Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0704107	07/30/2019
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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on reviews of the third quarter (Q3-2018), first quarter (Q1-2019) of the American Association of Bioanalysts (AAB) proficiency testing records, and interview with the technical consultant, it was determined that; the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. The findings included: a. AAB reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year: BUN 40% Q3-2018 Sodium 20% Q1-2019 b. For eight (8) out of nine (9) random patient test results reviewed covering period from 7/12 /2019 to 7/29/2019, eight (8) patients had Comprehensive Metabolic Panel ordered and analyzed by the laboratory during approximately the time that proficiency testing had failed which results could not be assured. c. The technical consultant and laboratory director confirmed (7/30/2019, 11:20), that the laboratory received the above unsatisfactory proficiency testing scores.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by:

	Based on reviews of test requisitions, final test reports, and interview with the technical consultant and laboratory director, it was determined that; the laboratory failed to transcribe or enter test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. The findings included: a. For one (1) out of nine (9) random patient test results reviewed covering period from 7/12/2019 to 7/29/2019, one (1) patient had a result for Basic Metabolic Panel without an order request from an authorized person. b. The technical consultant and laboratory director confirmed (7 /30/2019, 11:20) that the laboratory failed to follow test request as ordered.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on reviews of test requisitions, final test reports, and interview with the technical consultant and laboratory director, it was determined that; the laboratory failed to transcribe or enter test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. See D 5309.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of two (2) out of nine (9) random patient test results, instrument's printout, and an interview with the technical consult and , it was determined that; the laboratory failed to ensure that the results were accurately entered onto the patient's report (final test report) . The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. The findings included: a. Review of the laboratory's test records (testing requisition, instrument's print out, and final test reports); for patient number 1 test ordered on 7/18/2019 and patient number 2 test ordered on 7/23/2019, the Sodium test results from the instrument's print outs were different from the test results on the final reports. b. The technical consultant and laboratory director confirmed (7/30/2019, 11:20) that the laboratory failed to adequately entered manual or electronic system(s) to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry

	(whether interfaced or entered manually) to final report destination, in a timely manner.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on interview with the technical consultant and laboratory director, review of patients reports, and instrument's print out, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems. See D 5801