Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2122379	10/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cleveland Urology Associates - Antenucci	10500 Antenucci Blvd, Suite 101, Garfield Heights, OH	

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
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Consultant (LC), the laboratory failed to ensure that the accurate name and address of the laboratory location where the tissue biopsy testing procedures performed in the subspecialties of Histopathology and Cytology was indicated on the patient's final test report. This deficient practice had the potential to affect 2,000 out of 2,000 patient final test reports generated from 11/02/2022 through 10/28/2024. Findings Include: 1. Review of three out of three of the laboratory's Histopathology and Cytology final test reports revealed an incorrect address (19250 Bagley Road, Suite 107, Middleburg Heights, OH 44130) of where the tissue biopsy, fish and cytology slides were interpreted. 2. The LC confirmed the incorrect address was indicated on the patient's final test reports reviewed. The interview occurred on 10/28/2024 at 3:05 PM.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification

	requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and an interview with the Laboratory Consultant (LC), the Technical Consultant (TC) failed to provide technical oversight in accordance with 493.1413 of this subpart. This deficient practice had the potential to affect 4,050 out of 4,050 patient test results in the subspecialties of Bacteriology in this laboratory between 11/02/2022 through 10/28/2024. Findings Include: 1. The Technical Consultant (TC) failed to include and document monitoring the recording and reporting of test results in the evaluation of the competency of two out of four Testing Personnel (TP). (Refer to D6048) 2. The Technical Consultant (TC) failed to include and document the review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records in the evaluation of the competency of two out of four Testing Personnel (TP). (Refer to D6049) 3. The Technical Consultant (TC) failed to include and document direct observation of performance of instrument maintenance and function checks in the evaluation of the competency of two out of four Testing Personnel (TP). (Refer to D6050) 4. The Technical Consultant (TC) failed to include and document the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of the competency of two out of four Testing Personnel (TP). (Refer to D6051) 5. The Technical Consultant (TC) failed to include and document the assessment of problem solving skills in the evaluation of the competency of two out of four Testing Personnel (TP). (Refer to D6052) 6. The Technical Consultant (TC) failed to evaluate and document the second semi-annual competency of two out of four Testing Personnel (TP) who were responsible for moderate complexity urine culture (UCx) growth/no growth testing procedures during the first year the individuals tested patient specimens. (Refer to D6053)
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Consultant (LC), the Technical Consultant (TC) failed to include and document monitoring the recording and reporting of test results in the evaluation of the competency of two out of four Testing Personnel (TP). This deficient practice had the potential to affect 2,700 out of 2,700 patient urine culture (UCx) growth/no growth performed by TP#4 and TP#6 from 07/31/2023 through 10/28/2024. Findings Include: 1. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 09/04/2024, revealed four individuals were indicated as TP to performed UCx growth/no growth testing procedures. 2. Review of the laboratory's policies and procedures, provided on the date and within seven days of the inspection found instructions for competency assessment only on the "Performance Assessment" worksheet. 3. Review of the laboratory's "Performance Assessment" worksheets for UCx growth/no growth for TP#4's initial (07/31/23) and six month (01/22/24) assessments and TP#6's initial (07 /24/24) assessment did not find any indication that monitoring the recording and

	reporting of test results was included in the evaluation of competency. 4. The Inspector requested the laboratory's competency assessment policy and procedure and the 2023 and 2024 UCx growth/no growth testing competency assessment records for TP#4 and TP#6 that included monitoring the recording and reporting of test results in the evaluation of the competency from the LC. The LC confirmed the laboratory did not include and document monitoring the recording and reporting of test results in a policy and procedure or in the evaluation of the competency of TP#4 and TP#6, as required, and was unable to provide the requested documentation on the date or within seven days of the inspection. The interview occurred via electronic mail on 11/01 /2024 at 2:18 PM.