Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2080975	07/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Florida Physician Specialists Llc	710 Lomax St, Jacksonville, 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
D0000	A recertification survey was conducted on 7/9/19-7/11/19. Florida Physician Specialists Llc was found not in compliance with 42 CFR 493, requirements for clinical laboratories. Twelve CLIA Conditions were not met, all at the Immediate Jeopardy level: 42 CFR 493.801 Enrollment and testing of samples, 42 CFR 493.1201 Bacteriology, 42 CFR 493.1210 Chemistry, 42 CFR 493.1230 General Laboratory Systems, 42 CFR 493.1250 Analytic Systems, 42 CFR 493.1403 Laboratories Performing Moderate Complexity Testing; Laboratory Director, 42 CFR 493.1409 Laboratories Performing Moderate Complexity Testing; Technical Consultant, 42 CFR 493.1415 Laboratories Performing Moderate Complexity Testing; Clinical Consultant, 42 CFR 493.1441 Laboratories Performing High Complexity Testing; Laboratory Director, 42 CFR 1447 Laboratories Performing High Complexity Testing; Technical Supervisor, 42 CFR 493.1453 Laboratories Performing High Complexity Testing; Clinical Consultant, and 42 CFR 493.1459 Laboratories Performing High Complexity Testing; General Supervisor. Immediate Jeopardy was identified as beginning on 7/11/19 and is presently ongoing. .
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory was

	not enrolled in proficiency testing (PT) for bacteriology in 2018 or 2019. Findings include: Review of PT records and interview with Testing Person A at 2:50 p.m. on July 10, 2019 revealed that the laboratory did not have documentation to indicate that PT had been performed for the speciality of bacteriology in 2018 and 2019. Testing performed under this specialty includes Urine Culture and Sensitivity. Testing Person A confirmed the laboratory had not performed any PT testing for Urine Culture and Sensitivity since testing began in 2018. .
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of Bacteriology records and staff interviews, the laboratory failed to ensure quality control was performed each day of patient testing (refer to D5445); failed to check each batch of media for its ability to support growth (refer to D5477); and failed to document corrective actions on failed quality control (refer to D5783). The findings include: The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. .
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of Routine Chemistry records and staff interviews, the laboratory failed to ensure quality control was acceptable each day of patient testing (refer to D5481); and failed to perform calibration verification per the manufacturer's instructions (refer to D5439). The findings include: The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. .
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 review of personnel competency records, procedure manual, proficiency

	testing records, and staff interviews, the laboratory failed to ensure they have a personnel competency program (refer to D5209); failed to have Laboratory Director review of proficiency testing performance (refer to D5211); failed to verify accuracy twice annually of the Chemistry and Endocrinology testing (refer to D5217) and failed to have a quality assessment system in place for General Laboratory Systems (refer to D5291). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. .
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 staff interview, the laboratory failed to have a competency program in place to assess laboratory employees performing patient testing for two of two years reviewed (2018-2019). Findings include: The facility was unable to provide documentation of a competency program approved by the Laboratory Director and performed by a Technical Consultant for personnel performing laboratory testing for Urine Culture & Sensitivity, Urine Microscopic, Testosterone, and Prostatic specific antigen (PSA). The interview with Testing Person A on 7/10/19 at 12:30pm confirmed that no competency program with Technical Consultant oversight was in place for laboratory personnel. .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and staff interview, the laboratory failed to review proficiency test scores. Findings include: Review of API proficiency test records showed the Laboratory Director failed to review test scores for Chemistry for the 1st event and 2nd event of 2018. There was no documentation of a third event in 2018, or any events in 2019 to review. During interview on 7/10/19 at 2:50pm, Testing Person A confirmed the laboratory did not document review of proficiency test scores for the programs and events listed above. Testing Person A was unable to provide event scores for the 2nd event of 2018, or any PT testing documentation for 2019. .
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 staff interview, the laboratory did not perform proficiency testing for Total Prostate-specific antigen (PSA), Free PSA, and Testosterone testing in 2018 or 2019. Findings include: A record review of the American Proficiency Institute (API) proficiency testing (PT) for 2 events in 2018 showed a score of 0% for "Failure to Participate" for the 1st event of 2018. Testing Person A stated during an interview on 7/10/19 at 2:50pm that she was never made aware the samples had come in to be tested. There was no review of the PT failure made by the Laboratory Director. The 2nd event of 2018 did not have the attestation signed by the Laboratory Director or any Testing Personnel. There was no grade received from API to review at time of survey. During the interview with Testing Person A on 7/10/19 at 2:50pm, they were unable to locate the scores for the PT testing event. There was no documentation of a third testing event or any events in 2019. Upon further review of the API PT records, it was noted that the PT testing was being reported under CLIA 10D0268470. The interview with Testing Person A on 7/10/19 at 2:50pm confirmed that CLIA 10D0268470 was from an old laboratory that had been closed for nearly twelve years.
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 staff interview, the laboratory did not have a written quality assessment procedure that described the laboratory's processes for verifying patient confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing performance. Findings Include: On July 10th, 2019, the laboratory's procedure manual was reviewed. During the review, it was determined that the laboratory did not have a policy or procedure in place to monitor, assess, or correct problems with verifying patient confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing performance. Testing Person A acknowledged during on interview on 7/10/19 at 12:30pm, that there was no procedure available for review that included the information. .
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory did not have a written quality assessment policy for preanalytic systems. Findings include: Review of the procedure manual and interview with Testing Person A at 12:30pm on 7/10/19 revealed there was no quality assessment policy to monitor, assess, and correct problems identified in preanalytic systems. .

