Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D0879661	04/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Whasn-East	1934 E Sahara Ave, Las Vegas, NV	

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
D0000	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on April 24, 2018. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random audit of quality control results for the Affirm VP test system from 7/06/16 through 2/26/18 and an interview with the office administrator, the laboratory failed to perform controls for the Affirm VP test system by the use of a positive and negative control material each day of patient testing or by developing and approving a quality control specific to their tests system. Findings include: A random audit of quality control results from 7/06/16 through 2/26/18 found six of eight days in which patient testing was performed on the Affirm VP test system but the laboratory failed to perform a positive and a negative external control for Candida, Trichomonas and

	Gardnerella. This was confirmed by the office administrator at approximately 10:00 AM on April 24, 2018. The laboratory performs approximately 8,000 microbiology tests annually.
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 a review of the monthly quality assessment documentation, a review of the director approved policy and procedure manual regarding quality assessment and an interview with the office administrator, the laboratory director failed to ensure that the established quality assessment program was maintained to assure the quality of the laboratory services provided. Findings include: 1. The laboratory director failed to have a quality assessment system which monitored and ensured that quality control is performed every day of patient testing for the testing performed on the Affirm VP. 2. A random audit of quality control performed for the Affirm VP test system from 7/06 /16 through 2/26/18 found six of eight days in which quality control was not performed but patient testing was reported. This was confirmed by the office administrator at approximately 10:00 AM on April 24, 2018. The laboratory performs approximately 8,000 microbiology tests annually.