Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0278612	08/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Urology Center Of Florida Pa	550 Sw 3rd St Ste 305, Pompano Beach, FL	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain quality control records. Findings: 1. Review of the quality control documentation in the bacteriology, routine chemistry and urinalysis laboratory showed that the laboratory failed to retain the, "Certificate of Analysis" from the Uricult CLED/EMB urine culture paddles from 8/21/16 to 8/21/18. During an interview on 8/21/18 at 3:27 PM, Manager stated that they did not keep the certificates. 2. Review of the histopathology laboratory's quality control records showed that the records for all quality control and maintenance for 2017 were missing. During an interview on 8/23/18 at 11:24 AM, Manager stated the previous histology technician took the 2017 records to make a copy and had not returned them. 3. Review of the histopathology laboratory's quality control records showed that there were no records documenting the stain quality of the H&E stain from 8/21/16 to 8/23/18. During an interview on 8/23/18 at 11:30 AM, Manager stated that the clinical consultant might have the records.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems

	specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to monitor, evaluate and correct problems in the general laboratory systems. The bacteriology, routine chemistry and urinalysis laboratory failed to establish and follow a written policy to assess employees (D5209), verify the accuracy of test performed in urine colony counts, prostate specific antigen (PSA), pathology and cytology at least twice a year. (D5217), document proficiency testing evaluation and verification activities (D5221), and establish and follow a written quality assessment policy (D5291).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and interview, the bacteriology, routine chemistry and urinalysis laboratory failed to establish and follow a written policy to assess employees. Findings: Review of the bacteriology, routine chemistry and urinalysis laboratory's procedure manual showed that the laboratory failed to have a procedure on training and competency assessments for employees working in the bacteriology, routine chemistry and hematology laboratory. The laboratory also failed to document training and competency assessment on Testing Personnel B. During an interview on 8 /21/18 at 3:50 PM, Manager stated that they did not have a procedure on competency and they did not perform and document annual competency assessments on Testing Personnel B.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of test performed in urine colony counts, prostate specific antigen (PSA), pathology and cytology at least twice a year. Findings: 1. Record review of the the American Proficiency Institute (API) event test result showed the following failing score: 2016 Chemistry - Miscellaneous 3rd Event PSA 50% 2017 Chemistry - Miscellaneous 2nd Event PSA 33% 2017 Microbiology 1st Event Urine Colony Count 0% 2017 Microbiology 3rd Event Urine Colony Count 50% There were 3 events per year for Chemistry - Miscellaneous in 2016, Microbiology and 2 events per year for Chemistry - Miscellaneous in 2017. Corrective action documented for the 2017 Microbiology 3rd in 2016 Event Urine Colony Count did not address the issue of the falling score. No corrective action was documented for the falling scores in 2016 Chemistry - Miscellaneous 3rd Event PSA, 2017 Chemistry - Miscellaneous 2nd Event PSA, and 2017 Microbiology 1st Event Urine Colony Count. During an interview on 8/23/18 at

	2:30 PM, the Manager acknowledged that they had unsuccessful proficiency testing scores. 2. Review of the peer review records for pathology and cytology showed that peer review was performed only once in 2017. During an interview on 8/23/18 at 2:25 PM, the Manager was not aware if peer review was done more than once in 2017.