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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 38D0998803 | (X3) Date Survey Completed 02/15/2023 |
| Name of Provider or Supplier Medsurg Pathology Associates On Durham | Street Address, City, State 8192 Sw Durham Rd, Tigard, OR | |
| 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, specimen slides, and interviews the laboratory failed to establish written policies and procedures for an annual statistical comparison of three of three required nongynecologic statistics (refer to D5629); failed to establish written policies and procedures for the establishment, reassessment and documentation of individual workload limits (refer to D5633, D5637 and D5647); failed to establish written policies and procedures to prorate individual workload limits (refer to D5641); failed to establish written policies and procedures to ensure the laboratory maintained records of the total number of slides examined and the total number of hours spent examining slides per 24-hour period (refer to D5645); failed to establish written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory (refer to D5655); and failed to establish written policies and procedures to define the reporting system used for the descriptive nomenclature used to diagnose nongynecologic specimens (refer to D5657).</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> |

This STANDARD is not met as evidenced by:
Based on review of 47 laboratory policies and procedures, nongynecologic stain maintenance records and interview with the Laboratory Director/Technical Supervisor the laboratory failed to follow one written procedure. Findings include: 1. The procedure titled STAINING AND COVERSLIPPING PROCEDURE stated: "H. Changing the Stainer...-Filter Hematoxylin MWF, top off as needed -Filter Eosin once per month, top off as needed" 2. The Survey Team reviewed records titled RECORD OF FRESH REAGENTS USED. The laboratory failed to document the filtering of Hematoxylin and Eosin in 2021, 2022 and to the date of the survey in 2023. 3. During an interview on February 15, 2023 at 10:00 AM these findings were confirmed by Laboratory Director/Technical Supervisor.

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 statistical records and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics. The laboratory failed to document three of three required annual nongynecologic statistics for 2021 and 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics. Statistics include: -Number of nongynecologic cytology cases examined -Number of nongynecologic specimens processed by specimen type - Number of nongynecologic cases reported by diagnosis, including the number reported as unsatisfactory 2. The Survey Team requested and the laboratory failed to provide records of the three required annual statistics for 2021 and 2022. 3. During an interview on February 13, 2023 at 12:00 PM these findings were confirmed by Laboratory Director/Technical Supervisor.

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 and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure individual maximum workload limits were established for the Technical Supervisor who performed primary screening of nongynecologic cytology specimen slides. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the Technical Supervisor established individual maximum workload limits for the Technical Supervisor who performed primary screening of nongynecologic cytology specimen slides. 2. During an interview on February 13, 2023 at 8:53 AM these findings were confirmed by Laboratory Director/Technical Supervisor.

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 and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to reassess and adjust, when necessary, a maximum workload limit at least every six months for the Technical Supervisor who performed primary screening of nongynecologic cytology specimen slides. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor's workload limits would be reassessed at least every six months and adjusted when necessary. 2. During an interview on February 13, 2023 at 8:53 AM these findings were confirmed by Laboratory Director/Technical Supervisor.

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, lack of prorated workload limit records and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure that the workload limit for the Technical Supervisor would be prorated when examining slides in less than an eight-hour work day. The laboratory failed to provide documentation of a prorated workload limit for one of one Technical Supervisor in 2021, 2022 and to

the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limit for the Technical Supervisor when examining slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide records of a prorated workload limit for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Technical Supervisor includes: - Laboratory Director/Technical Supervisor 3. During an interview on February 13, 2023 at 8:53 AM these findings were confirmed by Laboratory Director/Technical Supervisor.

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 workload records and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure the laboratory maintained records of the total number of slides the Technical Supervisor examined per 24-hour period and the number of hours spent examining slides per 24-hour period. Cross refer to D6133 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the laboratory maintained records of the total number of slides the Technical Supervisor examined per 24-hour period and the number of hours spent examining slides per 24-hour period. 2. During an interview on February 13, 2023 at 8:53 AM these findings were confirmed by Laboratory Director/Technical Supervisor.

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 workload establishment records and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limit for the Technical Supervisor who performed primary screening of nongynecologic cytology specimen slides. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Technical Supervisor includes: -

Laboratory Director/Technical Supervisor 3. During an interview on February 13, 2023 at 8:53 AM these findings were confirmed by Laboratory Director/Technical Supervisor.

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, cytology slide preparations and corresponding final test reports and interview with the Laboratory Director /Technical Supervisor the laboratory failed to establish written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report one of seven nongynecologic cytology slide preparations from 2018 to 2023 as "Unsatisfactory for Evaluation". Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. The laboratory failed to identify and report one of seven nongynecologic cytology slide preparations from 2018 to 2023 as "Unsatisfactory for Evaluation" due to insufficient cellularity. Case includes: -MS19-1114 3. During an interview on February 15, 2023 at 10:00 AM these findings were confirmed by Laboratory Director/Technical Supervisor.

D5657

CYTOLOGY
CFR(s): 493.1274(e)(5)

(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. 2. During an interview on February 15, 2023 at 10:00 AM these findings were confirmed by Laboratory Director/Technical Supervisor.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to

process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of competency assessment records and interview the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of the Technical Supervisor who conducted analytic and postanalytic phases of cytology testing. The Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of the Grossing Technician who conducted preanalytic phases of cytology testing. The Laboratory Director failed to provide documentation of a competency assessment for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess, monitor and maintain the competency of the Technical Supervisor who conducted analytic and postanalytic phases of cytology testing. a. The Survey Team requested and the Laboratory Director failed to provide documentation of competency assessments for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 2. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess, monitor and maintain the competency of the Grossing Technician who conducted preanalytic phases of cytology testing. 3. During an interview on February 15, 2023 at 10:00 AM these findings were confirmed by Laboratory Director /Technical Supervisor.

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on microscopic review of 85 negative nongynecologic cases/162 slides and the corresponding final test reports from January 2018 through February 2023 and confirmation by Technical Supervisor on February 14, 2023 the Technical Supervisor failed to verify the accuracy of one nongynecologic cytology test. 1. MS19-1114 01/17 /2019 Fine Needle Aspiration, Left Neck LABORATORY DIAGNOSIS: No evidence of malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for evaluation due to scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for evaluation due to paucicellularity

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 written policies and procedures, lack of workload limit records and interview, the Technical Supervisor failed to establish individual workload limits and to reassess the workload limits at least every six months for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Cross refer to D5633 and D5637 Findings include: 1. The Survey Team requested and Technical Supervisor failed to provide documentation that Technical Supervisor established a maximum workload limit for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. (Refer to D5633) Technical Supervisor includes: -Technical Supervisor 2. The Survey Team requested and Technical Supervisor failed to provide records of a workload reassessment at least every six months for one of one Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. (Refer to D5637) Technical Supervisor includes: -Technical Supervisor 3. During an interview on February 13, 2023 at 8:53 AM these findings were confirmed by the Laboratory Director/Technical Supervisor.

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 polices and procedures, lack of laboratory workload records and interview with the Laboratory Director/Technical Supervisor one of one Technical Supervisor performing primary screening of nongynecologic cytology specimen slides failed to document the number of slides screened and the number of hours devoted to screening slides during each 24-hour period in 2021, 2022 and to the date of the survey in 2023. Cross refer to D5645 Findings include: 1. The Survey Team requested and the laboratory failed to provide records of the total number of slides screened and the total number of hours one of one Technical Supervisor devoted to screening nongynecologic cytology specimen slides during each 24-hour period in 2021, 2022 and to the date of the survey in 2023. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 2. During an interview on February 13, 2023 at 8:53 AM these findings were confirmed by Laboratory Director /Technical Supervisor.

D9999

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