

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2051233	(X3) Date Survey Completed 10/20/2023
Name of Provider or Supplier Pathologists Biomedical Labs, Pllc	Street Address, City, State 2701 Hospital Drive, Victoria, TX	
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 the laboratory failed to establish and follow written policies and procedures for the establishment, reassessment and documentation of individual workload limits (refer to D5633, D5637 and D5647); failed to establish and follow written policies and procedures to ensure that workload limits would be prorated when examining slides in less than eight hours (refer to D5641); failed to establish and follow 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); and failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified with the preparation of nongynecologic cytology specimen slides during the microscopic examination of the specimen slides (refer to D5791).</p>
D5633	<p>CYTOLOGY CFR(s): 493.1274(d)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory policies and procedures, lack of workload limit records and interview the laboratory failed to establish and follow written policies and procedures to establish an individual maximum workload limit for each Technical Supervisor who performed primary screening of nongynecologic cytology specimens. The Technical Supervisor failed to establish an individual maximum workload limit for three of three Technical Supervisors in January through December 2022 and January 2023 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 detail how the Technical Supervisor would establish maximum workload limits for each Technical Supervisor who performed primary screening of nongynecologic cytology specimens. 2. The Survey Team requested and the laboratory failed to provide documentation that the laboratory Technical Supervisor established an individual maximum workload limit for three of three Technical Supervisors in January through December 2022 and January 2023 to the date of the survey in 2023. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C 3. During an interview on October 17, 2023 at 10:10 AM, the Laboratory Director/Technical Supervisor A and Laboratory Practice Manager 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 workload limit reassessment records and interview the laboratory failed to establish and follow written policies and procedures to reassess and adjust when necessary, a maximum workload limit at least every six months for the Technical Supervisors who performed primary screening of nongynecologic cytology specimens. The Technical Supervisor failed to reassess a maximum workload limit for three of three Technical Supervisors in January through December 2022 and January 2023 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 detail how the Technical Supervisor would reassess a maximum workload limit for the Technical Supervisors at least every six months and adjust when necessary. 2. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor reassessed a maximum workload limit for three of three Technical Supervisors in January through December 2022 and January 2023 to the date of the survey in 2023. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C 3. During an interview on October 17, 2023 at 10:10 AM, the Laboratory Director /Technical Supervisor A and Laboratory Practice Manager 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, lack of workload limit records and interview the laboratory failed to establish and follow written policies and procedures to ensure that workload limits for the Technical Supervisors would be prorated when examining slides in less than an eight-hour work day. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate workload limits for the Technical Supervisors when examining slides in less than an eight-hour day, or with duties other than examining cytology specimen slides. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for three of three Technical Supervisors when examining slides in less than eight hours. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C 3. During an interview on October 17, 2023 at 10:10 AM, the Laboratory Director /Technical Supervisor A and Laboratory Practice Manager 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 and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish and follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined by each individual per 24-hour period and the number of hours individuals spent examining 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 examined by each individual per 24-hour period and the number of hours individuals spent examining slides per 24-hour period. 2. During an interview on October 16, 2023 at 10:50 AM, the Laboratory Director/Technical Supervisor A confirmed that the policy titled MANUAL CYTOPATHOLOGY SCREENING failed to establish a method to maintain the total number of slides evaluated by individuals or the number of hours each individual spent examining slides. Cross refer to D6133

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 workload limit records and interview the laboratory failed to establish and follow written policies and procedures to ensure records were available to document the workload limit for three of three Technical Supervisors who performed primary screening of nongynecologic cytology specimens in January through December 2022 and January 2023 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 Supervisors who performed primary screening of nongynecologic cytology specimens. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for three of three Technical Supervisors who performed primary screening of nongynecologic cytology specimens in January through December 2022 and January 2023 to the date of the survey in 2023. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C 3. During an interview on October 17, 2023 at 10:10 AM, the Laboratory Director/Technical Supervisor A and Laboratory Practice Manager confirmed these findings.

D5659

CYTOLOGY
 CFR(s): 493.1274(e)(6)

(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction.

