Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2112684	03/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wc Health	5412 Boulder Hwy, 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 on-site CLIA recertification survey conducted at your facility on March 14 and 16, 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.
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing results for the laboratory, a review of the API 2017 Order Confirmation for the 2017 proficiency testing events that the laboratory enrolled, a review of the CASPER Report 0096D which is designed to report laboratory proficiency testing scores for the laboratory and an interview with the program manager, the laboratory failed to authorize the release of proficiency testing information from the proficiency testing program to Health and Human Services (HHS) to determine compliance. Findings include: 1. There were no proficiency testing scores for any events for testing year 2017 from API that was indicated on the CASPER 0096D Proficiency Testing Scores report generated on 12/13/17 due to the laboratory not properly identifying the State Agency to receive the proficiency testing reports.. 2. The laboratory was enrolled in two different immunoassay events that were sent by API on 10/16/17, enrolled in one Chemistry 3 event sent by API on 8/28/17 and enrolled in one Hematology 3 event sent by API on 11/13/17. This was confirmed by the program manager on March 16,

	2018 at approximately 2:00 PM. The laboratory performs approximately 53,600 patient tests annually in the areas of Chemistry and Hematology.
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 a review of the API proficiency testing reports for testing years 2017 and 2018 in the testing categories of Chemistry and Hematology and an interview with the laboratory program manager, the laboratory failed to achieve satisfactory performance for Total Bilirubin testing in two consecutive events (refer to D2096).
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 a review of the API proficiency testing reports for testing years 2017 and 2018 in the testing categories of Chemistry and Hematology and an interview with the laboratory program manager, the laboratory failed to achieve satisfactory performance for Total Bilirubin testing in two consecutive events. Findings include: The laboratory failed to achieve a satisfactory score of at least 80% in the Total Bilirubin laboratory testing for the third event 2017 (60%) and the first event 2018 (40%). This was confirmed by the laboratory program manager on March 16, 2018 at approximately 2: 00 PM. The laboratory performs approximately 50,000 Chemistry tests annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it

	can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the validation documents of new laboratory tests that the laboratory began performing on patients starting 10/19/17, a review of the director approved policy and procedure manual for test method validation and an interview with the laboratory program manager, the laboratory failed to demonstrate the accuracy performance according to the established laboratory policy. Findings include: 1. The laboratory failed to meet the criteria of acceptability for accuracy of 10% of the comparable reference laboratory values for 8 of 23 non-toxicology chemistry analytes. 2. The following analytes failed to meet the director approved policy criteria for acceptability for accuracy of 10% of the value given by the reference laboratory: PSA, Free T4, TSH3, Total T3, Vitamin B12, Total Bilirubin, Glucose, and CO2. This was confirmed by the laboratory program manager on March 16, 2018 at approximately 3:00 PM. The laboratory performs approximately 50,000 chemistry patient tests annually.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random audit of patient test reports and quality control reports for Hematology and Chemistry from November 2016 through March 2018 and an interview with the laboratory program manager, the laboratory failed to perform at least two levels of quality control that would meet the director approved policy for quality control acceptability before reporting patient test results. Findings include: 1. The laboratory failed to meet the established criteria for quality control acceptability by having no controls have results outside of the 3 Standard Deviation (SD) range and /or having no more than two consecutive results outside of the +/- 2SD range on the same side of the mean. 2. A random audit of patient test reports and quality controls performed between November 2016 and March 2018 found on 11/01/17, the level one quality control for chemistry was performed and revealed that the Total Protein and ALT were outside of the 2SD limit. There was no documentation found of a level two quality control for chemistry performed on this date. 3. The laboratory failed to retrieve evidence that a second level of control was performed on 11/01/17 for 18 different chemistry tests performed on patients. 4. There were four patient tests for

	Total Protein and ALT that were reported on 11/01/17 with no acceptable chemistry quality control performed according to the director approved policy.. This was confirmed by the laboratory program manager on March 16, 2018 at approximately 3: 00 PM. The laboratory performs approximately 50,000 patient chemistry tests annually.
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 a review of API proficiency testing reports for testing years 2017 and 2018, a review of the director approved policy and procedure manual which includes instrument and methodology validation and the criteria for quality control acceptability, a review of the validation documents for Hematology and Chemistry for new instrumentation and methodologies, a random audit of patient test results and quality control results from November 2016 through March 2018 and an interview with the laboratory program manager, the laboratory director failed to verify that the procedures used are adequate to determine the accuracy of the tests performed (refer to D6013), failed to ensure that the proficiency testing samples are tested as required under subpart H of this part (refer to D6016), failed to ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided (refer to D6020), failed to establish and maintain a quality assessment system that would assure the quality of the laboratory services provided (refer to D6021) and failed to ensure that patient test results are reported only when the system is functioning properly (refer to D6025).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the validation documents of new laboratory tests that the laboratory began performing on patients starting 10/19/17, a review of the director approved policy and procedure manual for test method validation and an interview with the laboratory program manager, the laboratory director failed to ensure that the criteria of acceptability for accuracy validation was met according to the established laboratory policy. Findings include: 1. The laboratory failed to meet the criteria of acceptability for accuracy of 10% of the comparable reference laboratory values for 8 of 23 non-toxicology chemistry analytes. 2. The following analytes failed to meet the director approved policy criteria for acceptability for accuracy of 10% of the value