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Consultant (LC), the Technical Consultant (TC) failed to include and document the review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records in the evaluation of the competency of two out of four Testing Personnel (TP). This deficient practice had the potential to affect 2,700 out of 2,700 patient urine culture (UCx) growth/no growth performed by TP#4 and TP#6 from 07/31/2023 through 10/28/2024. Findings Include: 1. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 09/04/2024, revealed four individuals were indicated as TP to performed UCx growth/no growth testing procedures. 2. Review of the laboratory's policies and procedures, provided on the date and within seven days of the inspection found instructions for competency assessment only on the "Performance Assessment" worksheet. 3. Review of the laboratory's "Performance Assessment" worksheets for UCx growth/no growth for TP#4's initial (07/31/23) and six month (01/22/24) assessments and TP#6's initial (07 /24/24) assessment did not find any indication that the review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records was documented in the evaluation of competency. 4. The Inspector requested the laboratory's competency assessment policy and procedure and the 2023 and 2024 UCx growth/no growth testing competency assessment records for TP#4 and TP#6 that included the review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records in the evaluation of the competency from the LC. The LC confirmed the laboratory did not include and document the review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records in a policy and procedure or in the evaluation of the competency of TP#4 and TP#6, as required, and was unable to provide the requested documentation on the date or within seven days of the inspection. The interview occurred via electronic mail on 11/01/2024 at 2:18 PM.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not

	limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Consultant (LC), the Technical Consultant (TC) failed to include and document direct observation of performance of instrument maintenance and function checks in the evaluation of the competency of two out of four Testing Personnel (TP). This deficient practice had the potential to affect 2,700 out of 2,700 patient urine culture (UCx) growth/no growth performed by TP#4 and TP#6 from 07/31/2023 through 10/28/2024. Findings Include: 1. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 09/04/2024, revealed four individuals were indicated as TP to performed UCx growth/no growth testing procedures. 2. Review of the laboratory's policies and procedures, provided on the date and within seven days of the inspection found instructions for competency assessment only on the "Performance Assessment" worksheet. 3. Review of the laboratory's "Performance Assessment" worksheets for UCx growth/no growth for TP#4's initial (07/31/23) and six month (01/22/24) assessments and TP#6's initial (07/24/24) assessment did not find any indication that direct observation of performance of instrument maintenance and function checks was included in the evaluation of competency. 4. The Inspector requested the laboratory's competency assessment policy and procedure and the 2023 and 2024 UCx growth/no growth testing competency assessment records for TP#4 and TP#6 that included direct observation of performance of instrument maintenance and function checks in the evaluation of the competency from the LC. The LC confirmed the laboratory did not include and document direct observation of performance of instrument maintenance and function checks in a policy and procedure or in the evaluation of the competency of TP#4 and TP#6, as required, and was unable to provide the requested documentation on the date or within seven days of the inspection. The interview occurred via electronic mail on 11/01/2024 at 2:18 PM.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Consultant (LC), the Technical Consultant (TC) failed to include and document the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of the competency of two out of four Testing Personnel (TP). This deficient practice had the potential to affect 2,700 out of 2,700 patient urine culture (UCx) growth/no growth performed by TP#4 and TP#6 from 07/31/2023 through 10/28/2024. Findings Include: 1. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 09/04/2024, revealed four individuals were indicated as TP to performed UCx growth /no growth testing procedures. 2. Review of the laboratory's policies and procedures, provided on the date and within seven days of the inspection found instructions for competency assessment only on the "Performance Assessment" worksheet. 3. Review of the laboratory's "Performance Assessment" worksheets for UCx growth/no growth

