Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2289887	08/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Coastal Diagnostics, Llc	7 Sycamore Way, Unit 9 A, Branford, CT	

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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to investigate and take remedial action when unacceptable Proficiency Testing (PT) results were obtained in the specialty of Chemistry. Findings include: 1. Record review on 08/01 /2024 of the laboratory's 'Comparative Evaluation 2024 Chemistry - Core - 2nd Event' report from the American Proficiency Institute (API) revealed the following survey with an unacceptable result for Total Iron for 2 out of 5 PT samples: Event Sample ID Score 2nd Event CH-07and CH-09 Unacceptable 2. Record review on 08/01/2024 of the laboratory's 'API Proficiency Testing Performance Evaluation, Performance Review and Corrective Action' document revealed the following: a. "Re-ran CH-07 + CH-09 for Iron, Total on 6/24/24. Results satisfactory". b. Lack of documentation for a thorough investigation to and/or remedial action to prevent reoccurrence. 3. Staff interview on 08/01/2024 at 12:30 PM with Testing Personnel 1 confirmed the above findings.
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 record review and staff interview the laboratory failed to establish and follow written policies and procedures that ensure positive identification of the patient's specimen type on the final test report in the specialty of Microbiology. Findings Include: 1. Record review on 08/01/2024 of patient #1 final test results reported on 06/20/2024 revealed a specimen collection type of "Swab, Urine". 2. Record review on 08/07/2024 of patient #1 'Molecular Testing Requisition Form' received on 06/19/2024 revealed a specimen collection type of "Urine". 3. Staff interview on 08/01/2024 at 3:20 PM with Testing Personnel #1 (TP#1) confirmed the above discrepancy. TP#1 further commented that he/she does not know why the patients final test report says "Swab, Urine" and that it's been showing up on multiple reports. 4. The laboratory performs 60,000 tests annually in the specialty of microbiology.
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 record review of the 'Molecular Testing Requisition Form' and staff interview with laboratory personnel on 08/01/2024, it was determined that the Costal Diagnostics Laboratory failed to provide an accurate requisition form to identify the correct specimen type in the subspecialty of bacteriology. Cross Reference D5305 Standard: Test Request
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure the correct and validated specimen type is listed on the test requisition form in the subspecialty of bacteriology. Findings Includes: 1. Record review on 08/01/2024 of the laboratory's 'Molecular Testing Requisition Form' for the clients revealed the following: a. Acceptable specimen type in a check box form: i. Urine ii. Nasopharyngeal /Oropharyngeal Swab (NP/OP) iii. Saliva iv. Blood v. Other b. Lack of distinction between a nasopharyngeal or an oropharyngeal specimen based on the current check box format. c. Failure to include nasal specimen type as an acceptable sample type. 2. Record review on 08/01/2024 of the 'Validation Verification of the VIASURE SARS CoV-2, Flu and RSV RT-PCR Kit' revealed the following: a. 'Specimen Matrix: This validation will be completed only for clinical specimens that are collected with a nasal or nasopharyngeal swabs, shipped or transported dry, then rehydrated in nuclease free water'. b. Lack of documentation for validation of oropharyngeal swab is an acceptable specimen type. 3. Staff interview on 08/01/2024 at 2:21 PM with Technical Supervisor #1 (TS#1) and Testing Personnel # 1 confirmed the above findings. TS#1 further commented that they are unsure whether the received specimen type is nasal, nasopharyngeal or an oropharyngeal specimen based on the current established requisition form supplied to their clients. 4. The laboratory performs 60,000 tests annually in the specialty of microbiology.
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 record review and staff interview the laboratory failed to follow their established policies and procedures in the specialty of Microbiology. Findings Includes: 1. Record review on 08/01/2024 of the laboratory's 'Validation Verification of the VIASURE SARS CoV-2, Flu and RSV RT-PCR Kit' policy and procedure revealed 'Clinical Evaluation: Testing was performed on 20 clinical specimens; the samples were first tested at Coastal Diagnostics, then sent out to Tampa Bay Diagnostic Institute (CLIA ID: 10D2238542) to be verified'. 2. Record review on 08 /01/2024 of the laboratory's 'Viasure RPP Performance Verification Study' clinical correlation raw data revealed the following: a. 20 of 20 clinical samples were sent out to a reference laboratory for clinical evaluation. b. 10 of 20 clinical samples were tested positive for SARS-CoV-2, Flu A/B, RSV and the RNase P internal control with 100% correlation to the reference laboratory. c. 10 of 20 clinical samples were tested negative (Undetermined) for SARS-CoV-2, Flu A/B, RSV and the RNase P internal control 100% correlation to the reference laboratory. d. Lack of documentation of why the RNase P internal control was undetermined for the "true negative clinical samples". Note: The negative samples sent for evaluation were water samples. 3. Record review on 08/01/2024 of the 'Validation Verification Summary BioPathogenix (BPX) Antibiotic Resistance (ABR) Custom qPLEX Kit' policy and procedure revealed the following: a. "Due to the small sample size while conducting this validation, the established cutoff values will be evaluated in real time for a period of

