Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0668137	10/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ventura County Health Department Lab	2240 E Gonzales Rd Ste 160, Oxnard, 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 review of the WSLH Proficiency Testing (PT) records and interview with the laboratory director (LD) and the testing personnel (TP); it was determined that the laboratory failed to attain a score of least 80 percent of acceptable responses for Measles PCR testing. The findings included: 1. Based on review of PT records for the first event of 2021 (Q1-2021), WSLH reported an unsatisfactory score of 50% for Measles PCR testing performed on the ABI 7500 instrument as follow: Sample Result Acceptable Score MM-1 Negative Positive Fail MM-2 Negative Negative Pass MM-3 Negative Negative Pass MM-4 Negative Positive Fail MM-5 Negative Positive Pass MM-6 Negative Positive Fail 2. Based on the laboratory's testing declaration at the time of the survey on October 6, 2021 the laboratory reported approximately ten (10) tests results during the time the laboratory had unsatisfactory PT testing scores. 3. The LD and TP affirmed that the laboratory received the above unsatisfactory PT score.
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 the review of the proficiency testing (PT) records, lack of laboratory documentation, and interview with the laboratory director (LD); it was determined that the laboratory failed to provide documentation for remedial actions taken for improvement of proficiency testing performance, including appropriate additional training and technical assistance. Findings included: 1. Review of proficiency testing records revealed the lack of documentation for remedial activities for unsatisfactory PT results (example: Measles and Mumps corrective action report). 2. The LD confirmed the lack of documentation of corrective actions reports for proficiency testing unacceptable results (example: Measles and Mumps corrective action report).
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 the lack of laboratory written policies and procedures and interview with the laboratory director (LD) and testing personnel (TP); it was determined that the laboratory failed to have available and follow written policies and procedures for Measles and Mumps Virology testing performed in the laboratory. The findings included: 1. On the day of the survey October 6, 2021 at approximately 12:30 p.m. the laboratory failed to provide written policies and procedures for Measles and Mumps Polymerase Chain Reaction (PCR) performed in the laboratory. 2. For two (2) out of eight (8) randomly chosen patient test results reviewed covering period from 12/20 /2019 to 8/27/2021, for Measles and Mumps; the patients had tests ordered, analyzed, and reported for which the laboratory had no written policies and procedures available. 3. The LD and TP confirmed on 10/6/2021 at approximately 1:30 p.m. that the laboratory did not have written policies and procedures available for Measles and Mumps PCR testing.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the lack of the laboratory's verification of performance documentation for the high complexity testing for Measles and Mumps detection by the Polymerase Chain Reaction (PCR), interviews with the laboratory director (LD) and the testing personnel (TP), and two (2) randomly selected Measles and Mumps patient test

	records reviewed from 02/3/2020; the laboratory failed to demonstrate that it established performance specifications comparable to those established by the manufacturer. The Findings include: 1. The laboratory had no documentation to show that the Measles and Mumps detection by PCR performance specifications were performed prior to reporting patient test results. The laboratory must be able to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (A) Accuracy (B) Precision (C) Reportable range of test results for the test system (D) Sensitivity and (E) Specificity. 2. The laboratory was unable to provide for review additional documents using patient samples to establish the performance specifications in 1. 3. The LD affirmed at the time of the survey on 08/06 /2021 at approximately 2:00 p. m. that no documents could be retrieved to show that the Measles and Mumps detection by PCR performance specifications were performed prior to reporting patient test results when the laboratory went live testing and reporting Measles and Mumps diagnostic tests. 4. Based on the estimated annual tests volumes reported on 10/06/2021; the laboratory performed and reported approximately ten (10) Measles and Mumps PCR test. The accuracy, precision, and reliability of the reported results could not be assured.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour, lack of calibration records, and interview with the laboratory director (LD) and testing personnel (TP); it was determined that the laboratory failed to follow the thermometers' instructions on the periodic calibration of all thermometers (heating blocks, water baths, etc.) used in the laboratory. The findings included: 1. The laboratory used glass thermometers to monitor temperature on various equipment used in the laboratory. 2. The laboratory did not have available calibration documentation or calibration labels on the thermometers used in the laboratory. 3. The LD and TP affirmed on October 6, 2021 at approximately 2:00 p.m. that no calibration had been performed on the thermometers used in the laboratory. 4. According to the testing volume declaration at the time of the survey, the laboratory performed 84,224 tests annually.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on the deficiency cited (D5421), the laboratory director is herein cited for deficient practice in ensuring test system verification procedures were compliant with the regulations at 493.1253(b)(1) before the laboratory personnel was allowed to test patients' samples without confirming the manufacturer's performance specifications.
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 review the laboratory's policies & procedures, proficiency testing performance records, lack of corrective action records and documentation, and interview with the laboratory director; it was determined that the laboratory director failed to ensure that an approved corrective action plan policy exists and is followed when any proficiency testing result is found to be unsatisfactory performance. The findings include: See D2062.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory's written policies and procedures and interviews with the laboratory director (LD) and the testing personnel, it was determined that the LD failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. The laboratory had no written procedure for Measles and Mumps Polymerase Chain Reaction testing using the ABI 7500 instrument. Findings include: See D5401.