	for TP#4's initial (07/31/23) and six month (01/22/24) assessments and TP#6's initial (07/24/24) assessment did not find any indication that the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples was included in the evaluation of the TP competency. 4. The Inspector requested the laboratory's competency assessment policy and procedure and 2023 and 2024 UCx growth/no growth testing competency assessment records for TP#4 and TP#6 that included the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of the competency from the LC. The LC confirmed the laboratory did not include and document the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in a policy and procedure or in the evaluation of the competency of TP#4 and TP#6, as required, and was unable to provide the requested documentation on the date or within seven days of the inspection. The interview occurred via electronic mail on 11/01/2024 at 2:18 PM.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Consultant (LC), the Technical Consultant (TC) failed to include and document the assessment of problem solving skills in the evaluation of the competency of two out of four Testing Personnel (TP). This deficient practice had the potential to affect 2,700 out of 2,700 patient urine culture (UCx) growth/no growth performed by TP#4 and TP#6 from 07/31/2023 through 10/28/2024. Findings Include: 1. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 09/04/2024, revealed four individuals were indicated as TP to performed UCx growth/no growth testing procedures. 2. Review of the laboratory's policies and procedures, provided on the date and within seven days of the inspection found instructions for competency assessment only on the "Performance Assessment" worksheet. 3. Review of the laboratory's "Performance Assessment" worksheets for UCx growth/no growth for TP#4's initial (07/31/23) and six month (01/22/24) assessments and TP#6's initial (07 /24/24) assessment found "Assessment of Problem Solving" with blank lines next to "Satisfactory" and "Unsatisfactory". 4. The Inspector requested the laboratory's competency assessment policy and procedure and 2023 and 2024 UCx growth/no growth testing competency assessment records for TP#4 and TP#6 that included the assessment of problem solving skills from the LC. The LC confirmed the laboratory did not include and document the assessment of problem solving skills of TP#4 and TP#6, as required, and was unable to provide the requested documentation on the date or within seven days of the inspection. The interview occurred via electronic mail on 11/01/2024 at 2:18 PM.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least

	semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Consultant (LC), the Technical Consultant (TC) failed to evaluate and document the second semi-annual competency of two out of four Testing Personnel (TP) who were responsible for moderate complexity urine culture (UCx) growth/no growth testing procedures during the first year the individuals tested patient specimens. This deficient practice had the potential to affect 1,350 out of 1,350 patient urine culture (UCx) growth/no growth performed by TP#4 and TP#5 from 01/22/2024 through 10/28/2024. Findings Include: 1. Review of the laboratory's Form CMS-209, provided on the date of the inspection, approved, signed and dated by the Laboratory Director on 09/24/2024, revealed four individuals were indicated as TP to performed UCx growth/no growth testing procedures. 2. Review of the laboratory's "Quality Assurance Policy" policy and procedure, provided on the date of the inspection, approved, signed and dated by the Laboratory Director on 01/01/2017, did not find any instructions regarding the frequency of competency assessments and only found the following statement: "Personnel Assessment: will be reviewed annually. All employee files will be screened for evidence of personnel competency assessment." 3. Review of the laboratory's 2023 and 2024 competency assessment records, provided for the inspection, did not find any record of the following second semi-annual competency assessments during the TP's first year of patient UCx testing: first second Initial semi-annual semiannual TP#4 07/31/23 01/22/24 not done TP#5 08/07/23 02/14/24 not done 4. The Inspector requested the laboratory's competency assessment policy and procedure to include the required frequency of competency assessments and the semiannual competency assessment records for TP#4 and TP#5 from the LC. The LC confirmed the laboratory did not include the required frequencies of competency assessment in any policy and procedure and the TC did not assess and document the second semiannual competency of TP#4 and TP#5 during their first year of testing patient specimens according to the CLIA regulations and was unable to provide the requested documentation on the date of the inspection. The interview occurred via electronic mail on 11/01/2024 at 2:18 PM.
