Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0571882	04/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
County Of Riverside Doph Laboratory	4065 County Circle Dr, Ste 106, Riverside, 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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records for the second Virology event of 2023 (Q2-2023), and interviews with the laboratory technical supervisors (TSs) on April 10, 2024, the laboratory failed to test PT samples the same number of times that it routinely tests patient samples. The findings include: 1. WLSH reported for Q2-2023 a score of 80% for CDC Influenza-SARS-CoV-2 (FluSC2) assay. 2. As indicated by the corrective action report (CAR), the WSLH PT samples for FluSC2 assay for Q2-2023 were tested by two testing personnel (TP) before results were obtained from WSLH. 3. The laboratory TSs affirmed by interview on April 10, 2024, at approximately 12:30 p.m. that the PT samples are tested twice by two TP before Q2-2023 results were obtained. 4. The laboratory's testing declaration form submitted at the time of survey stated that the laboratory performs 3,927 Virology tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on the surveyors' observation during the laboratory tour and interviews with the technical supervisors (TSs), the laboratory failed to label reagents and solutions for preparation and expiration dates in various sections of the laboratory. The findings included: 1. Based on the surveyors' observation during the laboratory's tour on April 10, 2024, at approximately 1:00 p.m..; no preparation, lot number, or expiration date labels were used for 70% ethanol and de-ionized water in all laboratory sections. 2. Both TSs affirmed in an interview conducted 4/10/2024, at approximately 1:00 p.m. that the solutions mentioned in statement 1 were not labeled with the preparation date, lot number, and expiration dates. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 42,364 test samples.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyors' review of the Individualized Quality Control Plan (IQCP) document and its subsequent revisions and interviews with technical supervisors (TSs), the laboratory failed to follow-up the revised 07/13/2020 document. Findings include: 1. During the survey conducted on April 10, 2024, at approximately 1:45 p. m., the laboratory failed to provide a follow-up revision of the 7/13/2020 IQCP documentation for HIV Geenius stating "Two (2) levels of QC will be performed daily for five (5) days of testing after verification of HIV 1/2 Supplemental Assay test has been approved and signed by the Laboratory Director. If the QC performs as expected the laboratory may resume two (2) levels of QC only with each lot and shipment". 2. The TSs affirmed by interviews that quality control (QC) was performed for HIV Geenius following an incomplete IQCP program since July 13, 2020, revision. 3. No follow-up documentation of the 7/13/2020 revision was provided at the time of survey as stated in statement 1. 4. According to the laboratory's testing declaration signed by the laboratory director on 4/10/2024 submitted at the time of survey, the laboratory performed 3.927 Virology tests annually which includes HIV Geenius.
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 surveyor's observation during the laboratory tour, review of records, and interviews with the laboratory technical supervisors on April 10, 2024; the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D5417 and D5445.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's proficiency testing (PT) records, review of five (5) randomly selected patient records, and interviews with the laboratory technical supervisors on April 10, 2024; it was determined that the laboratory director failed to ensure that PT samples for Virology's CDC Influenza-SARS-CoV-2 assay for the second event of 2023 were tested as required under subpart H. of this part. See D2010.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on the evidence found on the corrective action report for the second event of 2023 (Q2-2023) proficiency testing, the Technical Supervisors are herein cited for deficient practice in establishing a complete quality control program appropriate for the HIV Geenius for testing performed and establishing the parameters for acceptable levels of analytic performance. Findings include: a. The Individualized Quality Control Plan laboratory document for the quality control program is incomplete and failed to meet all requirements. See D5445.