

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  38D0664019	<b>(X3) Date Survey Completed</b>  03/26/2018
<b>Name of Provider or Supplier</b>  Women's Care Laboratory	<b>Street Address, City, State</b>  590 Country Club Parkway, Eugene, 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>D5471</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of Microbiology records and interview with the Technical Supervisor (TS), the laboratory failed to perform the required Quality Control (QC) procedures on it's commercially prepared media and their Chlamydia assay as required by the CFR 493.1256. Findings include: 1. The TS confirmed that no end user QC is performed on each batch or lot number of media when it is received and before using for patient testing. 2. There is no written IQCP in place for commercially prepared media to replace the need for end user QC. 3. The laboratory failed to perform external QC (Manufacturer supplied with each kit) each day of use on patient samples with the QuickVue Chlamydia test made by Quidel. 4. There is no written IQCP in place for the QuickVue Quidel Chlamydia test. to replace the need for day of use performance of QC.</p>
<b>D6020</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based upon review of records and interview with the Technical Specialist (TS), the Laboratory Director (LD) failed to ensure that required Quality Control is performed according to regulations. Findings include: 1. There is no external QC being performed on the QuickVue Chlamydia assay each day of patient testing even though external QC materials are provided by the manufacturer with each kit. 2. There is no end user QC being performed on commercially purchased microbiological media, in particular, Todd Hewitt broth with Gentamycin and Naladixic Acid. 3. The methodology used (CAMP test) to rule out colonization with Group B Beta streptococcus from vaginal and/or rectal swabs is archaic and will miss a percentage of positive specimens.

**D6114**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(1)

The technical supervisor is responsible for selection of the test methodology that is appropriate for the clinical use of the test results.

This STANDARD is not met as evidenced by:

Based upon review of records and discussion with the Technical Supervisor (TS), the TS failed to select the most appropriate method of identification of an organism in their patient population. Findings include: 1. The practice of screening women for Group B beta streptococcus (GBS) helps prevent a potentially fatal disease in the newborn. Isolation and identification of the organism at 35 - 37 weeks gestation is routinely performed using current methods to detect the organism. The method currently being used at this laboratory will not pick up all strains of GBS as documented in peer reviewed literature such as The Journal of Clinical Microbiology (JCM), thus missing some of the actual positive patients.