This STANDARD is not met as evidenced by:
 Based on review of laboratory policies and procedures and interviews the laboratory failed to establish and follow written policies and procedures to ensure corrected cytology test reports indicated the basis for the correction on the test report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected cytology test reports indicated the basis for the correction on the test report. 2. During an interview on October 19, 2023 at 8:15 AM, the Survey Team reviewed the laboratory procedure titled PATHOLOGY REPORTS with the Laboratory Practice Manager. The procedure stated: "9. Any amendments to a final pathology and/or cytology report are amended by the pathologist on the case. A note is made in the computer system to indicate how and why the report was amended." a. The Laboratory Practice Manager confirmed that the laboratory policy was to "make a note in the internal system" and that the basis for the correction "was not in the final test report." The Laboratory Practice Manager confirmed there were no written policies or procedures to ensure the basis for the correction was on the corrected test report. 3. During an interview on October 19, 2023 at 10:20 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
 Based on review of laboratory policies and procedures, laboratory records, specimen slide preparations and interviews it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified with the preparation of nongynecologic cytology specimen slides during the microscopic examination of the specimen slides. The laboratory failed to document quality assessment activities related to excessively thick nongynecologic cytology specimen slide preparations from January 2023 to the date of the survey in 2023. Findings include: 1. The written policy and procedure PATHOLOGISTS DAILY ASSESSMENT OF CYTOLOGY SLIDE QUALITY stated: "Appropriate processing of material for cytologic assessment is imperative to promote optimal cytologic slide interpretation by the pathologist. Because slide interpretation is partially dependent on the technical quality of the cytologic preparation, there must be a process whereby pathologists can provide direct feedback to the cytology technical staff regarding the technical quality of the slide preparation. POLICY ACTION AND RATIONALE: The below form ("CYTOLOGY DAILY QUALITY ASSESSMENT RECORD") provides this mechanism for direct feedback." 2. The Survey Team requested and the laboratory failed to document the identification of technical quality problems of nongynecologic cytology specimen slide preparations. The laboratory failed to document the identification of technical quality of cytologic preparations of specimen slides on the CYTOLOGY DAILY QUALITY ASSESSMENT RECORD from January 2023 to the date of the survey in 2023. 3. The Survey Team observed 28 of 214 cases that included problems with the technical quality of the nongynecologic specimen slide preparations. The specimen slide preparations were excessively thick, specimen was migrating outside of the intended specimen preparation area on the slide and the specimen slide was compromised with obscuring air bubbles due to the excessively thick preparation. The result of the thick preparations limited the microscopic evaluation of the material on the specimen slide. Cases include: -C-23-0002 -C-23-0019 -C-23-0188 -C-23-0234 -C-23-0269 -C-23-0320 -C-23-0340 -C-23-0634 -C-23-0757 -C-23-0818 -C-23-0888 -C-23-1193 -C-23-1233 -C-23-1303 -C-23-1440 -C-23-1850 -C-23-2007 -C-23-2159 -C-23-2171 -C-23-2212 -C-23-2703 -C-23-3134 -C-23-3274 -C-23-3327 -C-23-3417 -C-23-3423 -C-23-3754 -C-23-3782 4. During interviews on October 18, 2023 at 10:40 AM and 1:40 PM Technical Supervisor B and the Laboratory Practice Manager confirmed these findings.

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 the lack of workload limit records and interview the Technical Supervisor failed to establish and reassess a maximum workload limit for three of three Technical Supervisors in January through December 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The Technical Supervisor failed to provide documentation that the Technical Supervisor established a maximum workload limit for three of three Technical Supervisors who performed primary nongynecologic

cytology slide examinations in January through December 2022 and January 2023 to the date of the survey in 2023. Refer to D5633 and D5647 2. The Technical Supervisor failed to provide documentation that the Technical Supervisor reassessed a workload limit at least every six months for three of three Technical Supervisors who performed primary nongynecologic cytology slide examinations in January through December 2022 and January 2023 to the date of the survey in 2023. Refer to D5637 and D5647 3. During an interview on October 17, 2023 at 10:10 AM, the Laboratory Director/Technical Supervisor A and Laboratory Practice Manager confirmed these findings.

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 workload records and interview with Technical Supervisor A and Technical Supervisor B three of three Technical Supervisors failed to document the number of slides evaluated and the number of hours devoted to screening slides during each 24-hour period in January through December 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. Three of three Technical Supervisors failed to document the total number of slides evaluated during each 24-hour period in January through December 2022 and January 2023 to the date of the survey in 2023. Technical Supervisors include: -Technical Supervisor A - Technical Supervisor B -Technical Supervisor C a. During an interview on October 16, 2023 at 10:50 AM, Technical Supervisor A and Technical Supervisor B confirmed that the CYTOLOGY DAILY QUALITY ASSESSMENT RECORD and DAILY CYTOLOGY SLIDE COUNT documents for January through December 2022 and January 2023 through September 2023 failed to include the total number of slides evaluated and specifically did not include the number of cytology cell block slides evaluated. 2. Three of three Technical Supervisors failed to document the number of hours devoted to screening slides during each 24-hour period in January through December 2022 and January 2023 to the date of the survey in 2023. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C a. During an interview on October 16, 2023 at 10:50 AM, Technical Supervisor A and Technical Supervisor B confirmed that the CYTOLOGY DAILY QUALITY ASSESSMENT RECORD and DAILY CYTOLOGY SLIDE COUNT documents for January through December 2022 and January 2023 through September 2023 failed to include the time the Technical Supervisors devoted to screening slides during each 24-hour period that slides were screened.

D9999

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