

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0865543	(X3) Date Survey Completed 06/05/2018
Name of Provider or Supplier Progressive Women's Care	Street Address, City, State 500 Gypsy Lane Third Floor, Bldg B, Youngstown, 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
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 record review and interviews with the Office Manager (OM) and Technical Consultant (TC) #2, the laboratory failed to follow their written policies and procedures for test result reporting. Findings Include: 1. Review of the laboratory's "Tab 6: Postanalytic Policies and Procedures" policy and procedure, approved, signed and dated by the Laboratory Director and provided on the date of the inspection, revealed the following instructions: "Record results for each organism and the positive and negative internal controls on the Affirm VPIII Lab Test Log...as you read the results...by testing personnel in the test log." "Procedure for Reporting Results to Providers ...results for the Affirm VPIII Microbial Identification test are reported to providers in your facility: X Written on laboratory report form which is then paced into the chart." 2. Review of two out of nine of the laboratory's 2017 and 2018 test records and test reports provided on the date of the inspection found an "Affirm VPIII Lab Testing Log" that included a running list of all patients that were tested, their patient ID#, date/time the specimen was tested, positive/negative internal control test results, Trichomonas/Gardnerella/Candida test results and the initials of the testing personnel. This record revealed two out of six patients' specimens tested on 07/12/2017, patients #5 and #6, did not have test results documented. 3. Review of the test reports for patient #5 and #6, as indicated above, for test date 07/12/2017, found documentation of negative test results for Trichomonas / Gardnerella / Candida for both patients in their charts. 4. The OM and TC#2 confirmed that the laboratory did</p>

not follow their written policy and procedure instructing the testing personnel to document BD Affirm VPIII test results on the ""Affirm VPIII Lab Testing Log". The interviews occurred on 06/05/2018 at 11:50 AM.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

****This is a repeat deficiency as cited on the 05/05/2016 CLIA inspection**** Based on direct observation and interviews with the Office Manager (OM) and Technical Consultant (TC) #2, the laboratory failed to label reagents and solutions to indicate their identity, expiration date, and other pertinent information (lot number) required for use. Findings Include: 1. Direct observation of the laboratory's wet mount preparation solutions revealed multiple vacutainer tubes, "BD Vacutainer...Serum...Sterile..." with a clear liquid inside the tubes that were stored in a drawer in each of the patient procedure rooms. There was no additional labeling to indicate the identity of the contents, the expiration dates, and the lot numbers. 2. The Surveyor requested the identity, expiration date and lot number of the contents of the BD Vacutainer tubes from the OM and TC#2. The OM and TC#2 stated the contents of the vacutainer tubes was saline, confirmed the lack of labeling information, and were unable to provide the specific lot numbers and expiration dates of each vacutainer tube on the date of survey. The interviews occurred on 06/05/2018 at 12:15 PM.

D6047

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

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

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 TC failed to include direct observation of routine patient test performance, patient preparation, specimen handling, processing, and testing in the evaluation of the competency of testing personnel (TP) #1 and TP#2 for the fern testing performed. Findings Include: 1. Review of the laboratory's "Procedures for Laboratory Personnel Training and Evaluation" policy and procedure, provided on the date of the inspection, found instructions to include direct observation of routine patient test performance, patient preparation, specimen handling, processing, and testing in the evaluation of the competency of TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 06/05/2018, revealed two individuals, including the Laboratory Director, were indicated as TP and performed fern testing. 3. Review of the laboratory's 2016 and 2017 fern testing competency assessment records for TP#1 and TP#2 did not find any documentation that indicated direct observation of routine test performance including patient

identification, preparation, specimen collection, handling, processing and testing were included in the competency assessment of TP#1 and TP#2. 4. The Surveyor requested the laboratory's 2016 and 2017 fern testing competency assessment records for TP#1 and TP#2 that included direct observation of routine patient test performance, patient preparation, specimen handling, processing, and testing from the OM and TC#2. The OM and TC#2 confirmed the TC did not document the competency of TP#1 and TP#2, as required, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 06/05/2018 at 8:45 AM.

D6048

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

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test 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 TC failed to include monitoring of the recording and reporting of fern test results in the evaluation of the competency of testing personnel (TP) #1 and TP#2. Findings Include: 1. Review of the laboratory's "Procedures for Laboratory Personnel Training and Evaluation" policy and procedure, provided on the date of the inspection, found instructions to include monitoring of the recording and reporting in the evaluation of the competency of TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 06/05/2018, revealed two individuals, including the Laboratory Director, were indicated as TP and performed fern testing. 3. Review of the laboratory's 2016 and 2017 fern testing competency assessment records for TP#1 and TP#2 did not find any documentation that indicated monitoring of the recording and reporting were included in the competency assessment of TP#1 and TP#2. 4. The Surveyor requested the laboratory's 2016 and 2017 fern testing competency assessment records for TP#1 and TP#2 that included monitoring of the recording and reporting from the OM and TC#2. The OM and TC#2 confirmed the TC did not document the competency of TP#1 and TP#2, as required, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 06/05/2018 at 8:45 AM.

