Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0547251	09/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Prostate Oncology Specialist, Inc	4650 Admiralty Way, Ste 111, Marina Del Rey, 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 review of the first quarter (Q1-2016), third quarter (Q3-2016), first quarter (Q1-2017) of the American Proficiency Institute (API) proficiency testing records, laboratory's proficiency testing comparative results records, random patient sampling test results and interview (9/10/2018, 1300) with the testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Bilirubin (Bili), Total, Cholesterol (Chol), Total, and Sodium (Na) analytes.The findings included: a. API reported the following unsatisfactory scores for the following analytes. Analyte: Score: Event/Year: Bili, Total 60% Q1 /2016 Chol, Total 40% Q3/2016 Na 40% Q1/2018 b. For twelve (12) out of twelve (12) random patient test results reviewed covering period from 7/11/2016 to 8/14 /2018, the laboratory analyzed and reported patients test results during the time the laboratory received unsatisfactory proficiency testing results which cannot be assured. Based on the laboratory's testing declaration submitted for 2016-2018, the laboratory analyzed and reported 125,000 Routine Chemistry tests which included the above failed analytes. c. The testing personnel affirmed (9/10/2018, 1300) that the laboratory received the above unsatisfactory proficiency testing scores.
D2121	HEMATOLOGY CFR(s): 493.851(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 review of the first quarter (Q1-2018), of the American Proficiency Institute (API) proficiency testing records, laboratory's proficiency testing comparative results records, random patient sampling test results and interview (9/10/2018, 1300) with the testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for White Blood Cell (WBC) differential, Eosinophils, and Neutrophils a. API reported the following unsatisfactory scores for the following analytes. Analyte: Score: Event/Year: WBC Diff 52% Q1/2018 Eosinophils 0% Q1/2018 Neutrophils 0% Q1/2018 b. For twelve (12) out of twelve (12) random patient test results reviewed covering period from 7/11/2016 to 8/14 /2018, the laboratory analyzed and reported patients test results during the time the laboratory received unsatisfactory proficiency testing results which cannot be assured. Based on the laboratory's testing declaration submitted for 2016-2018, the laboratory analyzed and reported 45,000 Hematology tests which included the failed proficiency testing analytes. c. The testing personnel affirmed (9/10/2018, 1300) that the laboratory received the above unsatisfactory proficiency testing scores.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the first quarters (Q1-2016), (Q1-2017)of the American Proficiency Institute (API) proficiency testing records, laboratory's proficiency testing comparative results records, and interview (9/10/2018, 1300) with the testing personnel, it was determined that the laboratory at least twice annually, the laboratory must verify the accuracy of: Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH) and Bilirubin (Bili), Direct The findings included: a. API reported the following unsatisfactory scores for the following analytes. Analyte: Score: Event /Year: FSH 50% Q1/2016 LH 0% Q1/2016 Bili, Direct 40% Q1/2017 b. For one (1) out of twelve (12) random patient test results reviewed covering period from 7/11 /2016 to 8/14/2018, the laboratory analyzed and reported patients test results during the time the laboratory received unsatisfactory proficiency testing results which cannot be assured. Based on the laboratory's testing declaration submitted for 2016-2018, the laboratory analyzed and reported 1,000 Endocrinology tests, which included the FSH and LH tests, and 125,000 Routine Chemisrty test which insluded the Bili, Direct test. c. The testing personnel affirmed (9/10/2018, 1300) that the laboratory received the above unsatisfactory proficiency testing scores.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's refrigerator temperature logs, and interview with the testing personnel, it was determined that the laboratory failed to document corrective action whenever the temperature of the refrigerator are out of required ranges, where quality contontol (QC) materials and other reagents for testing are stored. The findings included. a. The laboratory uses: Sysmex XN 330 for Complete Blood Count (CBC) analyses, Siemens Dimension Xpand for Routine Chemistry tests and Seimens Immulite 2000 Systems for Endocrinology tests. b. Based on the above manufacture's insert instructions, reagents and quality control (QC) materials are stored at 2-8 degrees Celsius for its stability. c. Based on observation and review of the refrigerator number #2 temperature log, which stores reagents and QC materials, the following temperatures were recorded by the laboratory personnel, which cannot be accounted for since there were no initials documented. Date: Ref. Range (2-8 degrees Celsius, recommended by the manufacturer.) Recorded Temp.: 1/29/18 9 1/30 /18 9 3/21/18 12 3/22/18 10 3/23/18 9 3/26/18 12 3/27/18 13 7/12/18 0 7/30/18 1 8/1 /18 10 d. The testing personnel affirmed (9/10/2018, 1300) that the laboratory has no documentation to show of any corrective action for the temperatures recorded that were out of ranges. And that the individual monitoring the refrigerator temperature did not document their initial for accountability. e. Based on the laboratory ' s annual test volume submitted for 2016-2018, the laboratory analyzed and reported 171,000 Routine Chemistry, Endocrinology and Hematology tests that could have been affected by the out of ranges refrigerator temperatures.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's refrigerator temperature logs, and interview (9/10 /2018, 1300) with the testing personnel, it was determined that the laboratory failed to document corrective action whenever the temperature of the refrigerator are out of required ranges, where quality contontol (QC) materials and other reagents for testing are stored. See D 5413.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review: of the API proficiency testing records, refrigerator temperature log (2018), and the lack of corrective action taken by the laboratory for out of range temperatures, it was determined that the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D 2087, D 2121, D 5217, D 5413, and D 5781.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on request, review and the lack of documentation for competency assessments, and interview (9/10/2018, 1300) with testing personnel, for two (2) out of two (2) testing personnel (TP) performing moderate complexity testing, it was determined that the laboratory technical consultant/laboratory director failed to perform and document the performance of individuals responsible for moderate complexity testing. The findings included: a. There was no documentation to show that the testing personnel were evaluated during the first six months and annually thereafter. The evaluations must include but are not limited to the following: Direct observations of the testing performed (including sample handling, processing and testing) Monitoring the recording and reporting of results Direct observation of instrument maintenance Review of intermediate worksheets, quality control records. Assessment of testing previously analyzed specimens (external QC and proficiently testing) Assessment of problem solving skills b. There are two (2) testing personnel (TP) listed on the CMS 209 and LAB 116 forms, TP #1, has no documentation of training (hired 7/2018) and competency, evaluation (time that he was analyzing and reporting patient tests.) TP#2, has no documentation of competency evaluations from 2016. 2017, and 2018. c. The testing personnel affirmed (9/10/2018, 1300) that no competency assessments was performed and documented by the laboratory director and or technical consultant.