Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2190443	09/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hope Health Systems	1726 Whitehead Rd, Woodlawn, MD	

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 standard operating procedure (SOP) and interview with the laboratory director (LD), the laboratory failed to ensure that the SOP included accurate and complete instructions for performing reverse transcription polymerase chain reaction (RT-PCR) testing to detect severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Findings: 1. The laboratory performed an RT-PCR assay that detected two nucleocapsid genes (N1 and N2) of the SARS-CoV-2 virus and the human RNAse P (RP) gene. 2. The assay used two positive controls: 1) one that included both the viral N1 and N2 gene targets (CoV_N) and 2) one that included

	the human RP target. The SOP stated to "Pipette 4 L of each CoV_N and RP control to the sample 96 well plate using a sample map in Table 5." The sample map was Table 8 and the SOP didn't specify that both controls were to be added to the same well. 3. The "B. Batch acceptance criteria" section of the SOP included the criteria for evaluating each positive and negative assay control. All controls had a cycle threshold (Ct) cutoff value of 35, so positive controls needed to show amplification with a Ct value less than or equal to 35 and negative controls needed to either show no amplification or amplification above Ct 35. 4. The "C. Patient Result Interpretation Criteria" section of the SOP stated that "If the Run/Batch has acceptable performance for negative and positive control, the individual patient result is interpreted and reported as per Table 6." The results interpretation was in Table 9 and didn't specify what the cutoff Ct values were for patient specimens. At 11:00 AM on 09/07/2023, the LD confirmed that patient specimens were evaluated with the same Ct cutoff values as the controls and that patients with Ct values greater than 35 were considered negative for that target. 5. Table 9 stated that a patient is only reported positive if both the N targets (N1 and N2) amplified and that if only one of the two N targets amplified then the action was to "Repeat PCR step." There were no instructions for what the test result would be or what actions to take if the repeated specimen still only had one amplified N target. 6. The assay program went up to 40 cycles and the instrument reported any result that had a Ct value between 35 and 40 cycles as having a Ct (defined as "Cp" in the instrument) value of "35.00" with a flag ">." The flag indicated "Late Cp call (last five cycles) has higher uncertainty" so that any patient or control result that was actually greater than 35 and should be interpreted as not detected was actually called equal to 35 and considered detected. The LD explained that the instrument was not able to display values above 35 and that any result with the ">" flag was reviewed by the testing personnel (TP) to ensure that the results displayed an appropriate amplification curve. The results were interpreted as detected if the amplification curve was considered acceptable. The practice of reviewing and accepting the amplification curves was not described in the SOP and the practice of interpreting a result with a Ct value greater than 35 as positive does not match the batch acceptance and patient result interpretation criteria. 7. During the survey on 09 /07/2023 at 12:15 PM, the LD confirmed that the SOP referenced incorrect Table numbers, did not specify that both positive controls should be located in the same well, did not include the acceptable Ct cutoff values for patient result interpretation, did not include instructions for what actions to take if repeated patient results still only amplified a single N target, and did not include instruction for how a result called "35.00" by the instrument with a ">" flag should be evaluated and interpreted by the TP.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the procedure manuals and interview with the testing person (TP)

	and laboratory director (LD), the LD failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: During the exit interview on 09/07/2023 at 12:10 PM, the TP and LD confirmed that the laboratory's approved procedure manual did not specify in writing the duties and responsibilities of the clinical consultant, and technical supervisor.