

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D2132076	<b>(X3) Date Survey Completed</b>  01/27/2021
<b>Name of Provider or Supplier</b>  P & C Labs, Llc	<b>Street Address, City, State</b>  1099 Medical Center Circle, Mayfield, KY	
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>D5032</b>	<p>CYTOLOGY CFR(s): 493.1221</p> <p>If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures for an annual evaluation and comparison of three of three laboratory statistics (refer to D5629); failed to establish written policies and procedures to establish and reassess a workload limit for the Laboratory Director/Technical Supervisor and the Cytotechnologist (refer to D5633, D5637); failed to establish written policies and procedures to prorate the workload limit for the Laboratory Director/Technical Supervisor and the Cytotechnologist when examining slides in less than an eight hour day (refer to D5641); failed to document the total number of slides and number of hours spent examining slides in each 24-hour period for the Laboratory Director/Technical Supervisor and the Cytotechnologist (refer to D5645); failed to establish written policies and procedures to document the workload limit for the Laboratory Director/Technical Supervisor and the Cytotechnologist (refer to D5647) and failed to establish written policies and procedures to ensure that unsatisfactory cytology slide preparations were identified and reported as unsatisfactory (refer to D5655). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.</p>
<b>D5205</b>	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p>

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of documentation and interview it was determined that the laboratory failed to establish a system for the documentation of complaints reported to the laboratory during the years 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written procedure for documentation of complaints made to the laboratory. 2. The Survey Team requested and the laboratory failed to provide documentation of complaints made to the laboratory 3. During an interview with the Survey Team at 8:40 AM on January 27, 2021 the Laboratory Director/Technical Supervisor confirmed these findings.

**D5311**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**

CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to document the conditions required for the transportation of cytology specimens from Facility A (CLIA #18D2132076) to Facility B (CLIA #18D0648508) for the years 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the documentation of the conditions required for the transport of cytology specimens from Facility A to Facility B. 2. During an interview with the Survey Team at 2:15 PM on January 25, 2021 the Laboratory Director/Technical Supervisor confirmed these findings.

**D5407**

**PROCEDURE MANUAL**

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to ensure that four of seven written policies and procedures were approved, signed and dated by the Laboratory Director/Technical Supervisor. Findings include: 1. The Laboratory Director/Technical Supervisor failed to approve, sign and date four of seven laboratory procedures in the JPMC (Jackson Purchase Medical Center) CYTOLOGY MANUAL Procedures include: -Non-Genital

Procedures by Body Site -Anatomic Quality Assurance Indicator Procedures -PCL Quality Management Program -Frozen Sections Fixation, Staining and Rapid Staining for FNA's 2. During an interview with the Survey Team at 10:15 AM on January 27, 2021 the Laboratory Director/Technical Supervisor confirmed these findings.

**D5629**

**CYTOLOGY**  
CFR(s): 493.1274(c)(5)

(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of three of three required statistics for nongynecologic cytology. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of three required statistics for nongynecologic specimens. Statistics include: a. The number of cytology cases examined; b. The number of specimens processed by specimen type; c. The number of patient cases reported by diagnosis to include unsatisfactory. 2. During an interview with the Survey Team at 8:40 AM on January 27, 2021 the Laboratory Director/Technical Supervisor confirmed these findings.

**D5633**

**CYTOLOGY**  
CFR(s): 493.1274(d)(1)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that individual maximum workload limits were established for the Laboratory Director/Technical Supervisor and the Cytotechnologist during the years 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that individual maximum workload limits were established for the Laboratory Director/Technical Supervisor and the Cytotechnologist. 2. The Survey Team requested and the laboratory failed to provide documentation of an individual workload limit for the Laboratory Director/Technical Supervisor and the

	<p>Cytotechnologist for 2019, 2020 and to the date of the survey in 2021. 3. During an interview with the Survey Team at 1:30 PM on January 25, 2021 the Laboratory Director/Technical Supervisor confirmed these findings.</p>
<b>D5637</b>	<p><b>CYTOLOGY</b> CFR(s): 493.1274(d)(1)(ii)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limit for the Laboratory Director/Technical Supervisor and the Cytotechnologist was reassessed and adjusted when necessary at least every six months during the years 2019 and 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the reassessment and adjustment when necessary of workload limits at least every six months for the Laboratory Director/Technical Supervisor and the Cytotechnologist. 2. The Survey Team requested and the laboratory failed to provide documentation of a reassessed workload limit for the Laboratory Director/Technical Supervisor and the Cytotechnologist during the years 2019 and 2020. 3. During an interview with the Survey Team at 1:30 PM on January 25, 2021 the Laboratory Director/Technical Supervisor confirmed these findings.</p>
<b>D5641</b>	<p><b>CYTOLOGY</b> CFR(s): 493.1274(d)(2)(ii)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory polices and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limits for the Laboratory Director/Technical Supervisor and the Cytotechnolgist would be prorated when examining slides in less than eight hours. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limits for the Laboratory Director/Technical Supervisor and the Cytotechnologist when examining slides in less than an 8-hour day. 2. During an interview with the Survey Team at 1:30 PM on January 25, 2021 the Laboratory Director/Technical Supervisor confirmed these findings.</p>
<b>D5645</b>	<p><b>CYTOLOGY</b> CFR(s): 493.1274(d)(3)</p>

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to ensure that the laboratory maintained records for the Laboratory Director/Technical Supervisor and the Cytotechnologist of the total number of slides and the total number of hours spent evaluating slides per 24-hour period. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained records of the total number of slides and total number of hours spent evaluating slides in 2019, 2020 and to the date of the survey in 2021. 2. The Survey Team requested and the laboratory failed to provide records of the total number of slides and total number of hours the Laboratory Director/Technical Supervisor spent evaluating slides during each 24-hour period in 2019, 2020 and to the date of the survey in 2021. 3. During an interview with the Survey Team at 1:30 PM on January 25, 2021 the Laboratory Director/Technical Supervisor confirmed these findings.

**D5647**

CYTOLOGY

CFR(s): 493.1274(d)(4)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that records were available to document the workload limit for the Laboratory Director/Technical Supervisor and the Cytotechnologist for the years 2019, 2020 and to the date of the survey in 2021. Cross refer to D5633 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that records were available to document the workload limit for the Laboratory Director/Technical Supervisor and the Cytotechnologist. 2. During an interview with the Survey Team at 1:30 PM on January 25, 2021 the Laboratory Director/Technical Supervisor confirmed these findings.

**D5655**

CYTOLOGY

CFR(s): 493.1274(e)(4)

(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

This STANDARD is not met as evidenced by:

	<p>Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory. 2. During an interview with the Survey Team at 8:40 AM on January 27, 2021 AM the Laboratory Director/Technical Supervisor confirmed these findings.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.</p>
<p><b>D6079</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(a)(b)</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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5629, D5633, D5637, D5641, D5645, D5647 and D5655.</p>
<p><b>D6130</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(c)(2)(3)</p>

(c) In cytology, the technical supervisor or the individual qualified under 493.1449(k) (2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the Technical Supervisor failed to establish and reassess the workload limits at least every six months and make adjustments when necessary for the Technical Supervisor and the Cytotechnologist in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5633 and D5637

**D6133**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(c)(6)

In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of documentation and interview it was determined that the Technical Supervisor failed to document the number of slides and failed to document the number of hours devoted to examining slides during each 24-hour period in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5645

**D9999**

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