

Division of Public and Behavioral Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  4264	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____	(X3) DATE SURVEY COMPLETED  01/30/2019
--	--	--	--

NAME OF PROVIDER OR SUPPLIER  PLANNED PARENTHOOD MAR MONTE (PPMM)	STREET ADDRESS, CITY, STATE, ZIP CODE 455 W 5TH ST, RENO, NEVADA ,89503
---	--

(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 State licensure periodic survey conducted at your facility on January 30, 2019, for State license #4264 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		
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 interview with laboratory personnel, the laboratory director failed to ensure that quality controls were performed according to manufacturer's instructions and documented to verify that the results of tests will be accurate and reliable. Findings include: The laboratory did not have the manufacturer's acceptable ranges for the current quality control lot number used for the Hemocue hemoglobin test to evaluate whether the control test results were acceptable. The ranges used to evaluate acceptability were for hematology controls lot #GH0218 which expired on 5/10/18 and the ranges were in use from March 2018 to present. The Hemoglobin Controls Client Logs used from May to December 2018 states, "Expected control ranges are found with each package. Ranges may change with each new lot number." The new Hemocue Control Log from January 2019 did not have	0004	When completing your Plan of Correction you must address all of the following: 1) How you will correct the specific finding(s) stated in the Statement of Deficiencies (MUST ADDRESS); New Hemocue controls had already been ordered at the time of the deficiency. Upon receipt of the controls, new high/low range sheet from the manufacturer will be placed in the log book and updated to reflect current ranges as indicated on the paper. A new QC will be run to verify the machine is functioning properly and the log sheet will be updated. 2) What measures or systematic change(s) will be put into place to ensure the deficient practice does not recur (MUST ADDRESS); Lab Log Sheet has been updated to include a line for controls expiration date and vial expiration dates. 3) How the corrective action(s) will be monitored to ensure the deficient practice will not recur (MUST ADDRESS); The Site Supervisor will update log book daily and upon new	02/06/2019

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: KATHERINE SCHOPP Title: Quality Management Clinician Date: 02/21/2019

Division of Public and Behavioral Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>4264</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>01/30/2019</b>	
NAME OF PROVIDER OR SUPPLIER  <b>PLANNED PARENTHOOD MAR MONTE (PPMM)</b>		STREET ADDRESS, CITY, STATE, ZIP CODE  <b>455 W 5TH ST, RENO, NEVADA ,89503</b>		
(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
	any information regarding the acceptable ranges. The laboratory supervisor interviewed during the on-site inspection on January 30, 2019 at approximately 11:30 AM stated she was not aware of changes in the acceptable ranges with each different lot number. Severity: 2		receipt of shipments of controls. The Quality Management Clinician (QMC) who oversees the lab log book will now be able to review expiration dates when reviewing that the lab log and QC is up to date. QMC will review lab book weekly to ensure compliance and site supervisor will review the book daily. 4) The title of the person responsible for ensuring the plan of correction is implemented (DO NOT INCLUDE PERSONAL NAMES, JUST USE THE TITLE) (MUST ADDRESS); Quality Management Clinician and Site Supervisor 5) The date the corrective action will be completed (MUST INCLUDE); 2/6/19 6) You must attach all supporting documents into the system (MUST INCLUDE). SEE ATTACHED DOCUMENTS INCLUDING: Lab Log Sheet and Images of new control and high/low sheet	