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 review of the laboratory procedure manual, quality control records, calibration records, temperature logs, and staff interviews, the laboratory failed to have a procedure manual signed by the laboratory director (refer to D5407); failed to document the temperature of the refrigerator (refer to D5413); failed to document calibration every 6 months (refer to D5439); failed to run quality control testing per procedure (refer to D5481); and failed to have a quality assessment procedure in place for analytic systems (refer to D5791). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. .
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 staff interview, the procedure manual had not been signed by the current laboratory director. Findings include: Review of the procedure manual on 7/10/19 showed that it had not been signed by the laboratory director. The interview with Testing Person A on 7/10/19 at 12:45pm confirmed the procedure manual had not been signed annually by any Laboratory Director since 2012. .
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 temperature log review and staff interview, the facility failed to ensure that the temperature of the refrigerator that stores quality control materials, reagents, and calibrators for chemistry and endocrinology was being monitored and documented in June 2019. Findings include: The review of the laboratory temperature logs on 7/10

	/19 showed no documentation of temperatures being recorded for the refrigerator in June 2019. The interview with Testing Person A on 7/10/10 at 2:00pm confirmed the temperature was not documented in June 2019. Testing Person A confirmed the refrigerator stores quality control materials, testing reagents, and calibrators needed for the Abbott Architect analyzer. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to keep records for calibration verification for chemistry for 1 of 2 years reviewed (2018 and 2019). Findings include: Review of the calibration verification data for the Abbott Architect chemsitry analyzer showed that the lab was missing all calibration verification records from 2018. Review of the laboratory's test menu showed that the laboratory performed the following chemistry tests: Total PSA, Free PSA, and Testosterone. Review of patient test reports showed that the lab performed 1309 Total and Free PSA tests, and 134 Testosterone tests between May 2018 and July 2019. Interview with Testing Person A on 7/10/19 at 1:30pm confirmed the calibration records were missing. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person #A, the laboratory failed to perform Bacteriology controls daily or establish an IQCP (Individualized Quality Control Plan) for 2 out of 2 years (2018-2019) reviewed. Findings Include: Review of QC (Quality Control) records for the Beckman Coulter Microscan Walkaway system revealed that QC was not performed each day of patient testing in 2018, and QC was not performed in 2019. 5590 patient Urine cultures had been performed since May 2018. During an interview on 07/10/19 at 3:00 PM, Testing Person #A confirmed that QC was not performed daily and there was no IQCP. .
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 record review and interview with laboratory personnel, the laboratory did not have documentation to indicate that they checked the physical characteristics of each batch of media, or that they checked each batch of media with control organisms. Findings include: Review of quality control records for urine cultures on 7/10/19 showed there was no documentation that indicated the physical characteristics of the media were not compromised, or that a positive and a negative organism was used for each lot number to check its ability to support growth and to produce the correct biochemical response. During an interview with Testing Person A at 2:30 p.m. on 7/10/19, it was confirmed the information was not documented. .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory reported patient results with controls that were not acceptable for 2 days reviewed out of 26 patient testing days from November 2018 - May 2019. Findings include: The quality control (QC) record review on 7/10/19 showed that on 12/12/18, only two levels of Free PSA were run prior to reporting patient results. On 5/8/19, the QC records showed only two levels of Total PSA were run prior to reporting patient results. The interview on 7/10/19 at 2:20pm with Testing Person A confirmed only two levels of QC were run on those days, and confirmed the procedure stated three levels (low, medium, high) were to be run on patient testing days. .