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 record review and interviews with the Laboratory Consultant, the Laboratory Director failed to provide overall management and direction in accordance with 493.1445 of this subpart. This deficient practice had the potential to affect 21,400 out of 21,400 patient test results in the subspecialties of Bacteriology, Routine Chemistry and Endocrinology in this laboratory between 11/02/2022 through 10/28/2024. Findings Include: 1. The Laboratory Director failed to ensure that testing systems developed for prostatic specific antigen (PSA), free PSA (fPSA) and Testosterone (Testo) tests performed in the laboratory provided quality laboratory services for all aspects of the test performance in the subspecialties of Routine Chemistry and Endocrinology. (Refer to D6082, Item 1) 2. The Laboratory Director

	failed to ensure that testing systems developed for urine culture (UCx) growth/no growth performed in the laboratory provided quality laboratory services for all aspects of the test performance in the subspecialty of Bacteriology. (Refer to D6082, Item 2) 3. The Laboratory Director failed to ensure that testing systems developed for tissue biopsy slide interpretations performed in the laboratory provided quality laboratory services for all aspects of the test performance in the subspecialties of Histopathology and Cytology. (Refer to D6082, Item 3) 4. The Laboratory Director failed to ensure that test accuracy verification (TAV) studies were adequate to determine the accuracy and precision for the prostatic specific antigen (PSA) and testosterone (Testo) tests conducted in the subspecialties of Routine Chemistry and Endocrinology. (Refer to D6086) 5. The Laboratory Director failed to enroll with a proficiency testing (PT) provider for urine culture (UCx) growth/no growth of bacteria for the tests performed in the subspecialty of Bacteriology. (Refer to D6088) 6. The Laboratory Director failed to establish and maintain a quality control (QC) program to assure the quality of the prostatic specific antigen (PSA), free PSA (fPSA) and testosterone (Testo) tests conducted in the subspecialties of Routine Chemistry and Endocrinology and identify failures as they occurred. (REfer to D6093, Item 1) 7. The Laboratory Director failed to establish a quality control (QC) program and ensure it was maintained to assure the quality of the urine culture (UCx) growth/no growth tests conducted in the subspecialty Bacteriology and to identify failures as they occurred. (Refer to D6093, Item 2) 8. The Laboratory Director failed to ensure the quality assessment programs were established and maintained to assure the quality of the laboratory services provided and to identify failure in quality as they occurred in the subspecialties of Bacteriology, Routine Chemistry and Endocrinology. (Refer D6094) 9. The Laboratory Director failed to ensure that patient prostatic specific antigen (PSA), free PSA (fPSA) and testosterone (Testo) test results were not reported until all corrective actions had been taken and the system was functioning properly. (Refer to D6097) 10. The Laboratory Director failed to provide approved policies and procedures to all personnel responsible for any aspect for the urine culture (UCx) growth/no growth, prostatic specific antigen (PSA), free PSA (fPSA) and testosterone (Testo) testing performed. (Refer to D6106)
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Item 1 Based on record review and an interview with the Laboratory Consultant (LC), the Laboratory Director failed to ensure that testing systems developed for prostatic specific antigen (PSA), free PSA (fPSA) and Testosterone (Testo) tests performed in the laboratory provided quality laboratory services for all aspects of the test performance in the subspecialties of Routine Chemistry and Endocrinology. This deficient practice had the potential to affect 16,000 out of 16,000 patient tests at this location from 11/02/2022 through 10/28/2024. Findings Include: 1. Review of the laboratory's PSA, fPSA and Testo policies, procedures and quality control (QC) documentation found instructions to establish QC ranges for PSA, fPSA and Testo. 2. The Inspector requested the laboratory's established QC range documentation for each QC lot number of PSA, fPSA and Testo used in 2023 and 2024 from the LC. The LC

