Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D1016842	10/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Whasn-City Center	517 Rose St, 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 October 8, 2019. 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.
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 a review of the American Proficiency Institute (API) proficiency testing results for testing years 2017, 2018 and 2019 in chemistry, a review of the corrective actions for test results that were found to be unacceptable and an interview with the laboratory manager, the laboratory failed to at least twice annually verify the accuracy of all non-regulated tests performed. Findings include: 1. The laboratory failed to, at least twice annually, verify the accuracy of all patient non-regulated laboratory tests performed in Chemistry. 2. For testing year 2017, the laboratory received a 100% for the API first event and a 67% for the second event of two events for the year, for the test Luteinizing Hormone. No other samples were tested to verify accuracy for this analyte. 3. For testing year 2018, the laboratory received a 100% for the API first event and a 67% for the second event of two events for the year, for the test CEA Tumor Markers. No other samples were tested to verify accuracy for this analyte. 4. For testing year 2018, the laboratory received a 100% for the API first event and a 67% for the second event of two events for the year, for the test 25-OH Vitamin D.

	No other samples were tested to verify accuracy for this analyte. This was confirmed by the laboratory manager on October 8, 2019 at approximately 1:30 PM. The laboratory performs approximately 500 patient laboratory Chemistry tests annually.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random review of patient laboratory testing from 11/14/17 through 5/17 /19, a review of the director approved policy and procedure manual and an interview with the laboratory manager, the laboratory failed to have a policy and procedure which indicates the criteria for acceptability of quality control performed before the reporting of patient laboratory tests. Findings include: 1. The laboratory failed to indicate in their policy and procedure manual, the criteria for acceptability of quality control results performed, before patient laboratory tests could be reported. 2. A random audit of patient laboratory tests from 11/14/17 through 5/17/19 revealed that one of five patient Complete Blood Count (CBC) was reported when the low level control, which is one of three Hematology quality controls, were out with no repeat low level quality control or other corrective action taken. This was confirmed by the laboratory manager on October 8, 2019 at approximately 3:00 PM. The laboratory performs approximately 200 Hematology patient laboratory tests annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of instrument comparison testing for the Affirm VP, a review of the director approved policy and procedure manual and an interview with the laboratory manager, the laboratory failed to follow the policy and procedure for the twice a year evaluation for the comparison of instruments that perform the same laboratory test. Findings include: 1. The laboratory failed to follow the director approved policy and procedure for the comparison of instruments that perform the same laboratory test with the Affirm VP. 2. The director approved policy and procedure manual states that six samples must be used in the evaluation of laboratory instruments that perform the same test for comparison. An evaluation of two Affirm VP instruments in April 2019 revealed that five samples were used in the evaluation. This was confirmed by the laboratory manager on October 8, 2019 at approximately 4: 00 PM. The laboratory performs approximately 3,500 patient Microbiology laboratory tests annually.