	given by the reference laboratory: PSA, Free T4, TSH3, Total T3, Vitamin B12, Total Bilirubin, Glucose, and CO2. This was confirmed by the laboratory program manager on March 16, 2018 at approximately 3:00 PM. The laboratory performs approximately 50,000 chemistry patient tests annually.
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 a review of the API proficiency testing reports for testing years 2017 and 2018 in the testing categories of Chemistry and Hematology and an interview with the laboratory program manager, the laboratory director failed to ensure satisfactory performance for Total Bilirubin testing in two consecutive events. Findings include: The laboratory failed to achieve a satisfactory score of at least 80% in the Total Bilirubin laboratory testing for the third event 2017 (60%) and the first event 2018 (40%). This was confirmed by the laboratory program manager on March 16, 2018 at approximately 2:00 PM. The laboratory performs approximately 50,000 Chemistry tests annually.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a random audit of patient test reports and quality control reports for Hematology and Chemistry from November 2016 through March 2018 and an interview with the laboratory program manager, the laboratory director failed to ensure at least two levels of quality control materials performed whicht would meet the director approved policy for quality control acceptability before reporting patient test results. Findings include: 1. The laboratory director failed to ensure that the established criteria for quality control acceptability was met by having no controls have results outside of the 3SD range and/or having no more than two consecutive results outside of the +/- 2SD range on the same side of the mean. 2. A random audit of patient test reports and quality controls performed between November 2016 and March 2018 found on 11/01/17, the level one quality control for chemistry was performed and revealed that the Total Protein and ALT were outside of the 2SD limit. There was no documentation found of a level two quality control for chemistry performed on this date. 3. There were four patient tests for Total Protein and ALT that

	were reported on 11/01/17. This was confirmed by the laboratory program manager on March 16, 2018 at approximately 3:00 PM. The laboratory performs approximately 50,000 patient chemistry 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 director approved policy and procedure manual for quality assessment, a review of the monthly quality assessment documents, a random audit of patient testing and quality control performed in the testing categories of Hematology and Chemistry from November 2016 to March 2018 and an interview with the laboratory program manager, the director failed to establish and maintain a system for quality assessment that would assure the quality of the laboratory services provided. Findings include: 1. The established laboratory quality assessment procedure failed to capture on 11/01/17 that there were two analytes, Total Protein and ALT, that were outside the 2 Standard Deviation (SD) range, that there was no evidence that the quality control was rerun for these analytes and that there was no evidence that a second level of control was performed. 2. The quality assessment procedure failed to capture that 18 chemistry analytes had no evidence that a level two chemistry quality control was performed on 11/01/17. 3. The quality assessment procedure did not capture that there were four patient tests for Total Protein and ALT that were reported on 11/01/17 with no acceptable quality control results for chemistry according to the director approved policy for quality control.. This was confirmed by the laboratory program manager on March 16, 2018 at approximately 3:00 PM. The laboratory performs approximately 50,000 patient chemistry tests annually.
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on a review of the instrument and methodology validation documents for Chemistry and Hematology, a random audit of patient test reports and quality control performed between November 2016 and March 2018 and an interview with the laboratory program manager, the laboratory director failed to ensure that the patient test results are reported only when the laboratory test systems are functioning properly. Findings include: 1. The laboratory failed to meet the criteria of

	acceptability for accuracy of 10% of the comparable reference laboratory values for 8 of 23 non-toxicology chemistry analytes. 2. The following analytes failed to meet the director approved policy criteria for acceptability for accuracy of 10% of the value given by the reference laboratory: PSA, Free T4, TSH3, Total T3, Vitamin B12, Total Bilirubin, Glucose, and CO2. 3. The laboratory director failed to ensure that the established criteria for quality control acceptability was met by having no controls have results outside of the 3SD range and/or having no more than two consecutive results outside of the +/- 2SD range on the same side of the mean. 4. A random audit of patient test reports and quality controls performed between November 2016 and March 2018 found on 11/01/17, the level one quality control for chemistry was performed and revealed that the Total Protein and ALT were outside of the 2SD limit. There was no documentation found of a level two quality control for chemistry performed on this date. 5. The laboratory failed to achieve a satisfactory score of at least 80% in the Total Bilirubin laboratory testing for the third event 2017 (60%) and the first event 2018 (40%). This was confirmed by the laboratory program manager on March 16, 2018 at approximately 4:00 PM. The laboratory performs approximately 50,000 Chemistry tests annually.