	stated the laboratory conducts weekly batch runs for PSA, fPSA and Testo and had run out of QC material before they completed 10 runs of each level of QC. The LC confirmed that the laboratory did not establish their own QC ranges. The interview occurred via a telephone conversation on 11/07/2024 at 8:23 AM. Item 2 Based on record review and an interview with the Laboratory Consultant (LC), the Laboratory Director failed to ensure that testing systems developed for urine culture (UCx) growth /no growth performed in the laboratory provided quality laboratory services for all aspects of the test performance in the subspecialty of Bacteriology. This deficient practice had the potential to affect 5,400 out of 5,400 patient tests at this location from 11/02/2022 through 10/28/2024. Findings Include: 1. Review of the manufacturer's Uricult package instructions found required instructions to conduct external quality control (QC) with each shipment and new lot number to confirm the media supports and inhibits growth prior to utilizing for patient UCx growth/no growth testing. 2. Review of the laboratory's policies and procedures provided on the date and within seven days of the inspection did not find any instructions to conduct external QC with each shipment and new lot number for the Uricult UCx growth/no growth testing media. 3. The Inspector requested the laboratory's external Uricult QC policy and procedure and documentation for each shipment and new lot number utilized in 2023 and 2024 from the LC. The LC confirmed the laboratory did not establish a Uricult QC policy and procedure, did not conduct any external Uricult QC on each shipment and new lot number in 2023 and 2024 and was unable to provide the requested documentation on the date or within seven days of the inspection. The interview occurred via a telephone conversation on 11/07/2024 at 8:23 AM. Item 3 Based on record review and an interview with the Laboratory Consultant (LC), the Laboratory Director failed to ensure that testing systems developed for tissue biopsy slide interpretations performed in the laboratory provided quality laboratory services for all aspects of the test performance in the subspecialties of Histopathology and Cytology. This deficient practice had the potential to affect 2,000 out of 2,000 patient tissue biopsy tests performed in this laboratory from 11/02/2022 through 10/28/2024. Findings Include: 1. Review of the laboratory's "Weekly - Microscope Maintenance" policy and procedure manual, approved by the Laboratory Director on 01/04/2017 and provided on the date of the inspection, found the following statements: "Good prevention maintenance includes regular cleaning of oculars and objectives." "Frequency: Weekly" "Document date and initials on the microscope weekly maintenance log..." 2. The Inspector requested the laboratory's microscope maintenance documentation for 2023 and 2024 from the LC. The LC provided the documentation for the microscope previously utilized for the discontinued urine microscopy procedures and was unable to locate any documentation for the microscope utilized for Histopathology/Cytology microscope. The interview occurred via a telephone conversation on 11/07/2024 at 8:23 AM.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Consultant (LC), the Laboratory Director failed to ensure that test accuracy verification (TAV) studies were adequate to determine the accuracy and precision for the prostatic specific

