Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D1016842	09/19/2018
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 generated as a result of the CLIA proficiency testing desk review, conducted off-site for your laboratory on September 19, 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.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on desk review of federal database CASPER Report 155D, American Proficiency Institute (API) proficiency testing (PT) evaluation forms, and review of

	the laboratory's Checklist for Corrective Action, the laboratory did not successfully participate in a proficiency testing program. The laboratory's failure to achieve an overall proficiency testing event performance for two out of three testing events resulted in unsuccessful proficiency testing performance in chemistry with an overall score of 68% for the third testing event of 2017 and the second testing event of 2018. Findings include: 1. The laboratory failed to maintain successful participation with the API PT program shown by the unsuccessful performance for chemistry with an overall score of 68% for the third event of 2017 and the second event of 2018. 2. The laboratory had the following unsatisfactory analyte scores for the third event of 2017: Albumin, 0% Total Cholesterol, 0% Glucose, 0% Total Protein, 0%, and BUN, 40%. 3. The laboratory had the following unsatisfactory analyte scores for the second event of 2018: Albumin, 60% Total Cholesterol, 60% Glucose, 60% Total Protein, 60%, and BUN, 60%.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of federal database CASPER Report 155D, API PT evaluations forms, and the Checklist for Corrective Action, the laboratory failed to achieve satisfactory performance for the same analytes in two out of three consecutive testing events. Findings include: The laboratory had the following unsatisfactory analyte scores for the third event of 2017: Albumin, 0% Total Cholesterol, 0% Glucose, 0% Total Protein, 0%, and BUN, 40%. The laboratory had the following unsatisfactory analyte scores for the second event of 2018: Albumin, 60% Total Cholesterol, 60% Glucose, 60% Total Protein, 60%, and BUN, 60%.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on desk review of federal database CASPER Report 155D, API PT evaluation forms, and API PT Checklist for Corrective Action, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory Director was not met. The laboratory director failed to provide overall management and direction in accordance with CFR 493.1407. Findings include: The laboratory director failed to ensure that the laboratory successfully participated in a PT program approved by CMS; as described in subpart 1 of this part for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)

	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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on desk review of federal database CASPER Report 155D, API PT evaluation forms, and API Checklist for Corrective Action, the laboratory director failed to ensure that proficiency testing samples were tested as required. Findings include: The laboratory failed to achieve satisfactory performance for the following analytes in the third event of 2017 and the second event of 2018. The laboratory had the following unsatisfactory analyte scores for the third event of 2017: Albumin, 0% Total Cholesterol, 0% Glucose, 0% Total Protein, 0%, and BUN, 40%. The laboratory had the following unsatisfactory analyte scores for the second event of 2018: Albumin, 60% Total Cholesterol, 60% Glucose, 60% Total Protein, 60%, and BUN, 60%.