

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2091956	(X3) Date Survey Completed 03/22/2023
Name of Provider or Supplier Ut Medical Group, Inc	Street Address, City, State 877 Jefferson Ave, Chandler Building, 4th Fl &, Memphis, TN	
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, lack of laboratory records and interviews the laboratory failed to establish written policies and procedures for an annual statistical evaluation for three of three nongynecologic cytology 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 ensure that the workload limit would be prorated when examining slides in less than eight hours (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) and failed to establish written policies and procedures to ensure unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory (refer to D5655).</p>
D5629	<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</p>

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 nongynecologic cytology statistic records and an interview with the Pathology Manager it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation for three of three required nongynecologic cytology statistics. The laboratory failed to document three of three required nongynecologic statistics for 2021 and 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation for three of three required nongynecologic cytology statistics. Statistics include: -The number of cytology cases examined -The number of specimens processed by specimen type -The number of patient cases reported by diagnosis, including the number reported as unsatisfactory 2. The Survey Team requested and the laboratory failed to provide the three of three required nongynecologic cytology statistics for 2021 and 2022. Statistics include: -The number of cases examined -The number of specimens processed by specimen type -The number of patient cases reported by diagnosis, including the number reported as unsatisfactory 3. During an interview on March 21, 2023 at 12:15 PM, the Pathology Manager 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 workload limit records and interviews the laboratory failed to establish written policies and procedures to ensure Technical Supervisor A established maximum workload limits for seven of seven Technical Supervisors who performed primary screening of nongynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure Technical Supervisor A established maximum workload limits for seven of seven Technical Supervisors who performed primary screening of nongynecologic cytology specimens. 2. During interviews on March 20, 2023 at 4:00 PM with Technical Supervisor B and on March 21, 2023 at 12:15 PM with the Pathology Manager these findings were confirmed.

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 individual workload limit records and interviews 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 seven of seven Technical Supervisors. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how Technical Supervisor A would reassess and adjust a maximum workload limit for seven of seven Technical Supervisors at least every six months and adjust when necessary. 2. During interviews on March 20, 2023 at 4:00 PM with Technical Supervisor B and on March 21, 2023 at 12:15 PM with the Pathology Manager these findings were confirmed.

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 interviews the laboratory failed to establish written policies and procedures to ensure that the workload limit for seven of seven Technical Supervisors would be prorated when examining slides in less than eight hours. The laboratory failed to prorate workload limits for seven of seven Technical Supervisors 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 limits for seven of seven Technical Supervisors when examining slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for seven of seven Technical Supervisors when examining slides in less than eight hours. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B - Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F -Technical Supervisor G 3. During interviews on March 20, 2023 at 4:00 PM with Technical Supervisor B and on March 21, 2023 at 12:15 PM with the Pathology Manager these findings were confirmed.

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 workload limit records and interviews the laboratory failed to establish written policies and procedures to ensure the laboratory maintained records of the total number of slides examined per 24-hour period and the number of hours 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 per 24-hour period and the number of hours spent examining slides per 24-hour period. 2. During interviews on March 20, 2023 at 4:00 PM with Technical Supervisor B and on March 21, 2023 at 12:15 PM with the Pathology Manager these findings were confirmed.

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 interviews the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for seven of seven Technical Supervisors 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 Supervisors. 2. The Survey Team requested and the laboratory failed to provide records of an established maximum workload limit for seven of seven Technical Supervisors in 2021, 2022 and to the date of the survey in 2023. Technical Supervisors include: - Laboratory Director/Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E - Technical Supervisor F - Technical Supervisor G 3. During interviews on March 20, 2023 at 4:00 PM with Technical Supervisor B and on March 21, 2023 at 12:15 PM with the Pathology Manager these findings were confirmed.

