

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2250813	<b>(X3) Date Survey Completed</b>  09/23/2022
<b>Name of Provider or Supplier</b>  Westwater Diagnostics Pllc	<b>Street Address, City, State</b>  407 E 25th St, Houston, TX	
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>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
<b>D5629</b>	<p>CYTOLOGY CFR(s): 493.1274(c)(5)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and staff interview, it was revealed that the laboratory failed to establish a written policy for an annual statistical evaluation of the number of non-gynecologic cytology cases reported as unsatisfactory. Findings include: 1. A review of the laboratory's policies revealed the laboratory failed to have a written policy for an annual statistical laboratory evaluation of the number of non-gynecologic cytology cases reported by diagnosis, to include unsatisfactory. 2. An interview with Technical Supervisor #2 on 9/23/22 at 10:30 a.m. in the laboratory, after review of the records, confirmed the above findings.</p>

**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 a review of laboratory's policies, the laboratory's records, and staff interview, it was revealed that the laboratory failed to establish written policies to ensure that the workload limit for two of two Technical Supervisors was reassessed at least every six months and adjusted when necessary in 2022. Findings include: 1. A review of the laboratory's policies revealed the laboratory failed to provide written policies to ensure that workload limits for two Technical Supervisors were reassessed at least every six months and adjusted when necessary in 2022. 2. A review of the laboratory's records revealed Technical Supervisor #1 and Technical Supervisor #2 started evaluating non-gynecologic cytology slides in January 2022. 3. Further review of the laboratory's record revealed there was no documentation of the reassessment of the workload limit for either Technical Supervisor by the time of the survey (elapsed time: 8 months). 4. An interview with Technical Supervisor #2 on 9/23/22 at 10:50 a. m. in the laboratory, after review of the records, confirmed the above 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's policies and staff interview, it was revealed that the laboratory failed to establish written policies to ensure that the laboratory maintained records of the total number of hours each technical supervisor spent evaluating non-gynecologic cytology slides during each 24-hour period. Findings include: 1. A review of the laboratory's policies revealed the laboratory failed to provide written policies to ensure that the laboratory maintained records of the total number of hours each technical supervisor spent evaluating slides during each 24-hour period. 2. An interview with Technical Supervisor #2 on 9/23/22 at 10:35 a.m. in the laboratory, after review of the records, confirmed the above findings.