

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0342280	(X3) Date Survey Completed 07/18/2018
Name of Provider or Supplier Progressive Women's Care	Street Address, City, State 7600 Southern Boulevard, Suite 1, Boardman, OH	
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
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Office Manager (OM) and Technical Consultant (TC) #2, the laboratory failed to maintain a test record system that included the records/test results for all BD Affirm patient specimen testing. Findings Include: 1. Review of one out of five of the laboratory's 2018 BD Affirm test records ("Affirm VPIII Lab Testing Log") and corresponding test reports, provided on the date of the inspection, did not find the negative test results for Trichomonas, Gardnerella and Candida documented on the Affirm VPIII Lab Testing Log as hand written on the final test report. 2. The OM and TC#2 confirmed that TP#8 did not follow the laboratory's procedure and failed to document the BD Affirm test results on the testing log prior to being transcribed on the test report, as required. The interviews occurred on 07/18/2018 at 11:50 AM.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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 and for assuring compliance with the applicable regulations. (e) The laboratory</p>

director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Office Manager (OM) and Technical Consultant (TC) #2, the Laboratory Director failed to ensure that prior to wet mount preparation, potassium hydroxide (KOH) and fern testing of patients' specimens, testing personnel (TP) #6 and TP#7 had demonstrated that they could perform this testing reliably to provide and report accurate results. Findings Include: 1. Review of the laboratory's competency assessment policy and procedure, provided on the date of the inspection, approved by the Laboratory Director, revealed instructions to assess the competency of new testing personnel initially and prior to patient testing. 2. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 07/17/2018, revealed three out of eight individuals newly listed (since the last CLIA inspection in 2016) and qualified by the Laboratory Director to perform moderately complex testing procedures. 3. Review of the laboratory's 2017 and 2018 training and competency assessment documentation, provided on the date of the inspection, did not find any wet mount preparation and KOH testing training and competency assessment documentation for TP#6 and TP#7 and fern training and competency assessment documentation for TP#7 prior to patient testing. 4. The Surveyor requested the laboratory's 2017 and 2018 wet mount preparation, KOH and fern training records for TP#6 and TP#7 as mentioned above from the OM and TC#2. The OM and TC#2 confirmed the laboratory did not document initial wet mount preparation, KOH and fern training and competency assessment as required for TP#6 and TP#7 and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 07/18/2018 at 11:15 AM.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Office Manager (OM) and Technical Consultant (TC) #2, the Technical Consultant failed to evaluate and document wet mount preparation, potassium hydroxide (KOH) and fern testing procedures for testing personnel (TP) #6 and TP#7, at least semiannually during the first year they tested patient specimens. Findings Include: 1. Review of the laboratory's competency assessment policy and procedure, provided on the date of the inspection, approved by the Laboratory Director, revealed instructions to assess the competency of new testing personnel initially, at six months and 12 months within the first year of testing patient specimens. 2. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 07/17/2018, revealed three out of eight individuals newly listed (since the last CLIA inspection in 2016) and qualified by the Laboratory Director to perform moderately complex testing procedures. 3. Review of the laboratory's 2017 and 2018 training and competency assessment documentation,

provided on the date of the inspection, did not find any six month wet mount preparation and KOH testing competency assessment documentation for TP#6 and TP#7, six month fern and 12 month wet mount preparation and KOH testing competency assessment documentation for TP#6. 4. The Surveyor requested the laboratory's 2017 and 2018 wet mount preparation, KOH and fern competency assessment records for TP#6 and TP#7 as mentioned above from the OM and TC#2. The OM and TC#2 confirmed the laboratory did not document semiannual wet mount preparation, KOH and fern testing competency assessment as required for TP#6 and TP#7 and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 07/18/2018 at 11:15 AM.