

Division of Public and Behavioral Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 3479	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 01/30/2018	
NAME OF PROVIDER OR SUPPLIER DESERT INN WOMENS CLINIC		STREET ADDRESS, CITY, STATE, ZIP CODE 1900 E DESERT INN RD, LAS VEGAS, NEVADA ,89169		
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0000	<p>Initial Comments - Chapter 652 Medical Laboratories</p> <p>Inspector Comments: INITIAL COMMENTS This Statement of Deficiencies was generated as a result of the on-site reactivation State licensure survey conducted at your facility on January 30, 2018, for State license #3479 REG. Please log into the Online Licensing System and complete the Plan of Correction. The Plan of Correction must be submitted within 14 days after receipt of this Statement of Deficiencies. 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>	0000		

If deficiencies are cited, an approved plan of correction must be returned within 10 days after receipt of this statement of deficiencies.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Name: FRANK SILVER Title: MD Date: 02/16/2018

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0022	<p>NAC652.282(7) - Lab Director Duties: Procedures & Results - A director shall ensure that: 7. Programs of quality control and quality assurance are established and maintained to ensure the quality of the laboratory's services and to identify any failure of quality when it occurs, and that records of such programs are maintained by the laboratory for at least 2 years.</p> <p>Inspector Comments: 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 and to identify any failures of quality when it occurs. 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. Severity level- 2</p>	0022	<p>A policy has been put in place by the lab director to assure the quality of laboratory services being provided. Quarterly assessment is to be done by either the laboratory director or the lead medical assistant by choosing 7-14 patients. These patients charts will be reviewed for the pre-analytics, analytics and post-analytics. The information collected will be recorded and kept for 2 years on a sheet created for this purpose. Also included will be a review and evaluation performed for the quality control on this quarterly basis. API will continue, the lead medical assistant or lab director will be responsible for monitoring quarterly.</p>	02/15/2018

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0055	<p>NAC 652.300(1) - Test Requests & Reports - 1. Except as otherwise provided in subsection 3, if a specimen is received by the laboratory, it must be accompanied by an authorized written request or a computerized authorization.</p> <p>Inspector Comments: 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. Severity level- 2</p>	0055	<p>Patient's chart that was recently reviewed, had no written order for the VP Affirm. It was collected by provider had a first and last name also a date of birth as 2nd patient identifier. This did not affect the patient's test results, therefore patient did not have to be contacted as the results were not affected. The Lab director has addressed his medical assistants to remind the provider to add the order if does not do so at time of collection. This will prevent any further missing of the orders in the patients chart. The lead MA will be monitoring this quarterly.</p>	02/12/2018
0068	<p>NAC 52.340(1)(b) - Reports: Contents - 1. A report by the laboratory to the source requesting the report must include, without limitation, the following: (b) The name and address of the reporting laboratory.</p> <p>Inspector Comments: 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. Severity level- 2</p>	0068	<p>New Affirm test results sheets have been created to reflect the Doctors address & name of clinic of where the specimen was collected. The test result sheet also has 2 patient identifiers, date and time of collection. The back office lead medical assistant has instructed the staff of the use of this new form. Old ones were destroyed to prevent re-occurrence the lead ma will monitor quarterly.</p>	02/12/2018

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0140	<p>NRS 652.080 - License Required; term; renewal; inactive - 1. Except as otherwise provided in NRS 652.217 and 652.235, no person may operate, conduct, issue a report from or maintain a medical laboratory without first obtaining a license to do so issued by the Division pursuant to the provisions of this chapter. 2. A license issued pursuant to the provisions of subsection 1 is valid for 24 months and is renewable biennially on or before the date of its expiration. 3. No license may be issued to a laboratory which does not have a laboratory director. 4. A license may be placed in an inactive status upon the approval of the Division and the payment of current fees. 5. The Division may require a laboratory that is located outside of this state to be licensed in accordance with the provisions of this chapter before the laboratory may examine any specimens collected within this state if the Division determines that the licensure is necessary to protect the public health, safety and welfare of the residents of this state.</p> <p>Inspector Comments: Based on a review of laboratory licenses in the State of Nevada laboratory database and an interview with the lead medical assistant, the laboratory failed to have a current State of Nevada laboratory license while performing patient laboratory testing. Findings include: 1. The laboratory failed to renew their State of Nevada laboratory license which had an expiration date of December 11, 2017. 2. The laboratory performed 23 Affirm VP patient laboratory tests from December 12, 2017 through January 12, 2018 with no current State of Nevada laboratory license. This was confirmed by the lead medical assistant on January 30, 2018 at approximately 11:00 AM. Severity level- 2</p>	0140	<p>Upon noticing the license had expired the license was immediately paid for and renewed, all office laboratory testing was stopped. The license had been placed on a wall towards the back of the lab not with the other licenses therefore it went unnoticed when it was done for renewal. Since then it has been moved location and a renewal list has been created for preventing this from happening. This list has been added to our quarterly review. The lab director has made the medical assistant aware of the importance in maintaining all licensing updated at all times. The lead ma will monitor quarterly.</p>	02/12/2018