Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0704107	04/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Premier Pathology	7630 Vineland Ave, Ste 202, Sun Valley, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, test requisition, instrument print out, final report and interview with the laboratory technical supervisor on April 24, 2024, at 12 pm, the laboratory failed to follow its procedure for sputum specimen acceptability and rejection for 1 patient out of 4 patients, reviewed. The findings include: 1. The laboratory's procedure stated that if sputum sample storage is required for the BioFire Pneumonia Panel FilmArray test, specimen can be held at 2-8 degree centigrade for up to 1 day after collection. However, the laboratory tested and reported the sample # 23111621 that was stored at 2-8 degree centigrade for more than 1 day. The test requisition showed that the sample, # 23111621, was collected on 11/15/2023. The laboratory received the sample, # 23111621, on 11/16/2023 and ran on BioFire instrument on 11/17/2023. The laboratory tested the sample about 2 days after the collection which exceeded the storage limit. The laboratory should have rejected the sample since it had exceeded the storage time limit and should not have been tested and reported the results. The test results showed that almost all the analytes tested in the panel were negative which could have been due to the compromised sample integrity. Therefore, the accuracy of the laboratory test results cannot be assured and may have potential to harm patients. 2. The laboratory technical supervisor on April 24, 2024, at 12 pm, affirmed that the sample, # 23111621, was stored longer time than the procedure instructed before

	testing. 3. The laboratory's testing declaration form signed by the laboratory director on 4/24/2024, stated that the laboratory performed approximately 80,304 molecular tests on BioFire instrument, annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's test report and interview with the laboratory technical supervisor on April 24, 2024, at 12 pm, the laboratory failed to indicate the test report date on its report. The findings include: 1. The laboratory's BioFire Pneumonia Panel FilmArray test report did not have the test report date. It contained draw and received dates, only. The test report date should be the date when the result was generated or any later date. This will ensure the sequence of testing orders and quality of the test. 2. The laboratory technical supervisor on April 24, 2024, at 12 pm, affirmed that the laboratory's test report lacked the report date. 3. The laboratory's testing declaration form signed by the laboratory director on 4/24/2024, stated that the laboratory performed approximately 80,304 molecular tests on BioFire instrument, annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, test requisition, instrument print out, final test report and interview with the laboratory technical supervisor on April 24, 2024, at 12 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harmed patients. The findings include: See D5311, D5805 and D6087.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, test requisition, instrument print out, final report and interview with the laboratory technical supervisor on April 24, 2024, at 12 pm, the laboratory director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results. The findings include: The laboratory personnel used a compromised sample to test and reported the test results, and potentially harmed patients. See D5311.