Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0643966	09/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
California Institute For Medical Research	2260 Clove Dr, San Jose, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records for quality control and an interview with the laboratory director (LD) on 9/21/2021 between 2 p.m. and 3:30 p. m., it was determined that there was not documentation to indicate the maintenance of the microscope in 2019 and 2020. Findings include: 1. On 9/21/21, an inspection was conducted between the hours of 2 p.m. and 3:30 p.m. 2. The equipment maintenance records were reviewed 3. There was not documentation indicating microscope maintenance in 2019 and 2020. 4. Laboratory documentation indicated that the microscope should have vendor maintenance annually. 5. The LD agreed with the assessment.