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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 21D0698733 | (X3) Date Survey Completed 12/06/2023 |
| Name of Provider or Supplier Anne Arundel Urology Pa | Street Address, City, State 600 Ridgely Ave Ste 210, Annapolis, MD | |
| 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 |
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| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of competency assessment records and interviews the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisor. The laboratory failed to assess the competency of one of one Technical Supervisors in 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 describe the process for assessing the competency of the Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for one of one Technical Supervisors in 2022 and January 2023 to the date of the survey in 2023. 3. During an interview on December 4, 2023 at 2:10 PM these findings were confirmed with the Laboratory Manager. 4. During an interview on December 6, 2023 at 9:40 AM these findings were confirmed with the Technical Supervisor.</p> |
| D5655 | <p>CYTOLOGY CFR(s): 493.1274(e)(4)</p> <p>(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.</p> |

This STANDARD is not met as evidenced by:
 Based on review of laboratory policies and procedures, nongynecologic cytology slide preparations and corresponding final cytology test reports and interviews the laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report five of nine unsatisfactory nongynecologic cytology slide preparations in October and November 2023 as being unsatisfactory for evaluation. Findings include: 1. The laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. a. The Survey Team identified four of nine nongynecologic cytology slide preparations reported by the laboratory as "Unsatisfactory" for evaluation and interpretation. There were no written policies or procedures to describe the criteria used to identify and report these specimens as being "Unsatisfactory" for evaluation and interpretation. Cases include: -C23-449 -C23-507 -C23-563 -C23-605 b. During an interview on December 5, 2023 at 11:20 AM the Technical Supervisor stated "I don't know if there is a policy but I think our criteria is 100 cells". c. During an interview on December 5, 2023 at 11:45 AM the Laboratory Manager confirmed there was no written policy or procedure to define "Unsatisfactory" for evaluation and interpretation. 2. The Survey Team identified five of nine nongynecologic cytology slide preparations reported by the laboratory as "Negative" in October 2023 and November 2023, as being "Unsatisfactory" for evaluation and interpretation. a. The Technical Supervisor confirmed this finding on December 5, 2023 and December 7, 2023. Refer to D6115

D5657

CYTOLOGY
 CFR(s): 493.1274(e)(5)

(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results.

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 for the laboratory's descriptive nomenclature used on cytology test reports. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the descriptive nomenclature used during the microscopic examination of nongynecologic urine cytology specimens. 2. During an interview on December 5, 2023 at 11:20 AM when asked what reporting terminology and criteria was used by the laboratory for reporting the patient's test results, the Technical Supervisor replied "I think it might be somewhere. My threshold is high when I report cases". 3. During an interview on December 5, 2023 at 11:45 AM when asked if the laboratory procedure manual provided criteria and description for reporting the patient's test results in the terminology used by the laboratory, the Laboratory Manager replied "I don't think we have that".

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records and interviews the Laboratory Director failed to ensure quality assessment programs were followed to identify, monitor and assess the quality of the analytic cytology services. The Laboratory Director failed to follow and maintain the laboratory's programs to monitor the accuracy of the diagnostic evaluations performed by the Technical Supervisor in 2022 and January 2023 to the date of the survey. Findings include: 1. The Laboratory Director failed to ensure quality assessment programs were followed to identify, monitor and assess the quality of the analytic cytology services. 2. The Laboratory Director failed to follow and maintain the laboratory's quality assessment programs to monitor the accuracy of the diagnostic evaluations performed by the Technical Supervisor. a. The QUALITY ASSURANCE policy titled CONSULTATION REVIEW stated: -"A review of all extra/intra-departmental consultation for pathology cases will be conducted to verify diagnostic consistency and maintain the highest standard of reporting accuracy possible. In addition, this will serve as a feedback mechanism for the pathologist to evaluate their diagnostic skills." b. The QUALITY ASSURANCE DOCUMENTS AND LOGS manual failed to include documentation of the monitoring, assessment or corrective actions when diagnostic evaluation discrepancies occurred with the Technical Supervisor's interpretation. Each of the following are mentioned in the QUALITY ASSURANCE policies and procedures: -internal proficiency program -second opinion log -peer pathologist review interpretation -send-out interpretation -second pathologist review interpretation -outside pathologist consultation interpretation -correlation log discrepant interpretations -correlative review with available surgical pathology/FISH testing result comparisons. c. During an interview on December 5, 2023 at 9:40 AM the Technical Supervisor stated "we don't do all of that for cytology". d. During interviews on December 5, 2023 at 3:15 PM and December 6, 2023 at 8:30 AM these findings were confirmed by the Laboratory Manager. 3. The Laboratory Director failed to follow and maintain the laboratory's quality assessment programs to monitor the competency of the Technical Supervisor to perform required tasks. a. The QUALITY ASSURANCE policy titled PERSONNEL COMPETENCY stated: -"The evaluation of personnel to assess their ability to perform tasks required of them will consist of the following:" b. The Laboratory Director failed to ensure tasks were assigned and failed to monitor required tasks for the Technical Supervisor. c. The laboratory failed to provide documentation of an evaluation and assessment of the Technical Supervisor to perform required tasks. Refer to D5209

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 microscopic review of 223 random negative nongynecologic cytology cases /446 slides and the corresponding final cytology test reports from October 2023 and November 2023 and confirmation by the laboratory Technical Supervisor on December 5, 2023 and December 7, 2023, the Technical Supervisor failed to verify

the accuracy of five nongynecologic cytology tests. 1. C23-00417 10/17/2023 Bladder Wash LABORATORY TECHNICAL SUPERVISOR DIAGNOSIS: Negative SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation; scant cellularity LABORATORY TECHNICAL SUPERVISOR RESCREEN DIAGNOSIS: "Agree" Unsatisfactory for Interpretation; scant cellularity 2. C23-00433 10/17/2023 Bladder Wash LABORATORY TECHNICAL SUPERVISOR DIAGNOSIS: Negative SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation; scant cellularity LABORATORY TECHNICAL SUPERVISOR RESCREEN DIAGNOSIS: "Agree" Unsatisfactory for Interpretation; scant cellularity 3. C23-00435 10/17/2023 Bladder Wash LABORATORY TECHNICAL SUPERVISOR DIAGNOSIS: Negative SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation; scant cellularity LABORATORY TECHNICAL SUPERVISOR RESCREEN DIAGNOSIS: "Agree" Unsatisfactory for Interpretation; scant cellularity 4. C23-00579 11/09/2023 Bladder Wash LABORATORY TECHNICAL SUPERVISOR DIAGNOSIS: Negative SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation; scant cellularity LABORATORY TECHNICAL SUPERVISOR RESCREEN DIAGNOSIS: "Agree" Unsatisfactory for Interpretation; scant cellularity 5. C23-00634 11/22/2023 Bladder Wash LABORATORY TECHNICAL SUPERVISOR DIAGNOSIS: Negative SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation; scant cellularity LABORATORY TECHNICAL SUPERVISOR RESCREEN DIAGNOSIS: "Agree" Unsatisfactory for Interpretation; scant cellularity

D9999

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