Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0719950	02/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Associates In Urology	3791 Katella Ave Ste 200, Los Alamitos, 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
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 2016 API (American Proficiency Institute) proficiency testing reports, laboratory proficiency testing records, and patients test reports for PSA; and interview with laboratory personnel, the laboratory failed to verify the accuracy of testing. Findings include: a. The laboratory chose to participate in API's proficiency testing program as the means to satisfy the requirement to verify the accuracy of testing for PSA. b. For 2016: event 2, the laboratory reported 1 unacceptable result out of 2; and thus, accuracy was not verified. c. Laboratory personnel affirmed (2//18) the aforementioned results. d. The reliability and quality of results reported for PSA could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 183 results for PSA each month during the timeframe August to November 2016. Examples are as follows: Date PSA results reported ---------- 8/09/16 6 8/24/16 10 8/25/16 3 8/26/16 11 8/29 /16 8 8/30/16 9 8/31 16 12
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a

	minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation of the Tosoh AIA 360 analyzer, review of 2016 - 2018 patients test reports, the lack of laboratory documents, and interview with laboratory personnel, the laboratory failed to perform and document procedures verifying instrument calibrations at least once every 6 months. Findings include: a. The laboratory tested for PSA using the Tosoh AIA 360 test system b. The laboratory was unable to provide for review documents verifying calibrations at least once every 6 months in 2016 to 2/12/18. c. Laboratory personnel affirmed (2/12/18) that the PSA test was calibrated using only two calibrators, 0 and 49.4, and that Cal Verifier material was not scheduled or used; and thus, the laboratory failed to verify PSA calibrations at least once every 6 months. d. The reliability and quality of results reported for PSA could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 2,200 results for PSA each year. .
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, 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 survey findings and cumulative nature of deficiencies cited, the Laboratory Director is herein cited for deficient practice as the Technical Consultant providing overall technical oversight of PSA testing. Findings include: a. The test system for PSA demonstrated inaccurate results, identified through proficiency testing. See D5217. b. Calibrations for the PSA test system were not verified as required, including at least once every 6 months. See D5439.