	antigen (PSA) and testosterone (Testo) tests conducted in the subspecialties of Routine Chemistry and Endocrinology. This deficient practice had the potential to affect 16,000 out of 16,000 patient PSA and Testo tests conducted in this laboratory from 11/02/2022 through 10/28/2024. Findings Include: 1. Review of the laboratory's "Policy and Procedure for Method Accuracy Verification serum PSA's, serum Free PSA's, serum Testosterone, microscopic urine sediment, and urine culture colony count", approved via signature and date by the Laboratory Director on 01/08/2023 found the following: "Acceptable Threshold: The Cleveland Urology Associates results and the reference lab results must be within the following ranges to be considered acceptable: Serum PSA within +/- 2.0 ng/mL of each other Serum Testosterone within +/- 100 ng/mL of each other" 2. Review of the laboratory's PSA and Testo TAV documentation provided on the date of the inspection revealed the following discrepant results with no corrective action indicated: PSA Testo 08/17/23 instrument 261 pg/dL ref lab 420 ng/dL 11/27/23 instrument 311 pg/dL ref lab 525 ng /dL 09/05/24 instrument 2.28 ng/mL ref lab 4.90 ng/mL 09/19/24 instrument 113 pg /dL ref lab 183 ng/dL 3. Review of the laboratory's 2023 and 2024 instrument QC printouts, the BioRad Liquichek Immunoassay Plus Control package instructions, proficiency testing (PT) provider evaluation summaries, reference laboratory (ref lab) test reports for test accuracy verification activities and the patient final test reports revealed the units of measure (UoM) for PSA, fPSA and Testo were inconsistent as follows: PSA fPSA Testo instrument ng/mL ng/mL ng/mL BioRad g/L g/L nmol/L PT ng/mL ng/mL ng/dL ref lab ng/mL % ng/dL final report ng/mL ng/mL pg/dL ng /mL; nanogram per milliliter g/L; microgram per liter nmol/L; nanomoles per liter ng /dL; nanograms per deciliter %; percent pg/dL; picograms per deciliter 4. The Inspector requested the laboratory's corrective action policy and procedure and the 2023 and 2024 corrective action documentation from the LC. The LC stated the laboratory did not establish a corrective action policy and procedure, the corrective action documentation was not able to be located if it was completed. The LC further stated the laboratory had been working with their Information Technology company to ensure the correct UoM were indicated correctly; however there had been no change as of the date of the inspection. The LC confirmed the TAV results indicated above were not within the laboratory's criteria for acceptability. The interview occurred via a telephone conversation on 11/07/2024 at 8:35 AM.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Consultant (LC), the Laboratory Director failed to enroll with a proficiency testing (PT) provider for urine culture (UCx) growth/no growth of bacteria for the tests performed in the subspecialty of Bacteriology. This deficient practice had the potential to affect 5,400 out of 5,400 patient UCx tests performed in this laboratory from 11/02/2022 through 10/28/2024. Findings Include: 1. Review of the laboratory's policies and procedures provided on the date of the inspection, did not find any PT policy and procedure and instructions to enroll with a PT provider for the UCx growth/no growth testing performed. 2. Review of the laboratory's PT documentation provided on the date of the inspection did not find PT enrollment documentation or any UCx growth/no growth PT records in 2023 and 2024. 3. The Inspector requested the laboratory's approved PT policy and

	procedure by the Laboratory Director and 2023 and 2024 UCx growth/no growth PT documentation from the LC. The LC confirmed the laboratory did not establish a PT policy and procedure, was not enrolled in UCx growth/no growth PT in 2023 and 2024 and was unable to provide the requested documentation on the date of the inspection. The interview occurred via a telephone conversation on 11/07/2024 at 8:10 AM.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) 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. This STANDARD is not met as evidenced by: Item 1 Based on record review and an interview with the Laboratory Consultant (LC), the Laboratory Director failed to establish and maintain a quality control (QC) program to assure the quality of the prostatic specific antigen (PSA), free PSA (fPSA) and testosterone (Testo) tests conducted in the subspecialties of Routine Chemistry and Endocrinology and to identify failures as they occurred. This deficient practice had the potential to affect 16,000 out of 16,000 patient PSA, fPSA and Testo tests conducted in this laboratory from 11/02/2022 through 10/28/2024. Findings Include: 1. Review of the laboratory's policies and procedures provided on the date and within seven days of the inspection did not find mention of PSA, fPSA and Testo QC and corrective action instructions. 