Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2166411	05/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Whasn-Central Laboratory	6250 N Durango Dr, 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 May 13, 2021. 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.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the director approved quality control plan for the Beckman

	Coulter AU480 chemistry analyzer, a review of quality control (QC) records for the Unsaturated Iron Binding Capacity (UIBC) for June 3, 2020, and an interview with the Laboratory Technical Consultant, the policy and procedure did not specify the corrective action steps to take when the QC results were outside the acceptable ranges established by the laboratory. Findings include: 1. The procedure entitled "Quality Control Plan AU480" did not provide specific step-by-step instructions for corrective action when the quality control values exceed the acceptable ranges established by the laboratory. 2. The Level 1 control value for the UIBC test performed on June 3, 2020 was outside the acceptable range established by the laboratory. The control value was 95.6 ug/dl, and the acceptable range established by the laboratory was 100.5-143.0 ug /dl. There was no documentation of corrective action for the unacceptable control result. 3. The Laboratory Technical Consultant stated during an interview conducted on May 13, 2021 at approximately 1:15 PM that the controls should have been rerun, and confirmed that the policy and procedure did not specify the corrective action steps needed to ensure accuracy of test results on each day of testing. The laboratory performs approximately 105,000 Microbiology tests, 24,000 Chemistry Tests, and 6000 Hematology tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of frozen Beckman Coulter Access 2 Calibrators, and ambient temperature storage of viral transport media and blood collection tubes, a review of the laboratory temperature log for February, 2021, and an interview with the Laboratory Technical Consultant, the laboratory failed to establish freezer temperature ranges in accordance with the manufacturer's instructions for the items stored frozen, and failed to monitor and record the ambient temperature for items stored in the storage room. Findings include: 1. Beckman Coulter Access 2 calibrator solutions for Vitamin D and Lutenizing Hormone (LH) were observed in the freezer of the supply room. The labels on the boxes of the calibrators stated that the acceptable storage temperature ranges for the Vitamin D and LH calibrators was between -30 degrees Celsius (C) and -20 degrees C. 2. The February, 2021 temperature log revealed that the established acceptable temperature range for the freezer was less than -20 degrees C. Further review revealed that the freezer temperature exceeded the acceptable range established by the manufacturer of the Beckman Coulter Access 2 calibrator solutions on 12 of 24 days. Further review revealed that two ambient temperatures were recorded on the temperature log. 3. Vacutainer brand blood collection tubes and viral transport media were observed in the storage room. The label on the boxes of the viral transport media stated that the acceptable storage temperature range was 2-25 degrees C. The label on the blood collection tubes stated that the acceptable storage temperature range was 4-25 degrees C. 4. The Laboratory Technical Consultant stated during an interview May 13, 2021 at approximately 3:30 PM that there was no thermometer and the ambient temperature was not documented for the supply room.

	The Technical Consultant further stated that the two room temperatures on the log referred to two separate areas of the laboratory. The Technical Consultant confirmed the findings regarding the established freezer temperature acceptable range, and the manufacturer's temperature requirements for the Beckman Coulter Access 2 calibrator solutions. The laboratory performs approximately 105,000 Microbiology tests, 24,000 Chemistry Tests, and 6000 Hematology tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of Biorad quality control solutions that were in use and stored in the refrigerator, the manufacturer's instructions for the Biorad quality control solutions, and an interview with the Laboratory Technical Consultant, the laboratory failed to ensure that the open dates, or modified expiration dates were written on the vials to prevent the use of expired quality control solutions. Findings include: 1. The Biorad Liquichek Multiqual Chemistry Controls, Levels 1, 2, and 3, Liquichek Specialty Immunoassay Control Levels 1, and 3, Liquichek Maternal Serum II Control Levels 1 and 3, Liquichek Immunoassay Plus Control Levels 1, and 3, and Liquichek Tumor Marker Controls Levels 1 and 3 were observed stored in the refrigerator with no open dates or modified expiration dates written on the vials. 2. The manufacturer's instructions stated that after opening, the Biorad Liquichek Multiqual Chemistry Controls, and the Liquichek Immunoassay Plus Control were stable for 14 days at 2-8 degrees Celsius. The manufacturer's instructions stated that after opening, the Liquichek Specialty Immunoassay Controls, the Liquichek Maternal Serum II Control, and Liquichek Tumor Marker Controls were stable for 30 days at 2-8 degrees Celsius. 3. The Laboratory Technical Consultant confirmed the findings during an interview conducted on May 13, 2021 at approximately 3:15 pm. The laboratory performs approximately 105,000 Microbiology tests, 24,000 Chemistry Tests, and 6000 Hematology tests annually.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected

