Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2190443	11/08/2021
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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of instrument printouts and email communication with the laboratory director (LD), the laboratory failed to ensure that accession numbers used to identify patients were correctly transcribed into the instrument to correctly identify severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) reverse transcription polymerase chain reaction (RT-PCR) test results for each patient in four of 32 batches reviewed. Findings: 1. The laboratory's SARS-CoV-2 RT-PCR assay detected two regions from the viral nucleocapsid (N) gene (N1 and N2) and the human RNase P gene (RP). 2. Instrument printouts for Batch 20 through Batch 44 were reviewed. 3. Results for target RP in Batch 23 showed that well D12 was labeled as "Pos N1." The positive control for target N1 was not analyzed by the laboratory for RP amplification and results for the other two gene targets showed accession number 10354 in this position. 4. Results for target RP in Batch 23 showed that well G11 was labeled with "140350." The results for the other two gene targets showed accession number 10350 in this position. 5. Results for target N1 in Batch 25 showed well A4 and well A5 both labeled with "10359". The results for the other two gene targets showed accession number 10358 followed by 10359 in these positions. 6. Results for target N1 in Batch 26 showed that well E2 was labeled with "103856." The results for the other two gene targets showed accession number 10386 in this position. 7. Results for target N2 in Batch 39 showed that well B8 was labeled with "10587" and well F4 was labeled with "1058/7." The results for the other two gene targets showed accession numbers 10580 and 10587, respectively, in these positions. 8. In an email attachment received on 11

	/08/2021 at 10:35 AM, the LD confirmed that patient specimen accession numbers were mislabeled in the RT-PCR instrument.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the procedure manual, instrument printouts, and quality control (QC) records, and email communication with the laboratory director (LD), the laboratory failed to document corrective actions and evaluate affected patients when controls did not meet the test system's criteria for acceptability for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) reverse transcription polymerase chain reaction (RT-PCR) testing. Findings: 1. The laboratory's SARS-CoV-2 RT-PCR assay detected two regions from the viral nucleocapsid (N) gene (N1 and N2) and the human RNase P gene (RP) which is found in clinical specimens and used as an internal control. 2. Section "D. Corrective action if control fails" of the updated SARS-CoV-2 RT-PCR testing procedure stated "1. If Negative control (NEC [negative extraction control] or NTC [negative template control]) fails, it indicates that there is a cross contamination in the workup procedure. The PCR cabinet needs to be decontaminated before making a new plate", "2. If Positive control fails, carefully examine the root cause of the failure. Contact LC 480 II service to check if the issues are coming from the machine, re-extract samples with proper care and new lot of control material", and "3. In case of control failure, document the incident on the Form-4 of SOP-GEN-2." 3. Section "7. Testing System (RT-PCR)" of the laboratory QC plan (SOP-GEN-2) stated that one of the quality indicators was "Daily controls" which were to be reviewed daily and recorded on a table. 4. Section "9. Quality Assurance" of the laboratory QC plan stated that the "laboratory general supervisor (GS) is responsible for keeping records of each quality indicator. Lab Director will review the records periodically, and guide the lab for appropriate action and quality assurance." 5. The daily QC results were recorded on a table titled "SARS-COV-2 RT PCR Control Chart" (QC Chart), which captured the date of testing, the batch number, results for all positive and negative controls, whether the QC was "Acceptable", and any additional comments. 6. The instrument printouts for all batches tested from 09/15 /2021 until 10/14/2021 were reviewed, which included Batch 20 through Batch 44. 7. Instrument printout review determined that for five of the 32 reviewed batches, Batches 21, 25 Rerun, 32, 32 Rerun, and 33, QC did not meet acceptance criteria and patient results were reported. Cross refer to D5481 I. 8. It was recorded in the QC Chart that the QC from Batch 21 was acceptable. Instrument printouts showed that the NEC failed for target N2. There was no documentation that the corrective actions defined in the procedure were performed. 9. The QC Chart did not include QC results from Batch 25 Rerun. Instrument printouts showed that the NTC failed for target RP. There was no documentation that the corrective actions defined in the procedure were performed. 10. It was recorded that the positive controls from Batches 32, 32 Rerun and 33 were not acceptable with the comment "Rerun" entered for each Batch. For

