Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0643589	09/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Monterey County Public Health Lab	1270 Nativdad Rd, Salinas, 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
D2029	MYCOBACTERIOLOGY CFR(s): 493.825(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 first quarter 2019 (Q1-2019), of the College of American Pathologist (CAP) proficiency testing records, random review of five (5) patient testing records, and interview with the laboratory director (LD) and testing personnel (TP); it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent in Mycobacteriology. The findings included: 1. For Q1-2019, CAP reported an unsatisfactory proficiency testing result for Mycobacteriology with score of 71% as follow: Sample Result Reported Expected Response Grade E-01 Rapid grower referred M. cheloni Good E-02 Slow grow photoch M. kansasii Good E-03 M. avium-intracellr M. fortuitum Unacceptable E-04 MTB Complex MTB complex Good E-05 Neg for Mycobacteria Neg for Mycob Good E-06 Smear neg Smear pos Unacceptable 2. Based on the laboratory's testing declaration submitted on 09/28/2021 signed by the LD, the laboratory analyzed and reported approximately 3,584 Mycobacteriology test including acid fast smears and organism identification. 3. The LD and TP affirmed on 09/28/2021 at approximately 12:30 p.m. that the laboratory received the above unsatisfactory score.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

	This STANDARD is not met as evidenced by: Based on direct observation of the facilities layout, observation of the of the laboratory's SARS-CoV-2 RNA (COVID-19) Polymerase Chain Reaction (PCR) testing, and interviews with the laboratory director (LD) and testing personnel (TP) on September 28, 2021 on its molecular amplification procedure; it was determined that the laboratory failed to ensure that the molecular amplification procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, reagent preparation, RNA extraction, amplification, and RNA detection. The findings included: 1. The laboratory performed PCR testing for the presumptive detection of SARS-CoV-2 using the TaqPath COVID-19 Combo kit PCR and amplification method on the ABI 7500 and Parker Elmer procedure and instrumentation. 2. During the laboratory tour on 09/28/2021 at approximately 12:00 p. m. the surveyor observed that preparation of PCR master mix reagents, positive controls, RNA extraction, and addition of template were all performed in the same area without unidirectional flow. 3. The LD and TP confirmed by interview on September 28, 2021 that the laboratory's molecular PCR testing for the presumptive detection of SARS-CoV-2 RNA was not set up in unidirectional flow areas. 4. Based on laboratory records, the laboratory performed and reported approximately 51,350 SARS-CoV-2 Real Time PCR molecular diagnostic tests since started testing by PCR molecular testing in March 2020.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on the surveyor's direct observations of the laboratory's SARS-CoV-2 testing processes and interview with the laboratory director and testing personnel on September 28, 2021, the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory were appropriate for the testing performed. Findings include: See D3005.