

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2060418	(X3) Date Survey Completed 11/18/2020
Name of Provider or Supplier Wiregrass Urology	Street Address, City, State 4300 West Main Street, Suite 102, Dothan, AL	
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 it was determined that the laboratory failed to establish written policies and procedures for the annual evaluation and comparison of three of three laboratory statistics (refer to D5629); failed to establish written policies and procedures to establish and reassess a workload limit for the Laboratory Director/Technical Supervisor (refer to D5633, D5637); failed to establish written policies and procedures to prorate the workload limit for the Laboratory Director/Technical Supervisor when examining slides in less than an eight hour day (refer to D5641); failed to establish written policies and procedures to maintain records of the total number of slides examined per 24 hour period (refer to D5645); failed establish written policies and procedures to document the workload limit for individuals examining slides (refer to D5647) and failed to establish written policies and procedures to ensure that unsatisfactory cytology slide preparations were identified and reported as unsatisfactory (refer to D5655). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.</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</p>

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 written policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for an annual evaluation of three required nongynecologic annual statistics during the years 2018 and 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual evaluation of the following three required annual statistics: a. The number of cytology cases examined; b. The number of specimens processed by specimen type; c. The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). 2. During a telephone interview on November 17, 2020 at 9:00 AM the Laboratory Director/Technical Supervisor confirmed there were no written procedures for evaluation of annual statistics.

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 policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that an individual maximum workload limit was established for the Laboratory Director/Technical Supervisor during the years 2018 and 2019 and to the date of the survey in 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that an individual maximum workload limit was established for the Laboratory Director/Technical Supervisor who performed the primary evaluation of nongynecologic cytology specimens. 2. The Survey Team requested and the laboratory failed to provide documentation of an individual workload limit for the Laboratory Director/Technical Supervisor for 2018, 2019 and to the date of the survey in 2020. 3. During a telephone interview with the Survey Team on November 17, 2020 at 9:00 AM the Laboratory Director/Technical Supervisor confirmed that there were no written policies and procedures for or records of workload limits.

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 policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limit for the Laboratory Director /Technical Supervisor was reassessed at least every six months during the years 2018, 2019 and 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the reassessment of workload limits at least every six months for the Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide documentation of a reassessed workload limit for the Laboratory Director/Technical Supervisor during the years 2018, 2019 and 2020. 3. During a telephone interview with the Survey Team on November 17, 2020 at 9:00 AM the Laboratory Director/Technical Supervisor confirmed the lack of written policies and procedures for or records of a six month reassessment of workload limits.

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 written laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limits for the Laboratory Director /Technical Supervisor would be prorated when examining slides in less than eight hours. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies or procedures to prorate the workload limits for the Laboratory Director/Technical Supervisor when examining slides in less than an 8-hour day. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for the Laboratory Director/Technical Supervisor during the years 2018 and 2019 and to the date of the survey in 2020. 3. During a telephone interview with the Survey Team on November 17, 2020 at 9:00 AM the Laboratory Director/Technical Supervisor confirmed that the laboratory did not have written policies and procedures for prorating the workload limit based on the examination of slides in less than eight hours.

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 written laboratory policies and procedures and interview it was determined that the laboratory failed to ensure that the laboratory maintained records for the Laboratory Director/Technical Supervisor of the total number of hours spent evaluating slides in 2018, 2019 and to the date of the survey in 2020. 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 hours spent evaluating slides in 2018, 2019 and to the date of the survey in 2020. 2. The Survey Team requested and the laboratory failed to provide records of the total number of hours the Laboratory Director/Technical Supervisor spent evaluating slides during each 24-hour period in 2018, 2019 and to the date of the survey in 2020. 3. During a telephone interview with the Survey Team on November 17, 2020 at 9:00 AM, the Laboratory Director/Technical Supervisor confirmed that the laboratory did not have written policies and procedures for documenting the total number of hours spent in examining slides for each 24 hour period.

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 written laboratory policies and procedures and interview, it was determined that the laboratory failed to establish written policies and procedures to ensure that records were available to document the workload limit for the Laboratory Director/Technical Supervisor for the years 2018, 2019 to the date of the survey in 2020. Cross refer to D5633 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that records were available to document the workload limit for the Laboratory Directors/Technical Supervisors. 2. During a telephone interview with the Survey Team on November 17, 2020 at 9:00 AM, the Laboratory Director/Technical Supervisor confirmed that the laboratory did not have written policies and procedures for documenting workload limits.

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 written laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and

reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory. 2. The Survey Team examined 296 urine cytology cases and corresponding final test reports from May 21, 2020 to November 4, 2020. The laboratory failed to identify 16 of 20 unsatisfactory urine cases. Cases include: NG-20S-1058 NG-20T-1026 NG-20W-1022 NG-20V-1020 NG-20V-1021 NG-20V-1023 NG-20V-1024 NG-20V-1025 NG-20W-1013 NG-20W-1014 NG-20W-1015 NG-20W-1004 NG-20W-1001 NG-20W-1003 NG-20W-1037 NG-20W-1084 3. During a telephone interview with the Survey Team on November 17, 2020 at 9:00 AM the Laboratory Director/Technical Supervisor confirmed that the laboratory did not have written policies and procedures specifying the criteria for an unsatisfactory nongynecologic slide preparation.

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 written laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for issuing a corrected report to include the basis for the correction. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for issuing a corrected report. 2. During a telephone interview with the Survey Team on November 17, 2020 at 3:40 PM, the Laboratory Director/Technical Supervisor confirmed that the laboratory did not have written policies and procedures for issuing an corrected report.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records and interview it was determined that 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 fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of written laboratory policies and procedures, laboratory records, cytology slide preparations and interview it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5629, D5633, D5637, D5641, D5645, D5647, D5655 and D5659

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 review of 296 negative nongynecologic cases/slides from May to November, 2020 and confirmation by the Laboratory Director/Technical Supervisor on November 19, 2020 it was determined that the Laboratory Director/Technical Supervisor failed to verify the accuracy of 16 nongynecologic cytology test results. Case/slides Include: 1. NG-20S-1058 May 28,2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 2. NG-20T-1026 June 17, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 3. NG-20W-1022 August 14, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 4. NG-20V-1020 August 14, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 5. NG-20V-1021 August 14, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 6. NG-20V-1023 August 14, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 7. NG-20V-1024 August 14, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS:

Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 8. NG-20V-1025 August 14, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 9. NG-20W-1013 September 2, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 10. NG-20W-1014 September 4, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 11. NG-20W-1015 September 4, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 12. NG-20W-1004 September 4, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 13. NG-20W-1001 September 4, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 14. NG-20W-1003 September 4, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 15. NG-20W-1037 September 14, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 16. NG-20W-1084 October 2, 2020 ThinPrep Urine LABORATORY DIAGNOSIS: Benign SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular

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 laboratory policies and procedures, lack of laboratory records and interview it was determined that the Technical Supervisor failed to establish and reassess the workload limits at least every six months and make adjustments when necessary for the Technical Supervisor in 2018, 2019 and to the date of the survey in 2020. Cross refer to D5633 and D5637

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 written laboratory policies and procedures and interview it was determined that the Technical Supervisor failed to document the number of hours devoted to examining slides during each 24-hour period in 2018, 2019 and to the date of the survey in 2020. Cross refer to D5645

D9999

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