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document proficiency testing (PT) evaluation and verification activities. Findings: Review of the American Proficiency Institute (API) PT records showed that the laboratory failed to verify that PT samples were run in the same manner as patients by signing the attestation statement. Attestation statements for the 2016 Microbiology 3rd Event was not signed by the testing personnel or the laboratory director and the 2017 Microbiology 3rd Event was not signed by the laboratory director. The API attestation statement stated, "Signature Required. Be sure that the appropriate personnel sign the statement below. Retain this Attestation Statement for your records along with the printed copy of the Result Form you submitted." Review of the API, "Proficiency Testing Performance Evaluation" form showed that the laboratory director failed to sign the PT performance evaluations for 2016 Chemistry - Group 2 3rd Event, 2017 Chemistry - Miscellaneous 2nd Event, 2016 Microbiology 3rd Event, and 2017 Microbiology 2nd Event, and the laboratory failed to document corrective action for 2016 Chemistry - Group 2 3rd Event and 2017 Chemistry - Miscellaneous 2nd Event. The API "Proficiency Testing Performance Evaluation" form stated, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures" During an interview on 8/21/18 at 4:00 PM and on 8/23/18 at 2:30 PM, the Manager acknowledged that the signatures and documentation of corrective action were missing.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish and follow a written quality assessment policy. Findings: Record review of the laboratory procedure manual showed that there was no quality assessment policy for their bacteriology, routine chemistry and urinalysis laboratory. During an interview on 8/21 /18 at 3:11 PM, the Manager stated that he was unable to find a quality assessment policy for the laboratory.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to monitor, evaluate and correct problems in the analytic systems. The laboratory director failed to approve, sign and date the procedure manuals for the histology laboratory (D5407). The laboratory used expired reagents in their histopathology laboratory (D5417). The bacteriology, routine chemistry and urinalysis laboratory failed to document the visual inspection of the media paddles, and failed to check and document each batch of urine culture media for its ability to support growth and select or inhibit specific organisms or have an Individualized Quality Control Plan (D5477). The histopathology laboratory failed to document all quality control (QC) procedures performed from 8/21 /16 to 8/23/18, (D5609). The histopathology laboratory failed to follow the written policy and procedure titled "Tissue Processor Maintenance Procedure" for documenting the changing or rotation of the stain for January 2018 through July 2018 (D5791).
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to approve, sign and date the procedure manuals for the histopathology laboratory. Findings: Review of the procedure manual titled, "Urology Center of Florida Pathology Laboratory Management Manual," "Urology Center of Florida Non-Gyn Cytology Procedure Manual," and "Urology Center of Florida Pathology Quality Control Manual" showed that the manuals were signed on 1/2012 and the signatures were not the laboratory director's signature. During an interview on 8/23/18 at 10:25 AM, the Manager stated that he did not know whose signature was on the procedure manual titled, "Urology Center of Florida Pathology Laboratory Management Manual." He said the procedure manuals titled, "Urology Center of Florida Non-Gyn Cytology Procedure Manual" and "Urology Center of Florida Pathology Quality Control Manual" were signed by the Clinical Consultant.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to record the humidity of the bacteriology, routine chemistry, urinalysis and the histopathology laboratory and failed to record the temperatures in the histology laboratory. 1. Review of quality control and maintenance logs showed that the humidity levels of the rooms where laboratory testing was performed in the bacteriology, routine chemistry, urinalysis laboratory and the histopathology laboratory were not recorded from 8/21/16 to 8/23 /18. During an interview on 8/23/18 at 2:45 PM, the Manager acknowledged that they did not record the humidity of the rooms where testing was performed. 