

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0972705	(X3) Date Survey Completed 01/08/2019
Name of Provider or Supplier Whasn-Nw	Street Address, City, State 7160 Smoke Ranch Rd, 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 January 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.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the director approved policy and procedure manual for laboratory quality assessment, a request for documentation of quality assessment for testing years 2017 and 2018 and an interview with the laboratory manager, the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. Findings include: 1. The laboratory director failed to follow the director approved policy and procedure manual for quality assessment which established that quality assessment would be performed and documented on a monthly basis. 2. There was no quality assessment performed and documented on a monthly basis for testing years 2017 and 2018. This was confirmed by the laboratory manager on January 8, 2019 at approximately 11:00 AM. The laboratory performs approximately 3,000 patient microbiology tests annually.</p>

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of personnel training and competency records and an interview with the laboratory manager, the laboratory director failed to ensure that prior to performing patient laboratory testing, all testing personnel have the appropriate training and have demonstrated competency to perform all testing operations to provide accurate and reliable test results. Findings include: The laboratory director failed to ensure that one of five testing personnel had documentation of training and competency to perform Affirm VP patient laboratory testing. This was confirmed by the laboratory manager on January 8, 2019 at approximately 10:00 AM. The laboratory performs approximately 3,000 patient microbiology tests annually.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of personnel training and competency records and an interview with the laboratory manager, the laboratory technical consultant failed to evaluate and document laboratory testing personnel semiannually during the first year the testing personnel performed patient testing. Findings include: The laboratory technical consultant failed to ensure that one of five testing personnel had semiannual documentation of competency to perform Affirm VP patient laboratory testing. This was confirmed by the laboratory manager on January 8, 2019 at approximately 10:00 AM. The laboratory performs approximately 3,000 patient microbiology tests annually.