Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2232685	02/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Empire City Laboratories, Inc	2180 Sw 71th Terrace Drive, Davie, FL	

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 onsite complaint visit, #2021017256, conducted on 02/01/2022 to 02/11/2022 at Empire City Laboratories. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. The following Condition was cited: -D3000 - Facility Administration.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) 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 lack of Covid 19 reporting records, laboratory testing records review and interview with Laboratory Director (LD), the laboratory failed to report 90,508 tests results to Florida Department of Health (FDOH) from 09/21/2021 to 02/02/2022. The laboratory failed to report 90,547 out of 90,547 tests to detect SARS CoV-2 virus using Polymerase chain reaction (PCR) test performed from 09/20/2021 to 02/02/2022 and 61 out of 61 test SARS-COV-2 nucleic acid test results to Florida Department of Health (FDOH) 09/20/2021 to 02/02/2021. Findings include: -Review of laboratory testing records from 09/20/2022 to Present, revealed that the laboratory performed the following tests: a) 90256 Roche cobas SARS- CoV PCR tests b) 291 Cepheid Xpert Xpress CoV-2/Flu/RSV plus PCR tests. c) 61 Mesa Biotech Inc Accula SARS-CoV-2 Nucleic Acid detection tests - The laboratory had no records of reporting the SARS

	CoV 2 tests results to the Florida Department of Health (FDOH) from 09/20/2021 to 02/02/2022. During an interview on 02/02/2022 at 6:30 PM, the LD confirmed the laboratory was not reporting results to FDOH for SARS CoV-2 test results from 09/20 /2021 to 02/02/2022 and the testing volume for this period was as listed above.
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to keep COVID-19 test requisitions for 7 out of 7 patients from 9/20/2021 -1/19/2022 for 2 years. Finding Include: Review of COVID-19 patient results from 9/20/2021 -1/19/2022 revealed the following: 1. Patient 1 was missing a requisition tested for COVID-19 test performed 9 /20/2021. 2. Patient 2 was missing a requisition tested for COVID-19 test performed 9 /21/2021. 3. Patient 3 was missing a requisition tested for COVID-19 test performed 9 /20/2021. 4. Patient 4 was missing a requisition tested for COVID-19 test performed 12/15/2021. 5. Patient 5 was missing a requisition tested for COVID-19 test performed 1/04/2022. 6. Patient 6 was missing a requisition tested for COVID-19 test performed 1/04/2022. 7. Patient 7 was missing a requisition tested for COVID-19 test performed 1/19/2022. During an interview on 2/01/2022 at 12pm, the Laboratory Director confirmed COVID-19 test requisitions were missing for 7 out of 7 patients from 9/20/2021 -1/19/2022.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to validate their laboratory information management system (LIMS) before use to ensure the specimen collection times and dates were transcribed on to final reports from the requisition since 9/20/2021. (see 5309)
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

	This STANDARD is not met as evidenced by: Based on observation, record reviewed, and interview, the laboratory failed to validate their laboratory information management system (LIMS) before use to ensure the specimen collection times and dates were transcribed on to final reports from the requisition since 9/20/2021. Finding Include: Review of LIMS records revealed CrelioHealth software was used as LIMS in the laboratory. There was a certificate of validation for the CrelioHealth without documentation the system was working for transcribing specimen collection date and times for requisitions. During an observation on 2/03/2022 at 5:03 PM of Digital COVID-19 requisitions on CrelioHealth software revealed that requisitions printed from the system would display a specimen collection date and time for the current date and time. Review of COVID-19 patient records revealed the following: 1. Patient 2293 was tested for COVID-19 on 12/16/2021. Patient 2293 COVID-19 requisition specimen collection time was 02/03/2022 at 4:52 PM. Patient 2293 final COVID-19 report revealed a received date and time for 12/16/2021 at 1:44 PM and specimen collection time and date for 12/16/2021 at 1:44 PM. 2. Patient 6279 was tested for COVID-19 on 12/16 /2021. Patient 6279 COVID-19 requisition specimen collection time was 02/03/2022 at 4:52 PM. Patient 6279 final COVID-19 report revealed a received date and time for 12/16/2021 at 12:13 AM and specimen collection time and date for 12/16/2021 at 12: 13 AM. 3. Patient 8127 was tested for COVID-19 on 12/16/2021. Patient 8127 COVID-19 requisition specimen collection time was 02/03/2022 at 5:01 PM. Patient 8127 final COVID-19 report revealed a received date and time for 12/16/2021 at 8:02 PM and specimen collection time and date for 12/16/2021 at 8:02 PM. During an interview on 2/4/2022 at 5:00 PM with the laboratory director, he revealed that 90,256 patients were tested for COVID-19 from 9/20/201 to present and confirmed the CrelioHealth software was not transcribing specimen collection times and dates.
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 record review and interview with Laboratory Director (LD), the laboratory's procedure manual failed to include the procedure for reporting SARS CoV-2 tests results to Florida Department of Health (FDOH) from 07/01/2021 to present. Findings

