

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1037342	(X3) Date Survey Completed 05/30/2019
Name of Provider or Supplier Pathcare Diagnostics, Inc	Street Address, City, State 1810 Fullerton Ave Ste 102, Corona, CA	
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
D5032	<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 to assess the competency of the Laboratory Director/Technical Supervisor (refer to D5209); failed to establish written policies and procedures for the annual evaluation and comparison of three of three non-gynecologic statistics (refer to D5629); failed to establish written policies and procedures for establishing workload limits, reassessing workload limits, prorating workload and documenting the number of slides examined and hours spent examining slides (refer to D5633, D5637, D5641 and D5645); and failed to establish written policies and procedures to ensure that unsatisfactory non-gynecologic 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>
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>

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 assess the competency of the Laboratory Director/Technical Supervisor in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for assessing the competency of the Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for the Laboratory Director /Technical Supervisor who performed microscopic evaluations during 2017, 2018 and to the date of the survey in 2019. 3. During an interview on 5/29/2019 at 4:30 PM, 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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation for three of three required statistics in 2017 and 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical laboratory evaluation of three required non-gynecologic statistics. - Number of cytology cases examined; - Number of specimens processed by specimen type; - Number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). 2. The Survey Team requested and the laboratory failed to provide records of an evaluation of three non-gynecologic annual statistics for 2017, 2018 and to the date of the survey in 2019. 3. During an interview on 5/29/2019 at 4: 30 PM, 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 a maximum workload limit was established by the Laboratory Director/Technical Supervisor for the Laboratory Director/Technical Supervisor. There was no workload limit for the Laboratory Director/Technical Supervisor who performed the primary evaluation of non-gynecologic cytology specimen slide preparations in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that a maximum workload limit was established by the Laboratory Director/Technical Supervisor for the Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide an established workload limit for the Laboratory Director/Technical Supervisor for 2017, 2018 and to the date of the survey in 2019. 3. During an interview on 5/29/2019 at 4:30 PM, the Laboratory Director/Technical Supervisor confirmed these findings.

D5637

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

(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.

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 was reassessed at least every six months and adjusted when necessary in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how the laboratory would reassess the workload limit of the Laboratory Director/Technical Supervisor at least every six months and adjust when necessary. 2. During an interview on 5/29/2019 at 4:30 PM, the Laboratory Director/Technical Supervisor confirmed these findings.

D5641

CYTOLOGY
CFR(s): 493.1274(d)(2)(ii)

(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;

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 ensure that the workload limit for the Laboratory Director/Technical Supervisor, when examining slides in less than an 8-hour workday and with duties other than slide examination,

would be prorated using a period of eight hours to determine the number of slides that may be examined. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to determine how to prorate the workload limit for the Laboratory Director/ Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for the Laboratory Director/Technical Supervisor in 2017, 2018 and to the date of the survey in 2019. 3. During an interview on 5/29/2019 at 4:30 PM, the Laboratory Director/Technical Supervisor confirmed these findings.

D5645

CYTOLOGY
CFR(s): 493.1274(d)(3)

(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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the laboratory maintained records for the Laboratory Director /Technical Supervisor of the total number of slides examined and the number of hours spent examining slides in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory would maintain records of the total number of slides examined by the Laboratory Director/Technical Supervisor during each 24-hour period and the number of hours spent examining the slides during each 24-hour period. 2. The Survey Team requested and the laboratory failed to provide records of the total number of hours the Laboratory Director/Technical Supervisor spent examining slides during each 24-hour period in 2017, 2018 and to the date of the survey in 2019. 3. During an interview on 5/29/2019 at 4:30 PM, 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:
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 non-gynecologic cytology 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 describe the laboratory's process to ensure that unsatisfactory non-gynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. During an interview on 5/29/2019 at 4:30 PM, the Laboratory Director/Technical Supervisor confirmed these findings.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of laboratory records and interviews, 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.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of laboratory records and interviews 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 D5209, D5629, D5633, D5637, D5641, D5645, D5655

D6130

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(c)(2)(3)

(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 an

	<p>individual workload limit for the Laboratory Director/Technical Supervisor and failed to reassess the workload limit at least every six months and make adjustments when necessary in 2017, 2018 and to the date of the survey in 2019. Cross Refer to D5633 and D5637</p>
D6133	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the Laboratory Director/Technical Supervisor failed to document the number of hours devoted to examining slides in each 24-hour period for 2017, 2018 and to the date of the survey in 2019. Cross refer to D5645</p>
D9999	<p>By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.</p>