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
	4264	A. BUILDING _____ B. WING _____	11/09/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD MAR MONTE (PPMM)	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 11/09/16, 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 10 working days. 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 requirements and interview with lab personnel, the laboratory director failed to ensure that laboratory tests were performed in accordance with the manufacturer's instructions of the test. Findings include: 1. Daily documentation of the laboratory room and refrigerator temperatures consistent with the manufacturer's temperature requirements for the performance of laboratory tests and the storage of laboratory supplies was not performed. The temperature records were missing for 12 days from the September 2016 chart and five days from the October 2016 chart. 2. The office manager confirmed the finding during the on-site inspection on 11/09/16 at approximately 11:30 AM. Severity: 1	0003	**1) How will you correct the specific finding(s) stated in the Statement of Deficiencies:** During an internal audit on 10/13/16 by Planned Parenthood Mar Monte's Advance Practice Clinician/Training, it was discovered that daily documentation of the laboratory room and refrigerator temperatures were not occurring; specifically dates in September and the first week in October were noted as missing. A plan of correction was initiated at that time. Intervention steps including the following: • reviewed procedure on how to properly document temperatures with all medical assistance staff on 10/13/16. • Additionally, reviewed the importance of accurate and timely completion of temperature log and its relevance to stored medications. Since initiation of plan of correction all temperatures have been recorded correctly. See attachment with plan of correction. **2) What measures of systematic change (s) will be put into place to ensure the deficient practice doesn't recur?** A medical assistant was assigned the	12/06/2016

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: LYNNETTE BRADY Title: Regional Operations Director Date: 12/07/2016

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			responsibility of documenting the temperatures at the start and close of each day; previously there was no one assigned to this task. The Health Center Manager will record the temperatures on days when the assistant is out of the office. Additionally, the temperature log was moved from a binder that was under the sink to the front of the fridge; making it more visible to see. **3) How the corrective action(s) will be monitored to ensure the deficient practice does not recur:** The Health Center Manager will be checking daily/weekly to ensure compliance. Outlook reminders have been placed on her computer as a means to prompt her. Additionally, the Director of Advance Practice Clinicians/Training will be conducting another audit of the logs in December and then on a quarterly basis through June 2017 to ensure adherence. **4) The title of the person responsible for ensuring the plan of correction:** The Health Center Manager **5) The date the corrective action will be completed:** December 1, 2016.	
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 ensure that the results of tests will be accurate and reliable. Findings include: 1. Quality control records were not available for review for the Hemocue hemoglobin tests from August to October 2016. 2. Quality control records were not available for review for the Consult	0004	**1) How will you correct the specific finding(s) stated in the Statement of Deficiencies**: The following interventions will be taken to correct the stated deficiencies: • The medical assistance will read the manufacturers' instructions on how to run and interpret the quality controls for each test. • An in-service will be held with all medical assistants to retrain them on how to correctly run and document quality controls for hemoglobin, HIV, and urine dipsticks. • The manufacturers' instructions on how to run quality controls and what are acceptable ranges for each test have been posted in the lab and placed in the health center's lab	12/07/2016

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	Diagnostics urine dipstick tests from August and October 2016. 3. The internal (built-in) controls for the urine pregnancy and HIV tests were not evaluated and documented to validate the accuracy of tests. 4. The laboratory did not have the manufacturer's acceptable ranges for the quality controls used for the Hemocue hemoglobin (lot #1601391) and the Consult Diagnostics urine dipstick tests (lot #UCD5120005) to evaluate whether the control test results were acceptable. Severity: 2		manual so that they are readily accessible. • **While reviewing the December Hemoglobin logs it was discovered that controls were being run every day; regardless of whether patients were seen or not. Controls only need to be run on days in which the instrument is in use. Additionally, it was noted that there were 6 days in which controls were outside of the range. Although patients were not seen on those days, the medical assistants needed to rerun the controls. An in-service will be held on December 13, 2016 to review with the medical assistants the proper procedure when running controls. Effective immediately the assistance will write the expected low and high ranges on the log to ensure they are able to identify when controls are out of range. The Center Manger will re-audit the hemoglobin log on a weekly basis to ensure compliance.** **2) What measures of systematic change (s) will be put into place to ensure the deficient practice doesn't recur?** A medical assistant will be assigned the responsibility of running and documenting all quality controls; previously there was no one assigned to this task. The Health Center Manager will run the controls, if needed, on the days the medical assistant is out of the office. **3) How will the corrective action(s) be monitored to ensure the deficient practice does not recur:** The Health Center Manager will be checking daily/weekly to ensure compliance. Outlook reminders have been placed on her computer as a means to prompt her. Additionally, the Director of Advance Practice Clinicians/Training will be	

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			conducting another audit of the logs in December and then on a quarterly basis through 2017 to ensure adherence. **4) The title of the person responsible for ensuring the plan of correction:** The Health Center Manager **5) The date the corrective action will be completed:** December 13 , 2016	

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140	NRS 652.110 - Validity and Display of Licenses - 1. A license issued pursuant to the provisions of this chapter is valid only for the laboratory premises for which it is issued and shall be prominently displayed in such laboratory. 2. Any such license shall become void 30 days after a change of laboratory directors or in the ownership or location of the laboratory. Inspector Comments: Based on review of the laboratory license and interview with the office manager, the laboratory license was void after a change of director effective 9/01/16. Findings include: The laboratory failed to submit an amendment application for change of laboratory director within 30 days after the effective date of the change on 9/01/16. The office manager confirmed the finding during the on-site inspection on 11/09/16 at approximately 12:30 PM. Severity: 1	140	**1) How will you correct the specific findings stated in the Statement of Deficiencies:** Planned Parenthood Mar Monte is in the process of hiring a physician who will act as the laboratory director. Planned Parenthood has selected a candidate and is in the process of completing a background check on the individual. The anticipated start date for this candidate is December 15, 2016. **The Health center will discontinue with patient testing until the state has issued a license with the new director.** **2) What measures of systematic change (s) will be put into place to ensure the deficient practice does not recur:** The Senior Medical Director is currently undergoing the process to obtain a NV Medical License and will then serve as the back- up laboratory director in the event there is a future loss of supervising physician for this health center. **3) How will the corrective action(s) be monitored to ensure the deficient practice does not recur:** The Senior Medical Director will communicate to the health center manager once the laboratory director has been hired and she will complete the amendment application. **4) The title of the person responsible for ensuring the plan of correction:** Senior Medical Director and Health Center Manager **5) The date the corrective action will be completed:** January 31, 2017	12/06/2016