	Batch 32, only three samples that did not amplify targets N1, N2, and RP were repeated on Batch 32 Rerun, the remaining samples were not re-extracted and re-tested. The three samples tested on Batch 32 Rerun and all samples from Batch 33 were not re-extracted and re-tested as defined in the procedure. There was no documentation of an investigation into the positive control failures as defined in the procedure. 11. The QC Chart did not include documentation of who recorded the QC results or if and when the LD reviewed the QC results or was consulted when QC results failed. 12. The laboratory did not provide documentation that the failed QC results were recorded on Form-4 of SOP-GEN-2 as stated in the testing procedure. 13. There was no documentation of corrective actions taken for patient results that were affected by the failed QC results. 14. There was no documentation of when the internal QC (target RP) failed to amplify and the corrective actions taken for the samples when the internal QC failed and for the patient results that were reported as "Not Detected" instead of "Invalid." Cross refer to D5481 II. 15. In an email attachment received on 11/08/2021 at 10:35 AM, the LD confirmed that "When QCs failed either both or 1 out of 2 duplicates, there should be an investigation of the reason for" QC failure and "Patient results should not be released when the QCs failed either both or 1 out of 2 duplicates."
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the allegation of compliance (AOC), the procedure manual, quality control (QC) records and email communication with the laboratory director (LD), the laboratory failed to monitor, assess, and correct problems identified in the analytic system for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) reverse transcription polymerase chain reaction (RT-PCR) testing. Findings: 1. The laboratory was cited for reporting patient results when QC failed to meet the laboratory's criteria for acceptability during the initial survey completed on 08/11 /2021. As part of the laboratory's AOC, it was stated that going forward, QC failures would be reviewed by both the general supervisor and the LD and the testing procedure was updated to define how and where to report failed QC and the corrective actions to take if a QC failure occurred. 2. It was determined on the revisit survey that the laboratory reported patient results when QC failed to meet the criteria for acceptability and no corrective actions were taken for the failed QC and the patient samples affected by the failed QC. Cross refer to D5481 I & II and D5783. 3. There was no documentation that the LD reviewed the QC results as stated in the AOC. 4. In an email communication received on 10/18/2021 as part of the revisit survey, the LD submitted an Excel spreadsheet detailing notes from a review of all batches tested since the completion of the initial survey. There was no documentation that a review of all batches tested was being performed on a regular basis at the time the testing was performed. 5. The laboratory did not have a QA policy or procedure in place to review and monitor the batches that were tested between the initial survey completed on 08/11 /2021 and the revisit survey started on 10/13/2021. 6. There was no documentation showing that the laboratory was monitoring the QC results as defined in the AOC and updated procedures. 7. In an email communication received on 11/08/2021 at 10:35

	AM, the LD confirmed that the laboratory released patient results when QC failed and no corrective actions were documented.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the procedure manual, instrument printouts, and quality control (QC) records, the laboratory director failed to ensure that QC failures were documented and investigated and corrective actions were taken for the failed QC and affected patient results (D6093), failed to ensure that there was a quality assessment program that monitored, assessed and corrected issues with the severe acute respiratory syndrome coronavirus 2 reverse transcription polymerase chain reaction testing (D6094), and failed to ensure patient test results were only reported when positive and negative controls met acceptance criteria and accurate patient results were reported when the sample internal controls did not meet acceptance criteria (D6097).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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: The laboratory director failed to ensure that quality control (QC) failures were documented and investigated and corrective actions were taken for the failed QC and affected patient results. Cross refer to D5481 I & II and D5783.
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: The laboratory director failed to ensure that there was a quality assessment program that monitored, assessed and corrected issues with the severe acute respiratory syndrome coronavirus 2 reverse transcription polymerase chain reaction testing. Cross refer to D5783 and D5791.