

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0951768	(X3) Date Survey Completed 11/29/2018
Name of Provider or Supplier Whasn-Meadows	Street Address, City, State 9120 W Post Rd Ste 200, 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	<p>This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on November 29, 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.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on a random audit of patient test results from January 1, 2017 through November 29, 2018 and an interview with the back office supervisor, the laboratory failed to ensure that patient test results were accurately and reliably transcribed from the point of entry to the final report destination. Findings include: 1. The laboratory failed to ensure that the Affirm VP II patient tests performed were accurately transcribed into the laboratory information system (LIS) and found on the patient final report. 2. A random audit of eight patient test results performed on the Affirm VP II instrument between January 1, 2017 through November 29, 2018 revealed one of eight patient test results that were found to be incorrectly recorded on the patient final test report. 3. A patient who had a specimen submitted to have an Affirm VP II test</p>

performed on January 3, 2017 and was received in the laboratory at 11:56 am was found to have a positive result for Candida and a negative result for Bacterial Vaginosis (Gardnerella). The patient final report indicated that the test was negative for Candida and positive for Bacterial Vaginosis (Gardnerella). This was confirmed by the back office supervisor on November 29, 2018 at approximately 5:15 PM. The laboratory performs approximately 13,722 patient microbiology tests annually.