2. Review of the histopathology quality control binder for 2016 showed that there was no record of temperatures being recorded from 8/21/16 to 12/31/16. Review of the monthly form used to record the performance of the maintenance from 1/1/18 to 7/30/18 showed a slash mark instead of a temperature reading and no records for August 2018 were found. Temperature readings for the freezer, refrigerator, oven, VIP paraffin, paraffin tank, paraffin chamber and hot plate, cold plate, water bath and room temperatures revealed that temperatures were not recorded from 8/21/16 to 12/31/16 and 1/1/18 to 8 /23/18. During an interview on 8/23/18 at 2:45, the Manager acknowledge that the temperature readings were not recorded.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory used expired reagents in their histology laboratory. Findings: During a tour of the histopathology laboratory the following reagents used in their histology laboratory were expired: Reagent Lot Number Expiration Date Quantity Hematoxylin 2 371492 11/2017 2 Hematoxylin 7211 382106 02/2018 1 Hematoxylin 7211 370208 10/2017 1 Hematoxylin 7211 273309 4/2015 1 Harris Hematoxylin 049611 3/18 1 Gill 3 Hematoxylin 30502 12/15 1 ClearView Hematoxylin 32448 10/15 1 Eosin-Y 382822 02/2018 4 Eosin Working Solution D182-12 07/02/16 1 Scotts Tap Water Bluing Solution B272-27 10/03/14 1 10% Formalin Fixative (NBF) 533403 AUG 2017 1 10% Formalin Fixative (NBF) 45342 DEC 2016 2 Pro-Par Clearant 5812 2017-10 1 Pro-Par Clearant 5606 2016-12 4 Pro-Par Clearant 5141 MAR. '15 1 During an interview on 8/21/18 at 1:30 PM, the Manager acknowledged that they were using expired reagents.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics

	of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview and record review, the bacteriology, routine chemistry and urinalysis laboratory failed to document the visual inspection of the media paddles, and failed to check and document each batch of urine culture media for its ability to support growth and select or inhibit specific organisms or have an Individualized Quality Control Plan from August 21, 2016 to August 23, 2018. Findings: Review of the quality control records revealed no documentation showing that the laboratory performed a visual inspection of the Uricult CLED/EMB (Cystine Lactose Electrolyte Deficient agar/Eosin Methylene Blue agar) urine culture paddles. The laboratories procedure titled, "Urine Culture Procedure Manual" in the section "Quality Control Procedures" stated the following: Upon arrival, a representative sample (2 vials per box) of Uricult paddles should be examined for the following characteristics with results recorded in the Quality Control Record: *Cracked Vials *Contamination *Unequal filling of paddles *Discoloration *Cracked Media *Media separation from paddle *Excessive number of bubbles *Dehydration *Freezing *Excess Moisture Review of quality control records noted the laboratory had no records showing that they had checked and documented the Uricult CLED/EMB urine culture paddles for their ability to support growth and select or inhibit specific organisms from August 21, 2016 to August 23, 2018. An IQCP was not found in the laboratories procedure manual. During an interview on 8/21/18 at 3:27 PM, the Manager stated that the laboratory personnel performed a visual check of the urine culture paddles but did not document it and that they did not have an IQCP.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview, the histopathology laboratory failed to document all quality control (QC) procedures performed from 8/21/16 to 8/23/18. Findings: 1. Review of the histopathology's quality control binder for 2016 showed that logs titled, "Urology Center (Prostates)" and "Non-Gyn Cytology Accessions" showed that patient testing was performed from 8/25/16 to 12/21/16. Review of the QC logs titled, "Tissue Processor Maintenance Log," "Hematoxylin and Eosin Staining Log Pathology," "Pathology Monthly Quality Assurance Checklist" and "Reagent Log" showed that the forms were not filled out. Review of the monthly forms used to record the performance of the maintenance for 2018 showed that for 1/1 /18 to 7/30/18 there was no reagent log. There were no monthly forms used to record the performance of the maintenance on the dates of 8/16/18 and 8/19/18 for patients listed on the "Urology Center Prostates" and Non-Gyn Cytology Accession" logs. During an interview on 8/23/18 at 11:24 AM, the Manager acknowledged that the forms were incomplete. 2. Review of the histopathology's quality control logs showed that there was no log for microscope maintenance from 8/21/16 to 8/23/18. During an interview on 8/23/18 at 2:39 PM, the Manager stated he did not know where the logs were.