D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that corrective actions taken in response to unacceptable controls obtained on the Microscan Walkaway were documented. Findings include: The quality control (QC) record review of the documents titled "QC Panel Report" showed QC was performed on 8/22/18, 8/23/18, 9/6/18, 9/19/18, 9/26/19, 10/31/18, and 11/7/18. The reports indicated "result is not applicable", and there was no documentation indicating what the laboratory did to correct the problem. The interview with Testing Person A on 7/10 /19 at 3:00pm confirmed the "Tested" result and "Expected" results did not match, but was unable to provide documentation of corrective action. .
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 staff interview, the laboratory did not have a written quality assessment policy for analytic systems. Findings include: Review of the procedure manual and interview with Testing Person A at 12:30pm on 7/10/19 revealed there was no quality assessment policy to monitor, assess, and correct problems identified in analytic systems. .
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 staff interview, the laboratory did not have a written quality assessment policy for post-analytic systems. Findings include: Review of the procedure manual and interview with Testing Person A at 12:30pm on 7/10/19 revealed that there was no quality assessment policy to monitor, assess, and correct problems identified in post-analytic systems. .

D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to provide sufficient over sight of the laboratory's specimen testing process. The findings include: 1. The Laboratory Director failed to oversee the laboratory operations. Refer to D6004. 2. The Laboratory Director failed to ensure the laboratory was correctly enrolled in proficiency testing. Refer to D6015. 3. The Laboratory Director failed to ensure the laboratory took corrective action when quality controls (QC) results were not run per procedure. Refer to D6020. 4. The Laboratory Director failed to ensure the laboratory had a Quality Assessment system in place. Refer to D6021. 5. The Laboratory Director failed to ensure the laboratory had a process in place to evaluate personnel competency of the staff performing moderate complexity testing. Refer to D6030. .
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions 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 record review and interview with the Laboratory Director, the Laboratory Director failed to effectively oversee the laboratory. Findings include: The review of the CMS 1539 on 7/9/19 showed the specialties of Bacteriology, Routine Chemistry, Urinalysis, Endocrinology, Pathology, and Cytology were active. At the time of survey, the CMS certificate on the wall indicated Pathology and Cytology only. The Laboratory Director stated to his knowledge, the other specialities were under a different CLIA certificate. An interview with the Laboratory Director on the CMS 116 was done on 7/9/19 between 4:30pm and 6:30pm. The Laboratory Director stated, "As indicated on the lab's posted permit, the current CLIA license is only for histology and cytology. I am fully responsible for this lab operation and compliance for histology and cytology only. I am not aware of any other specialties, and not responsible for other CLIA lab or specialties at the McIver clinic location." .
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) 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 interview, the laboratory director failed to provide overall management and direction to ensure the laboratory was enrolled in proficiency testing under their CLIA Certificate of Compliance number. The laboratory was enrolled in proficiency testing through the American Proficiency Institute (API) under a closed CLIA Certificate during 2018 for routine chemistry and endocrinology. Findings Include: Review of the American Proficiency Institute's (API) proficiency testing records showed that the CLIA number on the "Proficiency Testing Performance Evaluation" report was incorrect. During an interview with the Laboratory Director on 7/9/19 at 6:30pm, he stated, "I am fully responsible for this lab operation and compliance for histology and cytology only. I am not aware of any other specialties, and not responsible for other CLIA lab or specialties at the McIver clinic location." .
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person #A and the Laboratory Director, the Laboratory Director failed to identify that the laboratory failed to document the quality control (QC) every day of testing for 2 days out of 30 days reviewed. Findings include: The quality control (QC) record review on 7/10/19 showed that on 12/12/18, only two levels of Free PSA were run prior to reporting patient results. On 5/8/19, the QC records showed only two levels of Total PSA were run prior to reporting patient results. The interview on 7/10/19 at 2:20pm with Testing Person A confirmed only two levels of QC were run on those days, and confirmed the procedure stated three levels (low, medium, high) are to be run on patient testing days. In the interview with the Laboratory Director on 7/9/19 at 6:30pm, it was stated he was never made aware it was his responsibility to oversee any testing in the laboratory other than pathology and cytology. .
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to establish and follow a quality assurance program. Findings included: Review of the procedure manual and interview with Testing Person A at 12:30pm on 7/10/19 revealed that there was no quality assessment policy to monitor, assess, and correct problems identified in pre-analytic, analytic, and post-analytic systems. .
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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 failed to ensure a personnel competency program was in place to evaluate staff competency. Findings include: The facility was unable to provide documentation of a competency program approved by the Laboratory Director and performed by a Technical Consultant for personnel performing laboratory testing for Urine Microscopic, Testosterone, and Prostatic specific antigen (PSA). The interview with Testing Person A on 7/10/19 at 12:30pm confirmed that no competency program with Technical Consultant over sight was in place for laboratory personnel. .
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 staff interview, the laboratory failed to have a Technical Consultant. The findings include: 1. The laboratory failed to have the position of Technical Consultant filled. Refer to D6034 .
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the

	specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to employ a Technical Consultant to provide technical oversight of the testing process. Findings include: The CMS 116, signed on 7/9/19 by the Laboratory Director, does not list a Technical Consultant for the moderate complexity testing performed at this laboratory. In the interview with the Laboratory Director on 7/9/19 at 6:30pm, it was stated he was never made aware it was his responsibility to oversee any testing in the laboratory other than pathology and cytology. .
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a Clinical Consultant for the Urinalysis, Chemistry, and Endocrinology testing. The findings include: 1. The laboratory failed to have the position of Clinical Consultant filled. Refer to D6057. .
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a Clinical Consultant that provided consultation regarding laboratory patient's diagnosis, treatment, and management of care. Findings include: The CMS 116 lists the Laboratory Director has the Clinical Consultant. In the interview with the Laboratory Director on 7/9/19 at 6:30pm, it was stated he was never made aware it was his responsibility to oversee any testing in the laboratory other than pathology and cytology. .
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of

	identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have testing personnel that were capable of catching problems within the laboratory's overall testing process. Findings include: The review of PT records, QC records, temperature records, and lack of quality assessment showed the staff responsible for performing moderate complexity testing in the areas of Urinalysis, Chemistry, and Endocrinology was not capable of identifying, correcting, or notifying the Laboratory Director about the problems in the laboratory. Multiple interviews were conducted with Testing Person A on 7/10/19 between 12:30pm and 3:00pm. When asked to provide documentation of PT for 2019, they stated they "didn't know" why no PT had been done. When asked about incorrect quality control, they "didn't know" why it wasn't repeated. When asked about missing documentation for temperature records or quality assessment records, they "didn't know" why it wasn't done. .
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 staff interview, the laboratory director failed to provide sufficient oversight of the laboratory's high complexity specimen testing process. The findings include: 1. The Laboratory Director failed to oversee the laboratory operations. Refer to D6079. 2. The Laboratory Director failed to ensure the laboratory was correctly enrolled in proficiency testing. Refer to D6088. 3. The Laboratory Director failed to ensure the laboratory performed quality controls (QC). Refer to D6093. 4. The Laboratory Director failed to ensure the laboratory had a Quality Assessment system in place. Refer to D6094. 5. The Laboratory Director failed to ensure the roll of General Supervisor was filled. Refer to D6100. 6. The Laboratory Director failed to ensure the laboratory had a process in place to evaluate personnel competency of the staff performing high complexity testing. Refer to D6103. .
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 reapportions 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 record review and interview with the Laboratory Director, the Laboratory Director failed to effectively oversee the laboratory's high complexity testing of Bacteriology. Findings include: The review of the CMS 1539 on 7/9/19 showed the specialties of Bacteriology, Routine Chemistry, Urinalysis, Endocrinology, Pathology, and Cytology were active. At the time of survey, the CMS certificate on the wall indicated Pathology and Cytology only. The Laboratory Director stated that to his knowledge, the other specialities were under a different CLIA certificate. An interview with the Laboratory Director on the CMS 116 was done on 7/9/19 between 4:30pm and 6:30pm. The Laboratory Director stated, "As indicated on the lab's posted permit, the current CLIA license is only for histology and cytology. I am fully responsible for this lab operation and compliance for histology and cytology only. I am not aware of any other specialties and not responsible for other CLIA lab or specialties at the McIver clinic location." .
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 interview with laboratory personnel, the laboratory was not enrolled in proficiency testing (PT) for bacteriology in 2018 or 2019. Findings include: Review of PT records and interview with Testing Person A at 2:50 p.m. on July 10, 2019 revealed that the laboratory did not have documentation to indicate that PT had been performed for the speciality of bacteriology in 2018 and 2019. Testing performed under this specialty includes Urine Culture and Sensitivity. Testing Person A confirmed the laboratory had not performed any PT testing for Urine Culture and Sensitivity since testing began in 2018. .
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 with Testing Person #A, the laboratory failed to perform Bacteriology controls daily or establish an IQCP (Individualized Quality Control Plan) for 2 out of 2 years (2018-2019) reviewed. Findings Include: Review of QC (Quality Control) records for the Beckman Coulter Microscan Walkaway system revealed that QC was not performed each day of patient testing in 2018, and QC was not performed in 2019. 5590 patient Urine cultures had been performed since May 2018. During an interview on 07/10/19 at 3:00 PM, Testing Person #A confirmed that QC was not performed daily and there was no IQCP. .
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 staff interview, the Laboratory Director failed to establish and follow a quality assurance program for high complexity testing. Findings included: Review of the procedure manual and interview with Testing Person A at 12: 30pm on 7/10/19 revealed that there was no quality assessment policy to monitor, assess, and correct problems identified in pre-analytic, analytic, and post-analytic systems. .
D6100	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(10) The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4). This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to staff the laboratory with a General Supervisor. Findings include: The CMS 116, signed on 7/9 /19 by the Laboratory Director, lists a General Supervisor only for the specialties of Histopathology and Cytology. An interview with the Laboratory Director on the CMS 116 was done on 7/9/19 between 4:30pm and 6:30pm. The Laboratory Director stated, "As indicated on the lab's posted permit, the current CLIA license is only for histology and cytology. I am fully responsible for this lab operation and compliance for histology and cytology only. I am not aware of any other specialties and not responsible for other CLIA lab or specialties at the McIver clinic location." .
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 failed to ensure a personnel competency program was in place to evaluate staff competency of those performing high complexity testing. Findings include: The facility was unable to provide documentation of a competency program approved by the Laboratory Director and performed by a Technical Supervisor for personnel performing