2. Review of the laboratory's 2023 Beckman Coulter Access 2 instrument quality control (QC) printouts for PSA, fPSA and Testo, provided on the date of the inspection, revealed the following QC was not acceptable, no corrective action was conducted and documented and patient PSA, fPSA and Testo testing continued on the following dates: PSA fPSA Testo L1 L2 L3 L1 L2 L3 L1 01 /03/23 QCF QCF 01/17/23 QNS QCF QNS OVR QNS 02/07/23 QCFQCF QCFQCF 03/28/23 QCFQCF QCFQCF 05/02/23 QCFQCF QCF 06/06/23 QCFQCFQCF QCFQCF 06/13/23 QCFQCF QCFQCF 10/05/23 QCFQCFQCF QCFQCF 10/10/23 QCFQCF SYSQCFQCF SYS 11/21/23 QCF QCF 12/19/23 QCF 12/26/23 QCF QCF QCF 01/23/24 QCF 04/09/23 QCF QCF 08/13/24 QCF QCF 10/15/24 QCF L1, L2, L3; Level 1, Level 2, Level 3 QCF; quality control failed QNS; quantity not sufficient OVR; over SYS; system failure, QC canceled 3. Review of the laboratory's 2023 and 2024 instrument QC printouts, the BioRad Liquichek Immunoassay Plus Control package instructions, proficiency testing (PT) provider evaluation summaries, reference laboratory (ref lab) test reports for test accuracy verification activities and the patient final test reports revealed the units of measure (UoM) for PSA, fPSA and Testo were inconsistent as follows: PSA fPSA Testo instrument ng/mL ng/mL ng/mL BioRad g/L g/L nmol/L PT ng/mL ng/mL ng/dL ref lab ng/mL % ng/dL final report ng /mL ng/mL pg/dL ng/mL; nanogram per milliliter g/L; microgram per liter nmol/L; nanomoles per liter ng/dL; nanograms per deciliter %; percent pg/dL; picograms per deciliter 4. The Inspector requested the laboratory's PSA, fPSA, Testo QC and corrective action policies and procedures from the LC. The LC stated corrective action documentation was not able to be located if it had been completed. The LC further stated the laboratory had been working with their Information Technology company to ensure the correct UoM were indicated correctly; however there had been no change as of the date of the inspection. The LC confirmed the QC was out on the above listed dates with no corrective action documented and was unable to provide the requested policies and procedures on the date or within seven days of the

	inspection. The interview occurred via a telephone conversation on 11/07/2024 at 8:46 AM. Item 2 Based on record review and an interview with the Laboratory Consultant (LC), the Laboratory Director failed to establish a quality control (QC) program and ensure it was maintained to assure the quality of the urine culture (UCx) growth/no growth tests conducted in the subspecialty Bacteriology and to identify failures as they occurred. This deficient practice had the potential to affect 5,400 out of 5,400 patient UCx grow/no growth tests conducted in this laboratory from 11/02/2022 through 10/28/2024. Findings Include: 1. Review of the laboratory's policies and procedures provided on the date and within seven days of the inspection did not find any instruction of UCx growth/no growth QC with each shipment and each new lot number to confirm the culture media supported and inhibited growth. 2. Review of the laboratory's "Uricult Quality Control Record" found evidence that the laboratory recently implemented visual checks in September 2024 on the Uricult media with each shipment and lot number and documented these visual checks on 09/12/2024 and 10/06/2024. 3. The Inspector requested the laboratory's UCx growth/no growth QC policy and procedure and 2023 and 2024 QC documentation for each shipment and lot number of the Uricult media from the LC. The LC confirmed the laboratory did not establish a UCx growth/no growth QC policy and procedure. The LC further confirmed the laboratory did not conduct any QC activities as evidence that the Uricult media was able to support and inhibit growth and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 11 /07/2024 at 8:46 AM.
