Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0161740	12/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Troy Pediatrics, Llp	258 Hoosick Street, Suite 106, Troy, NY	

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
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on surveyor's review of the laboratory's form used to record the patient test results for SARS-CoV-2 performed on the Quidel Sofia analyzer, Quality Control (QC) results, the lot numbers, expiration date and an interview with the laboratory director, the laboratory failed to establish a written procedure for reporting the patient's tests results to the New York Bureau of Surveillance and Data systems, via the Electronic Clinical Laboratory Reporting System (ECLRS) from 10/21/20 through survey date. FINDINGS 1. The laboratory director confirmed on December 14, 2021 at approximately 10:30 AM, the surveyor's findings that the laboratory failed to establish a written procedure for reporting the patient's tests results for the SARS-CoV-2 to the New York Bureau of Surveillance and Data Systems from 10/21/20 through survey date. 2. The written procedure for reporting the required data must include: Test ordered using Logical Observation Identifiers Names Codes (LOINC) from Center for Diseases Control (CDC) Device identifier Test result and result date Accession number/specimen number Patient age, race, ethnicity's, zip code and county Ordering provider name, National Provider Identifier (NPI) number, address, and zip code Performing facility name and/or Clia number and zip code Specimen source, date ordered, and date collected Patient name (last, first, middle initial) and date of birth Patient address and phone number with area code 3. The laboratory personnel would add a check mark in the column when the data entry was entered into the NYS BSDS systems. 4. Approximately 106 patients were tested and reported during the above time.

D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor's review of 2020, 2021 American Proficiency Institute (API) Proficiency testing (PT) attestation statements and an interview with the laboratory director, the laboratory failed to rotate the testing of PT samples among five laboratory personnel, who routinely perform hematology automated Complete Blood Count (CBC) tests. Two out of three laboratory personnel performed the 2020 and 2021 events, as indicated by the signed attestation statements. FINDINGS. The laboratory director confirmed on December 14, 2021 at approximately 11:00 AM, the surveyor's findings that two of three laboratory personnel performed the 2020 and 2021 PT events, as indicated by the signed attestation statements. 2. The laboratory did not rotate the testing of the PT samples for the three out of five testing personnel, who routinely perform hematology CBC testing.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor's review of the Beckman Coulter AcT Diff hematology analyzer's QC records from June 1, 2019 through survey date and an interview with the laboratory director, the laboratory failed to retain the daily startup/background check printouts for the hematology analyzer from June 1, 2019 through survey date. FINDINGS: The laboratory director confirmed on December 14, 2021, at approximately 11;00 AM, the surveyor's findings that the laboratory did not retain the daily startup/background check printouts for the of the hematology analyzer from June 1, 2019 through survey date. a. The laboratory did retain the daily startup /background check printouts only when performing API PT testing for 2020 and 2021.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Assessment (QA) policy, QA review records for the calendar year 2019, 2020, 2021 and an interview with the laboratory director, the laboratory failed to follow their established QA policy for an

	ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. FINDINGS: 1. The laboratory director confirmed on December 14, 2021 at approximately 9:45 AM, that the laboratory failed to follow their established QA policy for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. The laboratory failed to: a. identify, take corrective action when the same two out of five testing personnel performed the hematology PT test events in 2020 and 2021. b. establish a reporting system for the SARS CoV-2 patient results to the NYSDOH c. retain the daily startup /background check printouts for the of the hematology analyzer d. follow the LifeSign manufacturer's instructions to monitor the room temperature and incubator temperatures for the Uricult Paddle System used to perform urine colony counts. e. ensure that the guidelines for the interpretation of urine colony counts was established. Refer to D1002, D2007, D3031, D5413 and D5807
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 surveyor's review of the laboratory's room temperature logs 2020 & 2021 and direct observation of the laboratory's thermometer used to record room temperatures. The review of the incubator temperature logs for 2020, 2021, the Lifesign packet insert for the Uricult Paddle System and an interview with the laboratory director, failed to follow the LifeSign manufacturer's instructions to monitor the room temperature and incubator temperatures for the Uricult Paddle System used to perform urine colony counts. FINDINGS: 1. The laboratory director confirmed on December 14, 2021 at approximately 11:30 AM, the surveyor's findings that the laboratory failed to ensure that the laboratory's room temperature was monitored by use of a National Institute for Standards and Technology (NIST) thermometer. a. The surveyor observed the thermometer on the laboratory wall used to record the room temperatures was a plastic thermometer, not a calibrated thermometer by NIST standards. b. The LifeSign manufacturer requires a storage temperature 46 to 77F and/or 7 to 25C for the Uricult Paddle System. c. The laboratory personnel did record the room temperature between 72 to 77F for the calendar years 2020 through survey date, however the current form in use did not have the ranges. 2. The laboratory established the incubator ranges from 34 to 38C as required by the manufacture for incubation of the Uricult Paddle System. a. The incubator temperatures recorded on the 2019 log sheet were out of range from July 2, 2019, though December 31, 2019 for the following months, number of days and temperature: July 2 -29, 2019 total # of 3 days @ 39C and 1 day @ 40C August 18-29, 2019 total # of 2 days @ 39C and 2 days @ 40C December 5 -31, 2019 total # of 8 days @ 39C and 5 days @ 40C b. The laboratory did not identify the out of range temperatures and take remedial action.
D5807	TEST REPORT

	CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on surveyor's review and observation for two patient Electronic Medical Record (EMR) charts for urine colony counts and an interview with the laboratory director, the laboratory failed to ensure that the guidelines for the interpretation of urine colony counts was established. FINDINGS: The laboratory director confirmed on December 14, 2021 at approximately 11:45 AM, that the laboratory was reporting the colony counts as either Positive or Negative. a. The laboratory did not establish an interpretation for the Positive as greater than 1000,000CFUmL, and Negative as less than 10,000CFUmL, as recommended by the LifeSign manufacturer for the Uricult Paddle System.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the surveyor's review of API PT records for the calendar years 2020, 2021 and confirmed in an interview with the laboratory director, at the time of this survey, the laboratory director failed to ensure that hematology PT specimens were tested in the same manner as patient specimens. Refer to D2007
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory's QA policy and confirmed in an interview with the laboratory director, at the time of this survey, the laboratory director failed to ensure that the laboratory's QA program was maintained for all phases of laboratory testing. Refer to: D5291
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 surveyor's review and observation for two patient Electronic Medical Record (EMR) charts for urine colony counts and an interview with the laboratory director, the laboratory director failed to ensure that the guidelines for the interpretation of urine colony counts was established. Refer to D5807