Division of Public and Behavioral Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	6237	A. BUILDING _____ B. WING _____	05/08/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NEVADA WOMENS CARE	1701 N GREEN VALLEY PKWY BLDG 3 STE B, HENDERSON, NEVADA ,89074

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
0000	Initial Comments - Chapter 652 Medical Laboratories Inspector Comments: This Statement of Deficiencies was generated as a result of the on-site reactivation State licensure survey conducted at your facility on May 8, 2018, for State license #6237 EXL. 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.	0000		
0003	NAC652.155(2)(b)(2) - Applicability - (b) The director, a designee of the director or a licensed physician at the laboratory at which the test is performed: (2) Ensures that the test is performed in accordance with instructions of the manufacturer of the test; Inspector Comments: Based on a review of laboratory records, manufacturer's requirement and an interview with laboratory personnel, the laboratory director failed to ensure that laboratory tests were performed in accordance with the manufacturer's instructions of the test. Findings include: The manufacturer's package insert available to the staff for the Consult 10 SG urinalysis dipsticks was not the most current version of the instructions. The insert available stated that the test strips were stable until the manufacturer's expiration date. The instructions on the bottle of the test strips stated not to use the test strips beyond 90 days after opening the bottle. The laboratory personnel confirmed the finding during an interview conducted on 5/8/18 at approximately 9:15 AM. Severity = 2	0003	The manufacturer's package insert for the Consult 10 SG urinalysis dipsticks was obtained from McKesson on 05/25/2018. Lot # URS80220007 Expiration Date: 04/09/2020. At Nevada Women's Care, every time a certified laboratory personnel opens a new box with a new bottle, the package insert will be displayed on the laboratory wall, for all to see. The medical director will monitor the new and current package insert's for the laboratory. The Head Office Nurse will ensure the plan of correction is implemented. The corrective action was completed on 05/26/2018. Attached, please see Exhibit A, Page 1 and 2.	05/25/2018

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: ROBERT A GATLIN Title: MD Date: 06/05/2018

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0004	NAC652.155(2)(b)(3) - Applicability - (b) The director, a designee of the director or a licensed physician at the laboratory at which the test is performed: (3) Validates and verifies the manner in which the test is performed by using controls which ensure that the results of the test will be accurate and reliable. Inspector Comments: Based on a review of laboratory records and an interview with laboratory personnel, the laboratory director failed to ensure that quality controls were performed according to manufacturer's instructions and documented to ensure that the results of tests will be accurate and reliable. Findings include: 1. The documented control results for the 10 SG urinalysis dipsticks were not consistent with the units used for reference in order to properly evaluate the acceptability of the results. The control results were recorded in "plus" units, but the reference ranges in use on the control log were in conventional units. 2. The controls for the 2 GP urinalysis dipsticks were not performed when opening a new bottle of test strips, as required by the manufacturer. The bottle of 2 GP test strips in use were opened on 4/9/18, but no control results were recorded on the logs for that date. The manufacturer's instructions state to "test commercially available positive and negative controls with each new lot, each new shipment of strips, and when you open a new bottle of reagent strips." 3. There was no documentation of the internal control for the urine hCG tests on the days of patient testing. 4. The findings were confirmed during an interview with the laboratory personnel conducted on 5/8/18 at approximately 9:45 AM. Severity = 2	0004	At Nevada Women's Care, on 05/11/2018, the Head Office Nurse rewrote the reference ranges for the 10 SG urinalysis dipsticks on the Control Log in Arbitrary Units for both the Normal and Abnormal controls. See Exhibit B, pages 1 and 2. The Head Office Nurse performed controls on the 2 GP urinalysis dipsticks for the bottle that was opened on 04/09/2018. See Exhibit C, pages 1 and 2. On 05/08/2018, the Head Office Nurse documented the Valid Internal Control on urine hCG testing, in each patient's chart performed on the day of testing. The office staff licensed to perform laboratory testing was informed and shown how to enter 10 SG urinalysis dipsticks in Arbitrary units on each Control Log. The office staff licensed to perform urine hCG testing was shown how to enter "Internal QC Valid" on each patients' chart performed on the day of testing. The Medical Director and the Head Office Nurse will monitor the corrections, and corrective actions of the office staff licensed to perform laboratory testing. The corrective action was completed on 05/11/2018. Please see exhibits attached.	05/11/2018

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0140	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. Inspector Comments: Based on a review of Division of Public and Behavioral Health records and an interview with laboratory personnel, the director failed to ensure that patient testing did not occur after the exempt laboratory license expired. Findings include: The laboratory license expired on 1/22/18. The laboratory personnel stated during an interview conducted on 5/8/18 at approximately 10:30 AM that patient testing had been performed after the license had expired. Severity = 2	0140	The correction of the expired laboratory license has been implemented. The Office Manager applied for and paid for a renewal of Nevada Women's Care Waived Testing License on March 1, 2018. All licensed laboratory personal working at Nevada Women's Care will monitor the expiration date of all laboratory licenses. The license has been requested and paid for to the State of Nevada. The Practice Manager for Nevada Women's Care will ensure the license will be renewed prior to the next expiration date. The corrective action will be completed when Nevada Women's Care receives their new Laboratory license. The renewal request for Nevada Women's Care license is in the Department of Health and Human Services Division of Public and Behavioral Health Bureau of Health Care and Compliance. Upon receipt of Nevada Women's Care current license, a calendar reminder will be documented in the office manager's Microsoft Outlook calendar. In addition, documentation of the expiration date of our current license will be noted in the Medical Director's calendar, and the Head Office Nurse's Microsoft Outlook calendar. The Head Office Nurse and the Office Manager will put alert's on their cell phones in the iPhone calendar, for 3 months prior to the expiration date of Nevada Women's Care Laboratory license.	03/01/2018