Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2244388	05/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Fast Lab Corp	285 Sills Rd, Bldg 8 Ste D, Patchogue, 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
D0000	A federal surveyor from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an announced CLIA validation survey at Fast Lab Corp. on May 28, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to not be in compliance with all condition-level CLIA requirements. The following condition and standard-level deficiencies were found during CLIA exempt-state validation survey performed on May 28, 2024.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the competency assessment policy, personnel competency assessment records and an interview with the laboratory director (LD) and clinical consultant (CC), the laboratory failed to establish a competency assessment policy that included the assessment of CC, technical supervisors (TS) and General supervisors (GS) for competency from May 2022 to May 2024. Findings Include: 1. Review of the laboratory's competency assessment procedure on May 28, 2024, at 4: 00 pm revealed, the laboratory competency assessment procedure in use, did not include the assessment of CC, TS and GS for competency from May 2022 to May 2024. 2. Interview with the LD and CC confirmed the above finding on May 28, 2024 at 4:30 pm.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of

	the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of laboratory's written policy and procedures, lack of received specimen documentation, and interview with laboratory director (LD) and Clinical consultant (CC), the laboratory failed to document the temperature for received viral test media (VTM) / Saline swab specimens used for the detection of SARS CoV 19 for specimens received from 2023 to 2024. Findings Include: 1. The Specimen Handling and Transportation Standard operation procedure (SOP), 3. Protocols, e. VTM / Saline Swabs states, "Virology swabs for SARS CoV19 must be submitted in a VTM or Saline swabs. Patients must be swabbed and container must be capped properly. Samples are good for 72 hours if kept refrigerated." and h. Couriers, states, "Specimens must be transported at the temperature indicated above or in the laboratory reference manual." 2. The laboratory specimen collection for COVID 19 for Q-Tower procedure, Storage and Transportation, bullet point number two states, "store specimen at 2 - 8 degrees Celsius for up to 72 hours after collection". 3. On May 28, 2204, at 2:50 pm, the laboratory was unable to provide documented specimen received temperatures for VTM / Saline swab specimen received by the laboratory from May 2023 to May 2024. 4. Interview with the LD and CC on May 28, 2024 at 2: 29 pm, confirmed the findings above.
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 Laboratory Director (LD) educational credentials and interview with the LD and clinical consultant (CC), the LD failed to meet the qualification requirements of 493.1443 from May 10, 2023, to May 30, 2024. Findings Include: Refer to 6078.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b) (1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a

	doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on review of the Laboratory Director (LD) educational credentials and interview with the LD and clinical consultant (CC), the LD failed to meet the qualification requirements of 493.1443 from May 10, 2023 to May 30, 2024. Findings Include: 1. Review of the LD's educational qualifications on May 28, 2024 at 9:45 am revealed, the LD completed a doctor in medicine in the Dominican Republic equivalent to a doctors of Medicine degree from the united states, A New York State Department of Health certificate of qualification, and registration certificates for clinical laboratory technologist and for pathology assistant. 2. On May 28, 2024, the laboratory could not provide a state licensed physician registration certificate for the current LD. 3. The laboratory performed 1,130 SARSCoV 2 samples during the LD directorship from May 10, 2023 to May 30, 2024. 4. Interview with the LD and CC on May 28, 2024 at 4:15 pm, confirmed the findings above.