

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0700410	(X3) Date Survey Completed 03/26/2019
Name of Provider or Supplier Premier Womens Health	Street Address, City, State 301 Ohio River Blvd, Suite 301, Sewickley, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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: Based on review of Laboratory procedure manuals and interview with testing personnel (TP) #6, the laboratory failed to establish a complete procedure to assess TP who performed Potassium Hydroxide (KOH) and wet mounts (2 of 2) examination and clinical consultant competency (6 of 7) from 09/20/2017 to the date of survey. Findings include: 1. On the day of survey, 03/26/2019, the laboratory failed to provide a complete written policy that reviews how to assess the competency of 2 of 2 TP performing KOH and wet mount examinations and 6 of 7 Clinical consultant's for competency in 2017, 2018 and 2019. 2. The TP #6 confirmed the findings above on 03 /26/2019 around 09:30 am.</p>
D5401	<p>PROCEDURE MANUAL 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: Based on review of Laboratory procedure manuals and interview testing personnel (TP) #6, the laboratory failed to establish a fern microscopic examination procedure</p>

from 2017 to the date of survey. Findings Include: 1. On the day of survey, 03/26/2019, TP#6 could not produce a procedure for the Fern Microscopic examination being performed onsite from 09/20/2017 to 03/27/2019. 2. TP#6 estimated about 20 fern microscopic examinations were performed yearly. 3. TP#6 confirmed the findings above on 03/26/2019 around 10:45 am.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review quality control (QC) records, and interview with testing personnel #6, the laboratory failed to document QC procedures performed on 107 of 107 patient specimens examined for Potassium Hydroxide (KOH), wet mount and fern examinations from 09/20/2017 to the date of survey. Findings Include: 1. On the day of survey, 03/26/2019, review of QC records revealed the laboratory did not document QC procedures for KOH, wet mount and fern examinations each day of patient testing from 09/20/2017 to 03/26/2019. 2. In 2017: - 5 KOH microscopic examinations were analyzed. - 5 wet mount microscopic examinations were analyzed. - 20 fern microscopic examinations were analyzed. 3. In 2018: - 13 KOH microscopic examinations were analyzed. - 13 wet mount microscopic examinations were analyzed. - 20 fern microscopic examinations were analyzed. 4. In 2019: - 13 KOH microscopic examinations were analyzed. - 13 wet mount microscopic examinations were analyzed. - 5 fern microscopic examinations were analyzed. 5. TP#6 confirmed on 03/26/2019 around 10:21 am, that QC were performed but not documented. *** Repeat Deficiency***

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on, the review of personnel competency assessment records, American Proficiency Institute (API) proficiency testing (PT) records and interview with the testing personnel (TP) #6, the Technical Consultant (laboratory director) failed to assess the competency through internal blind testing samples or external PT samples for 2 of 4 TP who performed Gardnerella, Trichomas and Yeast screening, 1 of 2 TP who performed KOH and Wet Mount examination and 4 of 5 TP who performed Fern Microscopic examination in 2017 and 2018. Findings Include: 1. On the day of survey, 03/26/2019, review of competency assessment records and API attestation statements, revealed the laboratory did not assess the test performance for: a. 2 of 4 TP who performed Gardnerella, Trichomas and Yeast screening. - TP #6 and #8 in 2017. - TP #6 and #7 in 2018. b. 1 of 2 TP who performed KOH and Wet Mount

examination in 2017 and 2018 (TP #6). c. 4 of 5 TP who performed Fern Microscopic Examination in 2017 and 2018 (TP#1, 2,4, and 5). 2. TP#6 confirmed the findings above on 03/26/2019 around 10:15 am