	by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the laboratory records for calibration verification for tests performed on the Beckman Coulter AU480 instrument, and an interview with the Laboratory Technical Consultant, the laboratory failed to perform calibration verification at least every six months for those tests that do not use calibration standards that include a minimum of a zero value, a mid-point value and a maximum value near the upper limit of the range to verify the reportable range for the test results. Findings include: 1. The calibration verification records for the Beckman Coulter AU 480 revealed that the calibration verification was not performed every 6 months in 2020 for the following tests: Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Total Bilirubin, Calcium, CO2, Creatinine, Glucose, Total Protein, Lipase, Uric Acid, Cholesterol, Triglycerides, HDL, Iron, and Unsaturated Iron Binding Capacity (UIBC). 2. The Laboratory Technical Consultant stated that the calibration verification was performed in September, 2020, but not performed in March, 2020 during an interview conducted on May 13, 2021 at approximately 3:15 PM. The Technical Consultant stated that the laboratory was unaware that the calibration verification was required every 6 months. The laboratory performs approximately 105,000 Microbiology tests, 24,000 Chemistry Tests, and 6000 Hematology tests annually.
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 review of the American Proficiency Institute (API) results and the corrective action taken for the 2020 Microbiology Event #2, the director-approved Individual Quality Control Plan (IQCP), the quality control results for June, 2020, and an interview with the Laboratory Technical Consultant, the laboratory failed to follow the established IQCP for the Quidel Solana Influenza A&B tests. Findings include: 1. A review of the API 2020 Microbiology Event 2 results revealed that the Influenza B test received a score of 60%. Samples Vir-07 and Vir-10 were reported as positive. The expected result for samples Vir-07 and Vir-10 was negative. 2. The corrective action that was documented for the failure stated that the external quality controls for the Quidel Solana Influenza B test were not performed during the month of June

	2020. The director approved IQCP for the Quidel Solana stated to perform the external quality controls with each new shipment of reagents, each new lot number of reagents, and at least once per month. 3. The Laboratory Technical Consultant confirmed the findings during an interview conducted on May 13, 2021 at approximately 11:00 AM. The laboratory performs approximately 105,000 Microbiology tests, 24,000 Chemistry Tests, and 6000 Hematology 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 the director approved procedure entitled "Correlation Studies," the data for the correlation studies for the Affirm VP III and the Cepheid Genexpert instruments, and an interview with the Laboratory Technical Consultant, the laboratory failed to establish criteria for acceptability for the twice per year correlation studies between the instruments to ensure accuracy of the test results. Findings include: 1. The policy entitled "Correlation Studies," and the data summaries for the correlation studies performed on March 16, 2020, September 14, 2020, and March 5, 2021 on the Affirm VP III instruments for Gardnerella vaginalis, Candida albicans, and Trichomonas vaginalis, and the those performed on the Cepheid Genexpert Polymerase Chain Reaction (PCR) instrument for Chlamydia trachomatis, Neisseria gonorrhea, SARS CoV-2, and Group B Streptococcus did not specify the criteria for acceptablility to evaluate the data and ensure that the correlation studies were acceptable. 2. The laboratory has seven Affirm VP III instruments and two Cepheid Genexpert instruments. 3. The Laboratory Technical Consultant confirmed during an interview conducted on May 13, 2021 at approximately 2:00 PM that the criteria for acceptablility of the correlation study data was not specified in the Correlation Studies policy or the data summaries. The laboratory performs approximately 105,000 Microbiology tests, 24,000 Chemistry Tests, and 6000 Hematology tests annually.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on observation of frozen Beckman Coulter Access 2 Calibrators, a review of the laboratory temperature log for February, 2021, and an interview with the Laboratory Technical Consultant, the laboratory failed to perform corrective action when the freezer temperature exceeded the manufacturer's established acceptable temperature storage range. Findings include: 1. Beckman Coulter Access 2 calibrator solutions for Vitamin D and Lutenizing Hormone (LH) were observed in the freezer of the supply room. The labels on the boxes of the calibrators stated that the

	acceptable storage temperature ranges for the Vitamin D and LH calibrators was between -30 degrees Celsius (C) and -20 degrees C. 2. The February, 2021 temperature log revealed that no corrective action was taken on 12 of 24 days on which the freezer temperature exceeded the acceptable range established by the manufacturer of the Beckman Coulter Access 2 calibrator solutions. 3. The Laboratory Technical Consultant confirmed the findings during an interview conducted on May 13, 2021 at approximately 3:30 PM. The laboratory performs approximately 105,000 Microbiology tests, 24,000 Chemistry Tests, and 6000 Hematology tests annually.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of the director-approved Quality Assurance Policy, the completed 2020 and 2021 quality assurance monthly checklists, and an interview with the Laboratory Technical Consultant, the director failed to ensure that the established quality assurance program was maintainted and was effective to detect and correct failures of quality when they occur. Findings include: 1. The second page of the Monthly Quality Assessment Checklist for April, 2021 was not completed in order to detect and assess the need for corrective action for any failures during the month. 2. The Monthly Quality Assessment Checklist for June, 2020 did not address the failure of the laboratory staff to take corrective action for the level 1 quality control result that was outside the acceptable range for unsaturated iron binding capacity (UIBC) on June 3, 2020. 3. The Monthly Quality Assessment reviews for 2020 and 2021 failed to detect and ensure that corrective action was taken when the proper storage temperatures for the Beckman Coulter Access 2 Calibrators for Lutenizing Hormone (LH), and Vitamin D were exceeded. The Monthly Quality Assessment reviews also failed to detect that the proper storage of blood collection tubes and viral transport media were not monitored and documented to protect the integrity of the supplies. 4. The Monthly Quality Assessment review for 2020 and 2021 did not detect and correct the failure to perform calibration verification every six months for the following tests performed on the Beckman Coulter AU480: Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Total Bilirubin, Calcium, CO2, Creatinine, Glucose, Total Protein, Lipase, Uric Acid, Cholesterol, Triglycerides, HDL, Iron, and Unsaturated Iron Binding Capacity (UIBC). 5. The Laboratory Technical Consultant confirmed the findings during an interview conducted on May 13, 2021 at approximately 4:15 PM. The laboratory performs approximately 105,000 Microbiology tests, 24,000 Chemistry Tests, and 6000 Hematology tests annually.