

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2265726	(X3) Date Survey Completed 08/23/2023
Name of Provider or Supplier Wise Pathology Laboratories, Llc	Street Address, City, State 609 Medical Center Dr Suite 2300, Decatur, 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
D0000	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures, patient test records, and confirmed in interview, the laboratory failed to ensure patient histopathology and cytology slides were labeled with at least 2 unique patient identifiers 15 of 24 slides in 2023 (random review). Findings included 1. Review of the laboratory procedure titled "HISPDN FINE NEEDLE ASPIRATION" revealed: "6.0 Procedure ... 6.1.4 Label an appropriate number of positively charged slides with the patient's last name and date of birth." The laboratory policy did not include labeling instructions to reliably identify patients using at least 2 unique patient identifiers to distinguish between specimens. 2. A random review of patient slides from 2023 revealed 15 slides labeled with laboratory accession number, slide number, stain/slide type, patient last name and first initial. The laboratory failed to ensure patient histopathology and cytology slides were labeled with at least 2 unique patient identifiers. 3. During an interview on 08/23/2023 at 2:18 pm, the Laboratory Director confirmed the above findings.</p>
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:

Based on direct observation and staff interview, the laboratory failed to ensure 2 of 2 reagents stored in secondary containers were labeled with proper identification, concentration, and poured/expiration dates. The findings included: 1. During a tour of the laboratory on 08/23/2023 at 12:38 pm, the surveyor observed the following in the storage room refrigerator: 1 coplin jar labeled: CHEMICAL: "METHENAMINE SILVER SOL" OWNER: "STATLAD KIT" MADE DATE: blank 1 coplin jar labeled: CHEMICAL: "AMMONIUM Silver" OWNER: "STATLAD" MADE DATE: blank The laboratory failed to label the secondary containers with lot numbers, concentration, and poured/expiration dates. Without proper labeling, the reagent could not be linked to an original container and therefore the expiration dates could not be determined. 2. During an interview on 08/23/2023 at 12:38 pm, the Histotechnician confirmed the laboratory failed to ensure reagents stored in secondary containers were labeled with proper identification, concentration, and poured /expiration dates.

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 written laboratory procedures, review of annual test counts and staff interview, the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established for 2 of 2 testing personnel performing cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations in 2022 until the date of the inspection in 2023. Findings included: 1. Review of the procedure manual found no written policy to ensure that the technical supervisor established a maximum workload limit for each testing personnel performing cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations. 2. Review of the annual test counts found the laboratory reported performing 408 cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations. 3. During an interview on 08/23/2023 at 11:36 am, the Laboratory Director confirmed the laboratory did not have a procedure to establish workload limits for the pathologists performing cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations.

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 written laboratory procedures, review of annual test counts and staff interview, the laboratory failed to establish written policies and procedures to reassess the workload limits at least once every six months for 2 of 2 testing personnel performing cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations in 2022 until the date of the inspection in 2023. Findings included: 1. Review of the procedure manual found no written policy to ensure that testing personnel workload limits were reassessed at least every six months for each testing personnel performing cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations. 2. Review of the annual test counts found the laboratory reported performing 408 cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations. 3. During an interview on 08/23/2023 at 11:36 am, the Laboratory Director confirmed the laboratory did not reassess workload limits for the pathologists performing cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations at least once every six months.

D5639

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

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;

This STANDARD is not met as evidenced by:
Based on the review of laboratory procedures, review of annual test counts and interview of facility personnel, the laboratory failed to establish written policies and procedures to ensure two of two testing personnel examined no more than 100 slides in an eight-hour workday in 2022 until the date of the inspection in 2023. Findings included: 1. Review of the procedure manual found no written policy to ensure each testing personnel performing cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations reviewed no more than 100 slides in a 24-hour period. 2. Review of the annual test counts found the laboratory reported performing 408 cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations. 3. During an interview on 08/23/2023 at 11:36 am, the Laboratory Director confirmed the laboratory did not have a procedure in place to ensure maximum workload limits for the pathologists performing cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations were not exceeded.

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 the review of written laboratory procedures, review of annual test counts and interview of facility personnel, the laboratory failed to establish written policies and procedures to ensure that slide examination records were maintained for 2 of 2 testing personnel performing cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations, to include the number of slides examined by each individual in a 24-hour period in 2022 until the date of the inspection in 2023. Findings included: 1. Review of the procedure manual found no written policy to ensure that slide examination records were maintained to include the total number of slides examined by each individual in a 24-hour period for each individual examining slides. 2. Review of the annual test counts found the laboratory reported performing 408 cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations. 3. During an interview on 08/23/2023 at 11:36 am, the Laboratory Director confirmed the laboratory did not maintain records that include the number of slides examined in a 24-hour period for the pathologists performing cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations at least once every six months.

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 staff interview, the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for the two of two testing persons performing cytology slide interpretation for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations in 2022 and to the date of the survey in 2023. Findings included: 1. Review of laboratory policies and procedures revealed the laboratory failed to have written policies and procedures to ensure records were available to document the workload limit for testing personnel performing cytology slide interpretation for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations. 2. The laboratory was asked to provide records of an established maximum workload limit for testing personnel performing cytology slide interpretation for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations 2022 and to the date of the survey in 2023. None were provided. 3. During an interview on 08/23/2023 at 11:36 am, the Laboratory Director confirmed the findings.

D5651

CYTOLOGY

CFR(s): 493.1274(e)(2)

(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(2) The report of gynecologic slide preparations with conditions specified in paragraph (e)(1) of this section must be

signed to reflect the technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, patient reports and staff interview laboratory failed to establish and follow written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report non gynecologic cytology test results. Findings included: 1. Review of laboratory policies and procedures revealed the laboratory failed to define the criteria used and the system of narrative descriptive nomenclature to report non gynecologic cytology test results. 2. A random review of patient reports revealed the following 1 of 5 patients were reported using the Bethesda category for which the laboratory failed to define the criteria used and the system of narrative descriptive nomenclature to report non gynecologic cytology test results: Patient ID: WC23-00214; date reported 08/09/2023 3. During an interview on 08/23/2023 at 2:18 pm, the Laboratory Director confirmed the above 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 review of written laboratory procedures, review of annual test counts and staff interview, the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established and reassessed at least once every six months for two of two testing personnel performing cytology slide interpretations for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations in 2022 until the date of the inspection in 2023. Refer to D5633, D5637, and D5639.

D6131

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(c)(4)

In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2) must perform the functions specified in 493.1257(d) and (e).

This STANDARD is not met as evidenced by:

Based on the review of written laboratory procedures, review of annual test counts and interview of facility personnel, the laboratory failed to establish written policies and procedures to ensure that slide examinations did not exceed the maximum count of 100 slides in 24 hours, workload limits were reassessed at least once every six months and records were maintained for all testing personnel performing cytology slide interpretation for Fine Needle Aspirate (FNA) and pleural/peritoneal aspirations, to include the number of slides examined by each individual in a 24-hour period in 2022 until the date of the inspection in 2023. Refer to D5633, D5637, D5639, D5645 and D5647.