	laboratory testing for Urine Culture and Sensitivity. The interview with Testing Person A on 7/10/19 at 12:30pm confirmed that no competency program with Technical Supervisor over sight was in place for laboratory personnel. .
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a Technical Supervisor. The findings include: 1. The laboratory failed to have the position of Technical Supervisor for Bacteriology filled. Refer to D6109. .
D6109	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to employ a Technical Supervisor to provide technical oversight of the Bacteriology testing process. Findings include: The CMS 116, signed on 7/9/19 by the Laboratory Director, does not list a Technical Supervisor for the high complexity testing Urine Culture and Sensitivity performed at this laboratory. In the interview with the Laboratory Director on 7/9/19 at 6:30pm, it was stated he was never made aware it was his responsibility to oversee any testing in the laboratory other than pathology and cytology. .
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a Clinical Consultant for the high complexity Urine Culture and Sensitivity testing. The findings include: 1. The laboratory failed to have the position of Clinical Consultant filled for Bacteriology. Refer to D6135. .
D6135	CLINICAL CONSULTANT QUALIFICATIONS

	CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a Clinical Consultant that provided consultation regarding laboratory patient's diagnosis, treatment, and management of care for Urine Culture and Sensitivity testing. Findings include: The CMS 116 lists the Laboratory Director has the Clinical Consultant. In the interview with the Laboratory Director on 7/9/19 at 6:30pm, it was stated he was never made aware it was his responsibility to oversee any testing in the laboratory other than pathology and cytology. .
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a General Supervisor. The findings include: 1. The laboratory failed to have the position of General Supervisor for Bacteriology filled. Refer to D6142. .
D6142	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a General Supervisor to provide everyday supervision of the laboratory high complexity testing process. Findings include: The CMS 116 lists the Laboratory Director has the General Supervisor for Histopathology and Cytology only. In the interview with the Laboratory Director on 7/9/19 at 6:30pm, it was stated he was never made aware it was his responsibility to oversee any testing in the laboratory other than pathology and cytology. .
D6179	TESTING PERSONNEL RESPONSIBILITIES

	CFR(s): 493.1495(b)(5) Each individual performing high complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, clinical consultant, or director. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have testing personnel that were capable of catching problems within the laboratory's overall high complexity testing process. Findings include: The review of PT records, QC records, temperature records, and lack of quality assessment showed the staff responsible for performing high complexity testing of Bacteriology was not capable of identifying, correcting, or notifying the Laboratory Director about the problems in the laboratory. Multiple interviews were conducted with Testing Person A on 7/10/19 between 12: 30pm and 3:00pm. When asked to provide documentation of PT for 2019, they stated they "didn't know" why no PT had been done. When asked to provide QC records for 2018 and 2019, they stated they "didn't know" why it wasn't printed or saved anywhere. When asked about missing documentation for temperature records or quality assessment records, they "didn't know" why it wasn't done.