the validation, including the dates performed, result acceptability, and the date patient testing started. During interview at approximately 11:10 a.m., the TS stated that the validation results were acceptable, but he confirmed that all documentation had not been signed by the laboratory director to indicate review and approval.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 review of the laboratory's quality assessment plan, the absence of records, and interview with TP (testing personnel) #2 on 12/16/21, the laboratory director failed to ensure that quality assessment policies were maintained to assure the quality of laboratory services provided. The laboratory's "LIS (LABORATORY INFORMATION SYSTEM) DATA MANAGEMENT POLICY" states on page 7 "... L. QUALITY SYSTEM ASSESSMENT 1. On a monthly basis, 10 patient reports

	will be pulled and evaluated in the same manner as the validation reports. 2. The assessment will be documented on the appropriate form. ..." There were no records available to indicate that the laboratory had pulled and evaluated 10 patient reports on a monthly basis. During interview at approximately 5:00 p.m., TP #2 confirmed that the laboratory had not performed the patient report evaluation on a monthly basis as specified in the procedure.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 review of personnel records and interview with TP (testing personnel) #2 on 12/16/21, the laboratory director failed to ensure that prior to testing patient specimens, 1 of 2 testing personnel (TP #1) had received appropriate training and had demonstrated they could perform all testing operations reliably to provide and report accurate patient test results. Review of personnel records for TP #1 revealed that there were no training records available. During interview at approximately 4:20 p.m., TP #2 stated that TP #1 interprets SARS-CoV-2 at a remote location. He verified there were no training records available for TP #1.
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 review of validation records and interview with TP (testing personnel) #2 on 12/16/21, the TS (technical supervisor) failed to document the review and approval of validation records for drug screen testing performed on the Beckman AU680 analyzer. Findings: 1. The TS failed to document review and approval for the revalidations performed for Buprenorphine and pH(potential of hydrogen) and the Incubation Study. Review of the laboratory's validation records revealed a revalidation was performed and completed for Buprenorphine on 12/30/19- 2/5/20 and for pH on 8/7 /19-9/17/19. The revalidation for each analyte included control raw data documented for each day of testing. There was no documentation available to summarize what was done, the reason performed, the review or evaluation of results to verify the accuracy and precision of each test, or approval by the TS. Review of laboratory's validation records also revealed an incubation study that was performed in March 2020. The incubation study included data and patient reports for 20 samples tested on week one, for 10 samples tested on week 2, and 10 samples that were tested on week 3. There was no documentation available to summarize what was done, the reason performed, the review or evaluation of results or approval by the TS. Interview with TP #2 at approximately 4:30 p.m. confirmed there was no evaluation or approval of the

	revalidations that were performed for Buprenorphine and pH or the Incubation Study. He stated the revalidations were performed when testing was added back to the laboratory's test menu. He confirmed the Incubation Study was completed when the Incubation times were changed from 55 minutes to 30 minutes.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the TS (technical supervisor) 12/16/21, the TS failed to evaluate the competency of the GS (general supervisor) for supervisory duties. Review of personnel records revealed the GS was hired in June 2019. Review of personnel records revealed the GS had technical competency evaluations in August and December 2019, December 2020, and June 2021. There was no documentation that the GS was evaluated for the performance of supervisory responsibilities. During interview at approximately 5:15 p.m., the TS confirmed that the GS had not been evaluated for performance of supervisory duties.