	include: Review of the Policy # IT.109 Electronic Clinical Lab Reporting System (ECLRS) signed by the LD on 07/01/2021, the policy failed to have the procedure for reporting SARS CoV-2 tests results to the FDOH. During an interview on 02/03/22 at 6:30 PM, the LD confirmed that the policy of reference failed to include the procedure for reporting SARS CoV-2 test results to FDOH.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to maintain instrument COVID-19 test results and controls information from their 2 Roche Cobas 680 instruments from 9/20/2021 to 2/1/2022. Finding include: During an observation on 2/03/2022 at 3:00 PM revealed 2 Roche Cobas 680 labeled optimums and bumblebee in use for COVID-19 PCR. Inspection of both instruments revealed instrument COVID-19 testing data along with controls were no longer store on the instruments from 9/20/2021 to 2/1/2022. Review of Roche Cobas 680 instrument manual stated Archive files are for long term storage and are in a zip format. Purge log files audit trail entries, messages, trace files, test results, configuration and settings that have been archived. Purge only the results that have been archived. During an interview on 2/4/2022 at 5:02 PM with the laboratory director, he revealed that 90,256 patients were tested for COVID-19 from 9/20/201 to present and confirmed COVID-19 test results were purged from 2 Roche Cobas 680 starting on 9/20/2021 to 2/1 /2022.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to validate their laboratory information management system before use to ensure it was properly exporting the correct COVID-19 tests in the final reports. (see 5801)
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to

	network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to validate their laboratory information management system (LIMS) before use to ensure it was properly exporting the correct COVID-19 tests in the final reports. Findings Included: Review of LIMS records revealed CrelioHealth software was used as LIMS in the laboratory. There was a certificate of validation for the CreiloHealth without documentation the system was working for exporting final reports. During an observation on 2/03/2022 at 5:03 PM of Digital COVID-19 Final reports on CrelioHealth software revealed that final Covid-19 patient reports with the wrong testing information. Review of Covid-19 patient records revealed the following: 1. Patient 1 was tested with Xpert Xpress SARS-COV-2 on 12/15/2021. Patient 1 COVID-19 final report states it was tested with Cobas 6800 SARS-COV-2. 2.Patient 2 was tested with Xpert SARS-COV-2 Flu RSV on 1/3/2022. Patient 2 COVID-19 final report states it was tested with Cobas 6800 SARS-COV-2. 3.Patient 3 was tested with Xpert SARS-COV-2 Flu RSV on 1/3/2022. Patient 3 COVID-19 final report states it was tested with Cobas 6800 SARS-COV-2. 4.Patient 4 was tested with Xpert SARS-COV-2 Flu RSV on 1/4/2022. Patient 4 COVID-19 final report states it was tested with Cobas 6800 SARS-COV-2. 5.Patient 5 was tested with Xpert Xpress SARS-COV-2 on 12/16/2021. Patient 5 COVID-19 final report states it was tested with Cobas 6800 SARS-COV-2. 6.Patient 6 was tested with Xpert Xpress SARS-COV-2 on 12/16/2021. Patient 6 COVID-19 final report states it was tested with Cobas 6800 SARS-COV-2. During an interview on 2/4/2022 at 5:04 PM with the laboratory director, he revealed that 90,256 patients were tested for COVID-19 from 9 /20/201 to present and confirmed the CreiloHealth was not releasing the correct test for COVID-19 test performed on patients.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to correct wrong COVID tests for final COVID-19 reports. The laboratory failed to correct two final COVID-19 reports using the same patient identifiers for two different patient's tests which could not identify which patient was tested and which one was not. Findings Include: Review of Xpert Xpress Covid-19 patient records revealed the following: 1. Patient 1 was tested with Xpert Xpress SARS-COV-2 on 12/15/2021. Patient 1 COVID-19 final report states it was tested with Cobas 6800 SARS-COV-2. 2. Patient 2 was tested with Xpert SARS-COV-2 Flu RSV on 1/3/2022. Patient 2 COVID-19 final report states it was tested with Cobas 6800 SARS-COV-2. 3. Patient 3 was tested with Xpert SARS-COV-2 Flu RSV on 1/3/2022. Patient 3 COVID-19 final report states it was tested

