Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2228650	01/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
First Rate Lab Llc	3189 Airway Ave, Ste C, Costa Mesa, CA	

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
D2056	VIROLOGY CFR(s): 493.831(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: . Based on observation of the BioRad CFX Opus 384 Real-time PCR test system, review of laboratory and API (American Proficiency Institute) proficiency testing records for 2023, and interview with laboratory personnel, it was determined the laboratory failed to attain a score of at least 80% in testing for SARSCoV2 using PCR methodology in 2023. Findings included: 1. The laboratory developed test (LDT) for SARSCoV2 utilized the BioRad CFX Opus 384 PCR test system. 2. The laboratory chose to participate in API's SARSCoV2 Liquid Molecular proficiency testing program that provided two unknown samples for each testing event. 3. For 2023: Event 3, the laboratory reported the unacceptable result of Negative for a Low Positive sample; and thus scored 50%. 4. The reliability and quality of results reported for SARSCoV2 test by PCR could not be assured. The laboratory reported 732 results during the timeframe July - December 2023 (by email on 1/09/24). .
D2062	VIROLOGY CFR(s): 493.831(d) (1) For any unsatisfactory 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 unsatisfactory testing events, 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 review of API and laboratory proficiency testing records documenting unsatisfactory testing, the lack of records, and interview with laboratory personnel, the laboratory failed to take and document remedial action to correct the problem identified with the SARSCoV2 PCR laboratory developed test. Findings included: 1. API provided a Low Positive sample for testing and the laboratory reported the result as Negative. See D2056. 2. Laboratory personnel affirmed (1/03/24 at 5PM) that the Ct (Cycle threshold) cutoff for the laboratory developed test was the root cause for reporting the erroneous negative result; and that no remedial action had been taken to correct the problem. 3. The reliability and quality of Negative results reported for SARSCoV2 PCR could not be assured when the laboratory developed test reported false negative results. The laboratory reported 6,000 SARSCoV2 PCR results annually (CMS116, 12/26/23). Five out of 12,000 records selected at random for review are, as follows: Date reported Accession number 6/07/22 FRL01299740 9/09 /22 FRL01302801 7/08/23 FRL01313823 10/10/23 FRL01317699 1/02/24 FRL01319690 .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on observation of microscopes, review of laboratory records, the lack of records verifying testing accuracy, and interview with laboratory personnel, it was determined the laboratory failed to verify the accuracy of Urinalysis by Microscopy in 2021-2023. Findings included: 1. The laboratory performed Urinalysis including microscopic examination (CLIA Application, 12/26/23; Laboratory Testing Declaration; 1/03/24). Test records selected at random for review are, as follows: Date Accession number 7/14/23 FRL01314021 7/17/23 FRL01313898 12/16/23 FRL01319902 12/16/23 FRL01319903 2. The laboratory failed to provide for review records verifying the accuracy of clinical urine microscopy at least twice annually in 2021, 2022, and 2023. 3. Laboratory personnel affirmed (1/03/24 at 5PM) the aforementioned lack of records; and thus, the failure to verify the accuracy of Urinalysis Microscopy. 4. The reliability and quality of results reported for Urinalysis Microscopy could not be assured when accuracy hadn't been verified. In 2023, the laboratory reported 1,564 results for Urine Microscopy (per email on 1/09/24). The laboratory annually reported 24,000 Urinalysis tests by waived dipstick and moderate complexity microscopy (Laboratory Testing Declaration, 1/03/24). .
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by:

	. Based on the findings and deficiency cited at D2062, the Laboratory Director is herein cited for deficient practice in ensuring that the laboratory developed test system for SARSCoV2 provided a satisfactory limit of detection during analysis. Findings included: 1. Under the Laboratory Director's review and approval, the laboratory developed test failed to identify Low Positive samples. .
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 the findings and deficiency cited at D2062, the Laboratory Director is herein cited for deficient practice in ensuring an approved remedial action plan is established, completed, and documented when a proficiency test result is graded as unacceptable or unsatisfactory. Findings included: 1. Under the Laboratory Director's administration, the laboratory failed to establish, complete, and document an approved remedial action plan when a proficiency test result is unacceptable (incorrect).