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 record review and an interview with the Laboratory Consultant (LC), the Laboratory Director failed to ensure the quality assessment programs were established and maintained to assure the quality of the laboratory services provided and to identify failure in quality as they occurred in the subspecialties of Bacteriology, Routine Chemistry and Endocrinology. This deficient practice had the potential to affect 21,400 out of 21,400 urine culture (UCx) growth/no growth, prostatic specific antigen (PSA), free PSA (fPSA) and testosterone (Testo) patient tests performed from 11/02/2022 to 10/28/2024. Findings Include: 1. Review of the laboratory's "Quality Assurance Policy", approved by the Laboratory Director via signature and date on 01 /01/2017 and provided on the date of inspection found instructions to conduct quality assessments annually. 2. Review of the laboratory's "Laboratory Quality Assessment Review Form" found blank assessment forms that were pre-signed by the Laboratory Director. 3. Review of the laboratory's 2023 and 2024 completed "Laboratory Quality Assessment Review Form"s did not find any documentation of problems identified and evaluated with corrective actions implemented for the failure to enroll in UCx proficiency testing, the failure to perform external quality control with each shipment and lot number of UCx Uricult media, the failures of PSA, fPSA and Testo quality control activities, the failures of PSA and Testo test accuracy verification activities and the failure to correct inconsistent units of measure for PSA, fPSA and Testo results. 4. The Inspector requested the laboratory's 2023 and 2024 QA documentation to include the above listed failures in quality with the laboratory's corrective actions

	from the LC. The LC confirmed the Laboratory Director pre-signed blank quality assessment forms and failed to identify and document failures in quality for the above listed items as they occurred. The interview occurred via a telephone conversation on 11/07/2024 at 8:37 AM.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Consultant (LC), the Laboratory Director failed to ensure that patient prostatic specific antigen (PSA), free PSA (fPSA) and testosterone (Testo) test results were not reported until all corrective actions had been taken and the system was functioning properly. This deficient practice had the potential to affect 16,000 out of 16,000 patient tests performed from 11/02/2022 through 10/28/2024. Findings Include: 1. Review of the laboratory's 2023 Beckman Coulter Access 2 instrument quality control (QC) printouts for PSA, fPSA and Testo, provided on the date of the inspection, revealed the following QC was not acceptable, no corrective action was conducted and documented and patient PSA, fPSA and Testo testing continued to be reported on the following dates: PSA fPSA Testo L1 L2 L3 L1 L2 L3 L1 01/03/23 QCF QCF 01/17/23 QNS QCF QNS OVR QNS 02/07/23 QCFQCF QCFQCF 03/28/23 QCFQCF QCFQCF 05/02/23 QCFQCF QCF 06/06/23 QCFQCFQCF QCFQCF 06/13/23 QCFQCF QCFQCF 10/05/23 QCFQCFQCF QCFQCF 10/10/23 QCFQCF SYSQCFQCF SYS 11/21/23 QCF QCF 12/19/23 QCF 12/26/23 QCF QCF QCF 01/23/24 QCF 04/09/23 QCF QCF 08/13/24 QCF QCF 10/15/24 QCF L1, L2, L3; Level 1, Level 2, Level 3 QCF; quality control failed QNS; quantity not sufficient OVR; over SYS; system failure, QC canceled 2. The inspector requested the laboratory's PSA, fPSA, Testo QC policy and procedure and corrective action policies and procedures from the LC. The LC confirmed the QC was out on the above listed dates with no corrective action documented and patient testing continued to be reported. The LC was unable to provide the requested policies and procedures and corrective actions on the date or within seven days of the inspection. The interview occurred via a telephone conversation on 11/07/2024 at 9:05 AM.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Consultant (LC), the Laboratory Director failed to provide approved policies and procedures to all personnel responsible for any aspect for the urine culture (UCx) growth/no growth, prostatic specific antigen (PSA), free PSA (fPSA) and testosterone (Testo) testing performed. This deficiency had the potential to affect 21,400 out of 21,400 patient tests conducted from 11/02/2022 through 10/28/2024. Finding Include: 1. Review of the laboratory's policies and procedures provided on the date and within seven days of

	the inspection did not find any mention of UCx growth/no growth proficiency testing (PT) or quality control (QC), PSA, fPSA and Testo QC and corrective action. 2. The Inspector requested the laboratory's UCx growth/no growth PT and QC, PSA, fPSA and Testo QC and corrective action policies and procedures approved by the Laboratory Director via signature and date from the LC. The LC confirmed the laboratory did not establish the above mentioned policies and procedures and was unable to provide the requested documentation on the date or within seven days of the inspection. The interview occurred via a telephone conversation on 11/07/2024 at 8:57 AM.