

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0997324	(X3) Date Survey Completed 01/30/2018
Name of Provider or Supplier Desert Inn Womens Clinic	Street Address, City, State 1900 E Desert Inn 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	This statement of deficiencies was generated as a result of the on-site CLIA recertification survey conducted at your facility on January 30, 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.
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on a random audit of eight patients from 5/4/16 through 9/29/17 for the Affirm VP laboratory test and an interview with the lead medical assistant, the laboratory failed to have a written or electronic request for the performance of the Affirm VP laboratory test by an authorized patient provider. Findings include: A random audit of eight patient laboratory test requests from an authorized provider from 5/4/16 through 9/29/17 found one of eight patients that had no written or electronic test request to perform an Affirm VP laboratory test. This was confirmed by the lead medical assistant on January 30, 2018 at approximately 11:00 AM. The laboratory performs approximately 1200 Microbiology tests annually.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where</p>

the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on a random audit of eight patients from 5/4/16 through 9/29/17 for the Affirm VP laboratory test and an interview with the lead medical assistant, the laboratory failed to indicate on the patients final test report the name and address of the location where the test was performed. Findings include: A random audit of eight patient final test reports from 5/4/16 through 9/29/17 for the Affirm VP laboratory test found that eight of eight patient final test reports indicated a different location than where the laboratory test was actually performed. This was confirmed by the lead medical assistant on January 30, 2018 at approximately 11:00 AM. The laboratory performs approximately 1200 Microbiology 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 and an interview with the lead medical assistant, the laboratory director failed to maintain a quality assessment program to assure the quality of laboratory services that are provided. Findings include: 1. There was no quality assessment performed that would review and evaluate the pre-analytic, the analytic and the post-analytic phases of laboratory testing to assure the quality of the laboratory tests provided. 2. The quality assurance policy that was established was to monitor the quality control that was performed. There was no documentation that a review and evaluation of the quality control was performed. This was confirmed by the lead medical assistant on January 30, 2018 at approximately 11:30 AM. The laboratory performs approximately 1200 Microbiology tests annually