

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 38D0922743	<b>(X3) Date Survey Completed</b> 02/13/2018
<b>Name of Provider or Supplier</b> Vgmhc - Beaverton Sbhc (Multisite)	<b>Street Address, City, State</b> 13000 Sw 2nd St, Beaverton, OR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Base on review of laboratory policies and procedures, competency record, and interview with the staff, it was determined that the laboratory failed to established written policies and procedures to assess the competency of the providers performing Provider Performed Microscopy Procedures (PPMP). Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process for assessing the competency of the providers performing PPMP. 2. The Survey Team requested and the laboratory failed to provide records of training and competency for the eleven providers performing PPMP at Virginia Garcia Memorial Center located at 1151 N. Adair Street, Cornelius OR. 97113. 3. These findings were confirmed by Nurse Practitioner 1 during an interview on 02/13/2018 at 11:30 AM.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by:</p>

Base on review of laboratory policies and procedure manuals, and interview with the staff , it was determined that the laboratory failed to provide written procedure manuals for laboratory testing personnel to follow. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedure manuals for the test assays performed at the 3 laboratory locations surveyed on 02/13/2018. These laboratories are (A)Virginia Garcia Memorial Center laboratory located at 1151 N. Adair Street, Cornelius OR. 97113. (B) Virginia Garcia School Base Health Clinic - Willamina located 110 NE Oaken Hills Drive, Willamina, OR. 97296. (C) Virginia Garcia School Base Clinic - Tigard High School located at 9000 SW Durham Rd, Tigard OR. 97224. 2. These findings were confirmed by Nurse Practitioner 1, Primary Care Clinic Manager, and Clinic Program Manager during an interview at laboratory (A) on 02/13/2018 at 11:30 AM. 3. These findings were confirmed by Nurse Practitioner A during an interview at laboratory (C) on 02/13/2018 at 15:00 PM. 4. These findings were confirmed by the medical provider and the medical assistant during and interview at laboratory (B) on 02/13/2018 at 17:15 PM.

**D5980**

PPM LABORATORY DIRECTOR  
CFR(s): 493.1355

The laboratory must have a director who meets the qualification requirements of 493.1357 and provides overall management and direction in accordance with 493.1359.

This CONDITION is not met as evidenced by:

Base on review of records and interview with the staff the laboratory director failed to fulfill the laboratory director's responsibilities to provide overall management of the laboratory . Refer to D5209, D5401, D5981, D5983 and D8105.

**D5981**

PPM LABORATORY DIRECTOR QUALIFICATIONS  
CFR(s): 493.1357

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of PPM procedures as specified in 493.19(c) and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if the licensing is required. (b) The laboratory director must meet one of the following requirements: (b) (1) Be a physician, as defined in 493.2. (b)(2) Be a midlevel practitioner, as defined in 493.2, authorized by a State to practice independently in the State in which the laboratory is located. (b)(3) Be a dentist, as defined in 493.2.

This STANDARD is not met as evidenced by:

Base on review of records and interview with the staff the laboratory director did not possess a current license issued by the Oregon Medical Board. Findings include: 1. The current laboratory director listed on the CLIA Certificate did not have a valid license issued by the Oregon Medical Board. The current status of the license is lapsed effective date 01/01/2018. 2. Discussion with the Medical Director and the Administrative personnel reveals that the current laboratory director is now retired. The Medical Director stated that "she is now stepping in to be the next laboratory director". A CMS 116 form was given to the the Administrative personnel to verify

and make the necessary changes and provide us with the required credentials for the new laboratory director. 3. These findings were confirmed by the Medical Director and Administrative personnel during an interview on 02/13/2018 at 12:30 PM.

**D5983**

**PPM LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1359

The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results.

This STANDARD is not met as evidenced by:

Base on review of records and interview with the staff the laboratory director failed to provide guidance to the overall operation and administration of the laboratory.

Findings include: I. A complaint survey was performed at Virginia Garcia Memorial Center laboratory located at 1151 N Adair Street, Cornelius OR. 97113. Findings include: 1. The Survey Team requested and the laboratory failed to provide the laboratory's standard operating procedures and manuals. 2. Eleven out of eleven providers performing direct wet mount and potassium hydroxide (KOH) preparations did not have their initial training, 6 months competency assessment and annual competencies on site at the time of survey. 3. There is no documentation of biannual verification of the Provider Performed Microscopy Procedures (PPMP) on wet mount and KOH preparations performed by the providers. 4. These findings were confirmed by Nurse Practitioner 1, Primary Care Clinic Manager, and Clinical Program Manager during an interview on 02/13/2018 at 11:30 AM. II. A complaint survey was performed at the Virginia Garcia School Base Health Clinic (SBHC) located at 110 NE Oaken Hills Drive, Willamina, OR. 97396. Findings include: 1. The surveyor requested and the laboratory failed to provide the laboratory's standard operating procedures and manuals. 2. There is a microscope in the laboratory, however, the medical provider is not performing any PPMP because supplies to perform testing are not available. 3. The laboratory only performs waived testing which includes urine pregnancy test, urine dipsticks, and rapid strep A test. 4. These findings were confirmed by the medical provider and the medical assistant during an interview on 02/13/2018 at 17:15 PM. III. A complaint survey was performed at the Virginia Garcia SBHC Tigard High School located at 9000 SW Durham Rd, Tigard OR 97224. Findings include: 1. The surveyor requested and the laboratory failed to provide the laboratory's standard operating procedures and manuals. 2. The surveyor notice a microscope on the counter, however, Nurse Practitioner A on site testified the microscope was not in use nor had it been used for "several years". She also testified that Nurse Practitioner B who works on different days, does not use the microscope either. No PPMP testing at this site. 3. The laboratory only performs waived testing which includes urine pregnancy test, urine dipsticks, rapid strep A test, and hemoglobin test. 4. These findings were confirmed by the Nurse Practitioner A during an interview on 02/13/2018 at 15:00 PM.

**D8105**

**BASIC INSPECTION REQUIREMENTS**

CFR(s): 493.1773(e)(f)(g)

(e) Reinspection. CMS or a CMS agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results. (f) Complaint inspection. CMS or a CMS agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part. (g) Failure to permit CMS or a CMS agent to conduct an inspection or reinspection

results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part.

This STANDARD is not met as evidenced by:

Base on review of records and interview with the staff the laboratory failed to show compliance with the requirements for PPMP. Findings include: 1. The Survey Team requested and the laboratory failed to provide policies and procedures for performing wet mount and KOH preparations. 2. The laboratory failed to provide documentation's of biannual verification for the wet mount and KOH preparations PPMP. 3. The laboratory failed to provide competency assessment of the providers performing PPMP. 4. These findings were confirmed by the Medical Director and Administrative personnel during an interview on 02/13/2018 at 12:30 PM.