Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1070679	07/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Valley Urology Inc	6113 N Fresno St Ste 101, Fresno, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and laboratory personnel interview on July 16, 2019, the laboratory failed to maintain documentation to indicate that the laboratory director attested to the routine integration of samples into the laboratory's patient workload using the laboratory's routine methods. The findings included: a. For the subspecialty of bacteriology, the laboratory participates annually in American Association of Bioanalysts (AAB) PT. b. Although the laboratory maintained copies of the PT attestation statements that were provided for the AAB 3rd bacteriology PT event of 2018 and 2nd bacteriology PT event of 2019, the copy of the attestation statement maintained by the laboratory was not signed by the laboratory director. c. The laboratory reported performing approximately 5,663 bacteriological patient tests annually.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's urine culture quality control (QC) testing log (January 2018) and interview with the technical supervisor on July 16, 2019, the laboratory failed to document all control procedures performed. The findings included: a. The laboratory performs urine cultures for bacterial identification and antimicrobial sensitivity on commercially prepared culture media and biochemical selective reagents utilizing commercially prepared control organisms. b. On the day of survey (7/16/19), the laboratory control logs provided, indicated the biochemicals being tested for the appropriate QC organisms, but did not include the lot numbers and expiration dates for the organisms, the reagents and the culture media. c. The laboratory did not document the lot number and expiration date of the antimicrobial (novobiocin) disk used in urine culture testing on the QC log. d. A review of nine (9) randomly sampled patient test records and urine culture worksheets from 8/29/17 to 7 /2/19 determined that 9 out of 9 urine culture QC tests did not have complete documentation. e. The technical supervisor stated by interview on 7/16/19 at 10.15 a. m. that the laboratory did not document the lot numbers and expiration dates on the QC logs. f. The laboratory reported performing 5,663 patient urine culture and microbial identification tests annually.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's histopathology grossing log and interview with the technical supervisor on 7/16/19, the laboratory failed to document all differential or special stain control slides stained with each patient slide or group of patient slides. The findings included: a. The laboratory performs urology histopathology differential staining for identification of prostatic and urogenital cancer. b. On the day of survey (7 /16/19), the laboratory's histopathology patient logs reviewed from 7/1/17 to 5/9/19 revealed that ten (10) out 10 randomly selected patient samples did not include an evaluation of the staining quality of the differential stains (H & E). c. The technical supervisor and histology technician stated by interview on 7/16/19 at 11.25 a.m. that the laboratory did not document the quality of staining for the histology slides performed. d. The laboratory reported performing 1,974 histology slide reviews annually.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

	This STANDARD is not met as evidenced by: a. The laboratory performs prostate-specific antigen (PSA) and testosterone testing on patient plasma specimens on an automated chemistry analyzer (Beckman Access 2). b. On the day of survey (7/16/19) the technical supervisor stated that the testing personnel who performs quality control testing), calibration and maintenance procedures for the automated chemistry analyzer (Beckman Access 2), is an unlicensed medical assistant. c. The laboratory failed to provide documentation of high school diploma or initial training and competency for the laboratory assistant performing moderate complexity testing on the day of survey. d. The technical supervisor confirmed by interview on 7/17/19 at approximately 1.45 p.m. that the laboratory did not maintain the documentation for the testing personnel performing moderate complexity testing on the automated chemistry analyzer. e. The laboratory reports performing approximately 7,775 PSA and testosterone patient tests annually.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on laboratory personnel competency assessment record review and interview with the technical supervisor on July 16, 2019, the laboratory director failed to ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. The findings included: a. The laboratory performs high complexity testing in bacteriology and histology, and moderate complexity testing in chemistry. The technical supervisor is testing personnel for bacteriology high complexity testing. Two (2) unlicensed personnel perform testing; one (1) for histology high complexity testing and one (1) moderate complexity testing in chemistry. b. The laboratory failed to include records documenting that the direct observation component of the six required CLIA competency assessment procedures had been performed pursuant to 42 C.F.R. 493.1451 (b)(8) when assessing testing personnel competency for 2018. c. The technical supervisor, who performs routine testing of patient specimens, did not have annual competencies assessed by the laboratory director. d. The technical supervisor affirmed by interview on 7/16/19 at 1.10 p.m. that direct observation had not been performed for the two (2) unlicensed personnel and that the laboratory director had not assessed the TS annual competencies. e. The laboratory reports performing approximately 14,498 patient tests annually.