	90 days to monitor effectiveness in reporting true positive and true negative specimen results. A quality assurance write-up will be made for the positivity and negativity rate of each Organism spanning the 90-day period. At the conclusion of the study, finalization in cutoff values will be decided". b. Lack of documentation of the final 90-day cut-off values evaluation listed in 3(a) above. 4. Staff interview on 08/01/2024 at 2:10 PM with the laboratory's technical supervisor confirmed the above findings. He /she further commented that the 10 negative clinical samples were water samples instead of a true negative patient samples, therefore invalidating the purpose of the clinical evaluation. 5. The laboratory performs 60,000 tests annually in the specialty of microbiology.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to investigate and take remedial action when unacceptable Proficiency Testing (PT) results were obtained in the subspecialty of Bacteriology. Findings include: 1. Record review on 08/01/2024 of the laboratory's 'Comparative Evaluation 2024 Microbiology' from the American Proficiency Institute (API) revealed the following analytes with an unacceptable result: a. Enterobacter cloacae, Event 1, Sample ID: UTI-04 b. Enterobacter cloacae Complex, Event 2, Sample ID: BCP-09 c. Enterococcus faecalis, Event 2, Sample ID: BCP-06 d. Morganella morganii, Event 2, Sample ID: JIP-04 e. Resistance Gene dfrA, Event 2, Sample ID: UTI-08 f. Resistance Gene ErmB, Event 2, Sample ID: UTI-07 g. Resistance Gene mefA, Event 2, Sample ID: UTI-07 h. Resistance Gene SHV, Event 2, Sample ID: UTI-08 i. Resistance Gene TetM, Event 2, Sample ID: UTI-07 2. Record review on 08/01/2024 of the laboratory's 'API Proficiency Testing Performance Evaluation, Performance Review and Corrective Action' document for the year 2024 event 1 and 2 revealed the following: a. "Repeated UTI-04 to check Enterobacter cloacae. Repeated but still not detected; samples were refrigerated for about 2 months before re-testing". b. "Retested ABR targets for UTI-07/08, and wound targets for BCP-06/09 and JIP-04. Expected targets detected for all samples". c. "Enterobacter cloacae incorrectly reported as E. cloacae complex; target not detected in repeat run". d. "E. faecalis exhibited unusual curve in original runs; not detected in subsequent repeat. Note regarding this curve added to SOP. (screenshot included w/corrective action reruns)". e. "Future detections of DfrA, DfrA1, DfrA5 will be reported to API as DfrA detected". f. Lack of documentation for a thorough investigation to and/or remedial action to prevent reoccurrence. 3. Staff interview on 08/01/2024 at 2:30 PM with Testing Personnel 1 confirmed the above findings.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

	This STANDARD is not met as evidenced by: Based on record review and staff interview the Technical Supervisor (TS) of the laboratory failed to provide technical and scientific oversight to the staff in the specialty of Microbiology. Findings include: 1. Record review on 08/01/2024 of the laboratory's "Technical Consultant/Supervisor Competency Evaluation" initial form signed by the Laboratory Director (LD) revealed the following TS responsibilities: Establishes a quality control program appropriate for the testing performed, establishes the acceptable levels of analytical performance, and ensure the levels are maintained throughout the testing process. 2. Record review on 08/01/2024 of the laboratory's "Quality Control Review Sheet" and "Specimen Quality Review Sheet" revealed the lack of documentation of the monthly review by the TS in 2024 for the following 5 months: March, April, May, June and July. For the month of March and April 2024 the sheets were signed by General Supervisor (GS). 3. Staff interview on 8 /1/2024 at 1:00 PM with the GS confirmed the findings in 2 above. 4. The laboratory performs 60,000 tests annually in the specialty of Microbiology.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on record review of the "Laboratory Personnel Report (CLIA)" CMS-209 form signed by the Laboratory Director on 07/31/2024 revealed the laboratory failed to have a qualified general supervisor (GS) for high complexity testing in the specialty of Microbiology. Refer to D6143.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have

	served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m). This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to have a qualified general supervisor (GS) for high complexity laboratory testing in the specialty of Microbiology. Findings Include: 1. Record review on 08/01/2024 of the laboratory's "Laboratory Personnel Report (CLIA)" CMS 209 form signed by the laboratory director (LD) submitted on-site revealed one GS was listed for high complexity in the specialty of Microbiology. 2. Record review on 08/01/2024 of the qualification documentation for GS listed above revealed the GS lacked 1 year of clinical laboratory training and experience in high complexity laboratory testing in the specialty of Microbiology as required by the regulations. 3. Record review on 08/01/2024 of the "Laboratory Director Verification" revealed the above GS was qualified by the Laboratory Director for the GS position on 11/28/2023. 4. Staff interview on 08/01/2024 at 10:30 AM with the GS revealed lack of 1 year of clinical training and experience to meet qualification requirements to provide general supervision in the specialty of microbiology. 5. The laboratory performs 60,000 high complexity microbiology tests annually.