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 interviews it was determined that the laboratory failed to establish written policies and procedures to ensure unsatisfactory non-gynecologic cytology slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the

	<p>laboratory failed to provide written policies and procedures to ensure that unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory for evaluation. 2. During interviews on March 20, 2023 at 4:00 PM with Technical Supervisor B and on March 21, 2023 at 12:15 PM with the Pathology Manager these findings were confirmed.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interviews 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 ensure that quality control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur (refer to D6093); failed to ensure quality assessment programs were established to assure the quality of cytology services and identify failures in quality as they occur (refer to D6094) and failed to follow written policies and procedures to assess the competency of seven Technical Supervisors, and when necessary identify methods to improve the skills of the Technical Supervisors (refer to D6103).</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of cytology quality control records and interviews it was determined that the Laboratory Director failed to ensure that quality control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Laboratory Director failed to ensure written policies and procedures for quality control programs were established and maintained for cytology. 2. The Laboratory Director failed to ensure records were maintained for a quality control program in cytology for 2021, 2022 and to the date of the survey in 2023. 3. During interviews on March 20, 2023 at 4:00 PM with Technical Supervisor B and on March 21, 2023 at 12:15 PM with the Pathology Manager these findings were confirmed.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:
 Based on review of laboratory policies and procedures, lack of quality assessment activity records and interview with the Pathology Manager it was determined that the Laboratory Director failed to ensure quality assessment programs were established to assure the quality of cytology services and identify failures in quality as they occur in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Laboratory Director failed to ensure written policies and procedures were established for a quality assessment program for all phases of cytology testing. 2. The Laboratory Director failed to ensure records were maintained for a quality assessment program in cytology for 2021, 2022 and to the date of the survey in 2023. 3. During an interview on March 21, 2023 at 12:15 PM, the Pathology Manager confirmed these findings.

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 with the Pathology Manager, the Laboratory Director failed to follow written policies and procedures to assess the competency of the Technical Supervisors. The Laboratory Director failed to assess the competency of seven of seven Technical Supervisors in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Laboratory Director failed to ensure the procedure COMPETENCY ASSESSMENT was followed. The policy stated: "To define the elements of competency test for laboratory testing personnel and to describe the incorporation of these elements into the annual performance evaluation process." 2. The Laboratory Director failed to provide documentation of competency assessments of seven of seven Technical Supervisors in 2021, 2022 and to the date of the survey in 2023. Technical Supervisors include: -Laboratory Director/Technical Supervisor A - Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F -Technical Supervisor G 3. During an interview on March 22, 2023 at 11:00 AM, the Pathology 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 interviews Technical Supervisor A

failed to establish a maximum workload limit and reassess workload limits at least every six months for seven of seven Technical Supervisors, who performed primary cytology slide examinations 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 the laboratory failed to provide records that Technical Supervisor A established a maximum workload limit for seven of seven Technical Supervisors who performed primary cytology slide examinations in 2021, 2022 and to the date of the survey in 2023. (refer to 5633) Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F -Technical Supervisor G 2. The Survey Team requested and the laboratory failed to provide records that Technical Supervisor A reassessed a workload limit at least every six months for seven of seven Technical Supervisors who performed primary cytology slide examinations in 2021, 2022 and to the date of the survey in 2023. (refer to 5637) Technical Supervisor includes: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F -Technical Supervisor G 3. During interviews on March 20, 2023 at 4:00 PM with Technical Supervisor B and on March 21, 2023 at 12:15 PM with the Pathology Manager these findings were confirmed.

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 the lack of cytology workload records and interviews it was determined that seven of seven 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 seven of seven Technical Supervisors devoted to screening cytology specimen slides during each 24-hour period in 2021, 2022 and to the date of the survey in 2023. (refer to D5645) Technical Supervisor includes: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F -Technical Supervisor G 2. During interviews on March 20, 2023 at 4:00 PM with Technical Supervisor B and on March 21, 2023 at 12:15 PM with the Pathology Manager these findings were confirmed.

D9999

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