	with Cobas 6800 SARS-COV-2. 4. Patient 4 was tested with Xpert SARS-COV-2 Flu RSV on 1/4/2022. Patient 4 COVID-19 final report states it was tested with Cobas 6800 SARS-COV-2. 5. Patient 5 was tested with Xpert Xpress SARS-COV-2 on 12/16 /2021. Patient 5 COVID-19 final report states it was tested with Cobas 6800 SARS-COV-2. 6. Patient 6 was tested with Xpert Xpress SARS-COV-2 on 12/16/2021. Patient 6 COVID-19 final report states it was tested with Cobas 6800 SARS-COV-2. The reports were not corrected for 6 out 6 COVID-19 patient reports with wrong test information. Review of Bumblebee Cobas 6800 instrument printout revealed sample ID 2109000009 was tested on 9/20/2021 for Covid-19 test result was invalid .sample ID 2109000009 was tested again on 9/21/2021 for COVID-19 test result was negative. Review of Covid -19 Cobas 6800 SARS COV-2 final reports revealed the following: 1. Patient 198836 was assigned a sample ID 2109000009. The final COVID-19 report revealed a received date and time for 9/20/2021 at 4:07 PM and Reporting time and date for 12/21/2021 at 3:07 PM. 2. Patient 199015 was assigned a sample ID 2109000009. The final COVID-19 report revealed a received date and time for 9/21 /2021 at 12:54 PM and Reporting time and date for 9/21/2021 at 3:51 PM. Patient 198836 and Patient 199015 final reports were not corrected. During an interview on 2 /4/2022 at 5:06 PM with the laboratory director, he revealed that 90,256 patients were tested for COVID-19 from 9/20/201 to present and confirmed COVID-19 reports were not correct for incorrect information.
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 record review and interview, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings: Cross Reference D6094: Based on record review and interview, the Laboratory Director failed to recognize their quality assessment (QA) plan failed to identify failures in the quality as they occurred from 09/20/2021 to 02/02/2022.
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 record review and interview, the Laboratory Director failed to recognize their quality assessment (QA) plan failed to identify failures in the quality as they occurred from 09/20/2021 to 02/02/2022. Findings Included: 1. Review of the "Deleted Accessions" binder showed there were seven documented errors in October and sixteen documented errors in November. The "Deleted Accessions" Binder included errors due to duplicate accession, mislabeled specimen, name error, deleted by mistake, and error during insurance update. Review of the laboratory's QA Matrix chart showed there were no "Data Entry Error/Person" for the months of October and

	November. On 02/03/2022 at 5:07 PM, the Accessioning Supervisor stated she did not report the errors for the QA Matrix Report. 2. Review of an incident report "Fact File" signed by the Laboratory Accessioning Staff on 12/10/21, indicated that an accessioning error resulted in a labeling error and test results being sent to the wrong patient. Review of the laboratories QA Matrix Report showed there were no "Data Entry Error/Person" for the month of December. On 02/03/2022 at 4:55 PM, the Laboratory Director stated he did not know about the labeling error. 3. Review of COVID-19 patient results from 09/20/2021 -01/19/2022 revealed the laboratory's QA plan failed to identify that test requisitions were missing for seven of seven patients. (See D 3027) 4. Review of the Laboratory Information Management System (LIMS) records, revealed the laboratory's QA plan failed to identify that the laboratory failed to validate their laboratory information management system (LIMS) before use to ensure specimen collection times and dates were transcribed on to final reports and requisition since 9/20/2021. (See D5309) 5. Review of the laboratory's quality control records and patient test results on the Roche Cobas 680 instruments, revealed the laboratory's QA plan failed to identify that the laboratory failed to maintain instrument COVID-19 test results and controls information from their 2 Roche Cobas 680 instruments from 9/20/2021 to 2/1/2021. (See D5789) 6. Review of LIMS records, revealed the laboratory's QA plan failed to identify that the laboratory failed to validate their laboratory information management system before use to ensure it was properly exporting the correct Covid-19 tests in the final reports. (See D5801) 7. Review of patient test result reports, revealed the laboratory's QA plan failed to identify that the laboratory failed to correct test method used on the final COVID-19 reports, and failed to correct two final COVID-19 reports using the same patient identifiers for two different patients test. (See D5821)