D6049

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

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

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 include the review of intermediate test results or worksheets, quality control (QC) records and preventive maintenance records in the evaluation of the competency of testing personnel (TP) #1 and TP#2. Findings Include: 1. Review of the laboratory's "Procedures for Laboratory Personnel Training and Evaluation" policy and procedure, provided on the date of the inspection, found instructions to include the review of intermediate test results or worksheets, QC records and preventive maintenance records in the evaluation of the

competency of TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 06/05/2018, revealed two individuals, including the Laboratory Director, were indicated as TP and performed fern testing. 3. Review of the laboratory's 2016 and 2017 fern testing competency assessment records for TP#1 and TP#2 did not find any documentation that indicated the review of intermediate test results or worksheets, QC records and preventive maintenance records were included in the competency assessment of TP#1 and TP#2. 4. The Surveyor requested the laboratory's 2016 and 2017 fern testing competency assessment records for TP#1 and TP#2 that included the review of intermediate test results or worksheets, QC records and preventive maintenance records from the OM and TC#2. The OM and TC#2 confirmed the laboratory did not document the competency of TP#1 and TP#2, as required, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 06/05/2018 at 8:45 AM.

D6050

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

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

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 TC failed to include direct observation of the performance of microscope maintenance and function checks in the evaluation of the competency of testing personnel (TP) #1 and TP#2. Findings Include: 1. Review of the laboratory's "Procedures for Laboratory Personnel Training and Evaluation" policy and procedure, provided on the date of the inspection, found instructions to include direct observation of the performance of microscope maintenance and function checks in the evaluation of the competency of TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 06/05/2018, revealed two individuals, including the Laboratory Director, were indicated as TP and performed fern testing. 3. Review of the laboratory's 2016 and 2017 fern testing competency assessment records for TP#1 and TP#2 did not find any documentation that indicated that direct observation of the performance of microscope maintenance and function checks were included in the competency assessment of TP#1 and TP#2. 4. The Surveyor requested the laboratory's 2016 and 2017 fern testing competency assessment records for TP#1 and TP#2 that included direct observation of the performance of microscope maintenance and function checks from the OM and TC#2. The OM and TC#2 confirmed the TC did not document the competency of TP#1 and TP#2, as required, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 06/05/2018 at 8:45 AM.

D6052

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

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

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 TC failed to include the assessment of problem solving skills in the evaluation of the competency of testing personnel (TP) #1 and TP#2. Findings Include: 1. Review of the laboratory's "Procedures for Laboratory Personnel Training and Evaluation" policy and procedure, provided on the date of the inspection, found instructions to include the assessment of problem solving skills in the evaluation of the competency of TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 06/05/2018, revealed two individuals, including the Laboratory Director, were indicated as TP and performed fern testing. 3. Review of the laboratory's 2016 and 2017 fern testing competency assessment records for TP#1 and TP#2 did not find any documentation that indicated that the assessment of problem solving skills were included in the competency assessment of TP#1 and TP#2. 4. The Surveyor requested the laboratory's 2016 and 2017 fern testing competency assessment records for TP#1 and TP#2 that included the assessment of problem solving skills from the OM and TC#2. The OM and TC#2 confirmed the TC did not document the competency of TP#1 and TP#2, as required, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 06/05/2018 at 8:45 AM.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:

****This is a repeat deficiency as cited on the 05/05/2016 and 09/17/2014 CLIA inspections**** Based on record review and interviews with the Office Manager (OM) and Technical Consultant (TC) #2, the Technical Consultant failed to evaluate and document the performance of testing personnel (TP) who were responsible for moderately complex testing, at least annually after the first year. Findings Include: 1. Review of the laboratory's "Procedures for Laboratory Personnel Training and Evaluation" policy and procedure, provided on the date of the inspection, found instructions for annual competency assessments after the first year of testing patient specimens. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 06/05/2018, revealed six individuals, including the Laboratory Director, were indicated as TP to perform moderately complex testing procedures. 3. Review of one out of two of the TP's 2016 and 2017 competency assessment records for fern testing procedures did not find any documentation that indicated that an annual competency assessment of TP#1 was conducted in 2017. 4. Review of two out of two of the TP's 2016 and 2017 competency assessment records for wet mount preparation and potassium hydroxide (KOH) testing procedures did not find any documentation that indicated that annual competency assessments of TP#1 and TP#2 were conducted in 2016 and 2017. 5. Review of two out of six of the TP's 2016 and 2017 competency assessment records for BD Affirm testing procedures did not find any documentation that indicated that annual competency assessments of TP#1 and TP#2 were conducted in 2016. 6. The Surveyor requested all of the laboratory's 2016 and 2017 competency assessment records for the above listed testing procedures for TP#1 and TP#2 from the OM and TC#2. The OM and TC#2 confirmed the laboratory

did not document the competencies of TP#1 and TP#2, as required, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 06/05/2018 at 8:45 AM.