D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview, the histopathology laboratory failed to follow the written policy and procedure titled, "Tissue Processor Maintenance Procedure" for documenting the changing or rotation of the stain from January 2018 through July 2018. Findings included: Review of the policy, "Tissue Processor Maintenance Procedure" read, C = Change: change the reagents completely. R = Rotate: to rotate the reagents containers to the next lot. A = Add: to add to the reagent containers if low volume. Check Mark = Ok: reagent containers is checked. Change Tissue processor every two weeks, due to once a week processing. The laboratory staff used a monthly form to record the performance of the maintenance of the H&E stain. Review of the laboratory's monthly maintenance log from January 2018 through July 2018 showed that all testing days were checked off with a slash. There was no indication on the form that the laboratory staff had changed, rotated, or added to the reagents for the H&E stain. During an interview on 8/23/18 at 2:45 AM, the Manager acknowledged that the monthly forms to record the maintenance in the histology laboratory had slash marks and were not documented properly.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to monitor, evaluate and correct problems in the postanalytic systems. The test report did not identify the location where the professional component was performed (D5805) and the histopathology laboratory failed to follow a written policy to monitor, access and correct problems for their QA program (D5891).
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 interview, the test report did not identify the location where the professional component was performed. Findings: Review of the 2018 peer review performed for FISH (Fluorescence in situ hybridization) testing for bladder cancer showed that the name and address of the location where the professional component was performed was not listed for five out of five patient test reports. During an interview on 8/23/18 at 2:43 PM, the Manager acknowledged that the name and address where the professional component was performed was not listed on the test report.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview, the histopathology laboratory failed to follow a written policy to monitor, access and correct problems for their QA program. Findings: Review of the histopathology's quality assurance (QA) program records showed that the laboratory failed to perform the, "Pathology Monthly Quality Assurance Checklist" from 8/21/16 to 8/23/18. The QA program included a monthly checklist titled, "Pathology Monthly Quality Assurance Checklist" and a "Quality Assurance Documentation Schedule." The QA schedule noted the following: 1. The Monthly Q.C. Worksheet: This form should be completed at the end of each month and signed by the lab director and filed in Q.C. log under the corresponding month. Add comments when needed to ensure quality control. During an interview on 8/23 /18 at 2:45 PM, the Manager stated he did not know where they were. 1
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 interview, the laboratory director failed to provide overall management and direction. The laboratory director failed to ensure that an approved correction action plan was followed when proficiency testing (PT) results were unacceptable (D6092). He failed to ensure that quality control was established and maintained (6093), and that a quality assessment program was established and maintained (6094). He failed to ensure that policies and procedures were established to assure that individuals performing testing were competent and to ensure competency was maintained and documented (D6103), and failed to approve, sign and date the procedure manuals for the histopathology laboratory (D6106).

D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure that an approved correction action plan was followed when proficiency testing (PT) results were unacceptable. Findings: Review of the API, "Proficiency Testing Performance Evaluation" form showed that the bacteriology, routine chemistry and urinalysis laboratory failed to document corrective action for 2016 Chemistry - Group 2 3rd Event and 2017 Chemistry - Miscellaneous 2nd Event. The API, "Proficiency Testing Performance Evaluation" form stated, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures" During an interview on 8/21/18 at 4:00 PM and on 8/23/18 at 2:30 PM, the Manager acknowledged that signatures and documentation of corrective action were missing.
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: Based on record review and interview, the laboratory director failed to ensure that quality controls were established and maintained. Findings: 1. Review of quality control records showed that the bacteriology, routine chemistry and urinalysis laboratory did not have any records showing that the laboratory performed a visual inspection of the Uricult CLED/EMB (Cystine Lactose Electrolyte Deficient agar /Eosin Methylene Blue agar) urine culture paddles. The laboratories procedure titled, "Urine Culture Procedure Manual" in the section, "Quality Control Procedures," noted the following: Upon arrival, a representative sample (2 vials per box) of Uricult paddles should be examined for the following characteristics with results recorded in the Quality Control Record: *Cracked Vials *Contamination *Unequal filling of paddles *Discoloration *Cracked Media *Media separation from paddle *Excessive number of bubbles *Dehydration *Freezing *Excess Moisture Review of the quality control records did not have any documentation to show that the laboratory had checked and documented the Uricult CLED/EMB urine culture paddles for their ability to support growth and select or inhibit specific organisms from August 21, 2016 to August 23, 2018. An IQCP was not found in the laboratories procedure manual. During an interview on 8/21/18 at 3:27 PM, the Manager stated that the laboratory personnel performed a visual check of the urine culture paddles but did not document it and that they did not have an IQCP. 2. Review of the quality control documentation in the bacteriology, routine chemistry and urinalysis laboratory showed that the laboratory failed to retain the, "Certificate of Analysis" from the Uricult CLED/EMB urine culture paddles from 8/21/16 to 8/21/18. During an interview on 8/21/18 at 3:27 PM, the Manager stated that they did not keep the

	certificates. 3. Review of the histopathology laboratory's quality control records showed that the records for all quality control and maintenance for 2017 were missing. During an interview on 8/23/18 at 11:24 AM, the Manager stated the previous histology technician took the 2017 records to make a copy and had not returned them. 4. Review of the histopathology laboratory's quality control records showed that there were no records documenting the stain quality of the H&E stain from 8/21/16 to 8/23/18. During an interview on 8/23/18 at 11:30 AM, the Manager stated that the clinical consultant might have the records.
