Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2182273	03/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Integrated Health, Llc	14617 Perkins Road, Baton Rouge, 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 on March 10, 2021 at Integrated Health, CLIA ID # 19D2182273. 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 client service instructions and interview with personnel, the laboratory failed to ensure detailed written instructions for providers to maintain integrity of samples were established. Findings: 1. In interview on March 10, 2021 at 9:35 am, the Technical Supervisor stated that the laboratory has not started to receive patient samples for testing as of date of survey. 2. Review of the laboratory's client service form revealed the laboratory did have instructions provided for clients; however, the laboratory did not include (not an all inclusive list) the following instructions: a) specimen collection, handling and sampling b) specimen transportation with temperature requirements c) time frame for receiving of specimens d) record logs for sample receipt e) storage processes for specimens 2. In interview on March 10, 2021 at 12:44 pm, the Technical Supervisor stated the client service form did not include the above instructions. The Technical Supervisor confirmed the instructions provided to clients was not complete.
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 policy and procedure manual review and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following policies: a) Complaint Investigations to include how to address, document, and handle complaints or problems reported to the laboratory b) Communications to include system to identify and document problems with breakdown in communication c) Twice a year instrument comparison of test results for alternate testing or blind samples 2. In interview on March 10, 2021 at 12:44 pm, Technical Supervisor confirmed the laboratory did not include the identified policies.
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 policies and procedures as well as interview with personnel, the laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include detailed instructions for the following: a) Stability for the Extraction Control VTM media from Beaver Biomedical b) Bridging between analyzers for SARS CoV 2 RNA testing 2. In interview on March 10, 2021 at 12:44 pm, Technical Supervisor confirmed the above policies were not included in the laboratory's policy manual.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and

	test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of manufacturer's temperature requirements, and interview with personnel, the laboratory failed to monitor the room temperature where reagents and supplies are stored per manufacturer requirements. Findings: 1. Observation by surveyors during the laboratory tour on March 10, 2021 at 9:30 am revealed the laboratory did not monitor the room temperature of the laboratory where the following supplies were stored: a) 3D Med Andis Viral RNA Auto Extraction and Purification Kit: Lot NEO5200503 Expiration 5/20/21 b) 3D Med Andis Viral RNA Auto Extraction and Purification Kit: Lot NEO5200504 Expiration 5/24/21 2. Review of the manufacturer's storage requirements for the above supplies revealed the following: 15-25 degrees celsius. 3. In interview on March 10, 2021 at 12:44 pm, the Technical Supervisor confirmed the laboratory did not monitor the room temperature of the laboratory.
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 direct observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5413.
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 personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Findings: 1. The laboratory failed to ensure detailed written instructions for providers to maintain integrity of samples were established. Refer to D5317. 2. The laboratory

	failed to establish a complete policy and procedure manual. Refer to D5401. 3. The laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Refer to D5403.