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 interview, the laboratory director failed to ensure that a quality assessment program was established and maintained. Findings: 1. Record review of the bacteriology, routine chemistry and urinalysis laboratory procedure manual showed that there was no quality assessment policy for their bacteriology, routine chemistry and urinalysis laboratory. During an interview on 8/21/18 at 3:11 PM, the Manager stated that he was unable to find a quality assessment policy for the laboratory. 2. Review of the histopathology's quality assurance (QA) program records showed that the histopathology laboratory failed to perform the, "Pathology Monthly Quality Assurance Checklist" from 8/21/16 to 8/23/18. The QA program included a monthly checklist titled, "Pathology Monthly Quality Assurance Checklist" and a "Quality Assurance Documentation Schedule." The QA schedule read, "1. The Monthly Q.C. Worksheet: This form should be completed at the end of each month and signed by the lab director and filed in Q.C. log under the corresponding month. Add comments when needed to ensure quality control." During an interview on 8/23 /18 at 2:45 PM, the Manager stated he did not know where they were.
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 record review and staff interview, the laboratory director must ensure that policies and procedures are established to assure that individuals performing testing are competent and to ensure competency is maintained and documented. Findings: Review of the bacteriology, routine chemistry and urinalysis laboratory's procedure manual showed that the laboratory failed to have a procedure on training and competency assessments for employees working in the bacteriology, routine chemistry and hematology laboratory. The laboratory also failed to document training

	and competency assessment on Testing Personnel B. During an interview on 8/21/18 at 3:50 PM, the Manager stated that they did not have a procedure on competency and they did not perform and document annual competency assessments on Testing Personnel B.
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 interview, the laboratory director failed to approve, sign and date the procedure manuals for the histology laboratory. Findings: Review of the procedure manual titled, "Urology Center of Florida Pathology Laboratory Management Manual," "Urology Center of Florida Non-Gyn Cytology Procedure Manual," and "Urology Center of Florida Pathology Quality Control Manual" showed that the manuals were signed in 1/2012 and that the signatures were not the laboratory director's signature. During an interview on 8/23/18 at 10:25 AM, the Manager stated that he did not know whose signature was on the procedure manual titled, "Urology Center of Florida Pathology Laboratory Management Manual" and that the signature on the procedure manuals titled, "Urology Center of Florida Non-Gyn Cytology Procedure Manual" and "Urology Center of Florida Pathology Quality Control Manual" was the signature of the Clinical Consultant.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high 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 interview, the laboratory failed to evaluate and document the performance of the testing personnel in the histology laboratory at least semiannually during the first year. Findings: Review of the histopathology laboratory's Quality Assurance program under the section labeled, "Personnel Policies" read, "All personnel who perform tests have documented training for these tests." Documentation of training for the histology laboratory Testing Personnel A hired in the beginning of 2018 was not available for inspection. During an interview on 8/23/18 at 2:30 PM, the Manager acknowledged that a competency assessment was not performed on Testing Personnel B.