Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1106904	05/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Southern Urology	120 Rue Louis Xiv Bldg #2, Attn Mike Fontenot, Lafayette, LA	

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 performed on May 23, 2024 through May 24, 2024 at Southern Urology, CLIA ID # 19D1106904. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation; review of manufacturer's instructions, laboratory policies, and patient records; as well as interview with personnel, the laboratory failed to follow manufacturer's instructions for intended use of the quantitative beta human chorionic gonadotropin (hCG) test. Findings: 1. Observation by surveyor during the laboratory tour on May 23, 2024 at 1:23 p.m. revealed the laboratory utilized a Beckman DXI 600 analyzer for quantitative beta hCG testing. 2. Review of the manufacturer's instructions for use (IFU) and laboratory policy under the section "Intended use" revealed "This assay is intended for use as an aid in the early detection of pregnancy." 3. Further review of the IFU under the section "Limitations" revealed "This assay is only intended as an aid in the early detection of pregnancy." 4. Review of the final report for patient ID 54301 revealed the laboratory utilized the test as a tumor marker. 5. In interview on May 24, 2024 at 11:40 a.m., the Technical Consultant stated the laboratory only utilizes the test for male patients for tumor markers and does not use the test for pregnancy screening.

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 observation, review of laboratory temperature records and manufacturers' instructions for use, as well as interview with personnel, the laboratory failed to define acceptable room temperature and humidity limits within the manufacturers' required ranges for the main laboratory. Findings: 1. Observation by surveyor during the laboratory tour on May 23, 2024 at 1:23 p.m. revealed the laboratory stored the following supplies in the main laboratory: a) Beckman Coulter Iris System Cleanser - storage requirements 20 - 28 degrees Celsius b) Siemens Multistix 10 SG Reagent Strips for Urinalysis - storage requirements 15 - 30 degrees Celsius 2. Review of the laboratory's 2023 temperature logs for the main laboratory revealed the laboratory defined the acceptable room temperature limits as 10 - 25 degrees Celsius which exceeded the manufacturers' acceptable lower limits. 3. In interview on May 23, 2024 at 1:41 p.m., the Technical Consultant confirmed the laboratory's temperature ranges exceeded the manufacturers' limits as identified above. 4. Further observation revealed the Sysmex XP-300 Hematology Analyzer in use for hematology patient testing. Also, the Beckman Coulter DxU Iris was in place undergoing validation studies. 5. Review of the operator's manual for the analyzers revealed the following humidity requirements: a) Sysmex XP-300 Hematology Analyzer - operating environment relative humidity 30% to 85% b) Beckman Coulter DxU Iris - operating environment humidity 20% to 80% 6. Review of the laboratory's 2023 humidity logs for the main laboratory revealed the laboratory defined the acceptable humidity limits as 10 - 80 % Celsius which exceeded the manufacturers' acceptable lower limits. 7. In interview on May 23, 2024 at 5:09 p.m., the Technical Consultant confirmed the humidity limits defined by the laboratory exceed the manufacturers' requirements as identified above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation and review of maintenance logs, the laboratory failed to perform weekly maintenance on the Vitros XT 3400 analyzer as required by the laboratory for two (2) of thirty (30) weeks reviewed. Findings: 1. Observation by surveyor during the laboratory tour on May 23, 2024 at 1:23 p.m. revealed the laboratory utilized a Vitros XT 3400 analyzer for chemistry testing. 2. Review of maintenance logs from September 2023 through April 2024 for the Vitros XT 3400

	revealed the following required weekly maintenance tasks: "Clean Tip Sealer - Clean Sample Supply - Clean Tip Locator - Clean DISPENSE BLADE and SENSORS - Clean Leak Pad - Clean Touchscreen Monitor and Keyboard - Process VITROS MicroSensor Check Fluids I and II" 3. Further review of the laboratory's maintenance logs revealed the laboratory did not perform weekly maintenance as follows: a) January 2024 - one (1) of five (5) weeks not performed b) April 2024 - one (1) of five (5) weeks not performed
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 review of laboratory policies and interview with personnel, the laboratory failed to follow their Individual Quality Control Plan (IQCP) for quality control of microbiology media. Findings: 1. Review of the laboratory's policy "IQCP Final & Quality Assessment for Microbiology Exempt Media & Disk Diffusion" section "Final QCP" revealed the following: - "Visual inspection of representative units of 'exempt media' for any physical defects or contamination upon receipt." - "Maintenance of logs to record media received, any defects observed and any interactions with manufacturer about defective media. Also record any instances where defective media was used for patient's specimens and any resultant reporting errors. Supervisor to review these logs monthly for any trends warranting attention." 2. In interview on May 24, 2024 at 10:07 a.m., the Technical Supervisor stated laboratory personnel perform a visual inspection of new shipments of media when they are received into the laboratory, but they do not document this. 3. Review of laboratory quality control logs revealed no documentation of the laboratory's visual inspection of microbiology media.
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 review of the laboratory's policy and patient records as well as interview

	with personnel, the laboratory failed to ensure the normal reference range on the final test report matched the normal reference range in the laboratory's policy for urinalysis testing. Findings: 1. Review of the laboratory's policy "Urinalysis (Chemical Screening) and Urinalysis Microscopic Procedure" revealed the following normal reference ranges: - "pH 5.0 -9.0 - Specific Gravity 1.001 - 1.035 - Urobilinogen 0.2 - 1.0 mg/dL" 2. Review of the laboratory's final patient report for Patient ID 105300A revealed the following normal reference ranges for urinalysis testing: - Specific Gravity 1.005 - 1.030 - pH 4.5 - 8.0 - Urobilinogen 0.0 - 1.0 3. In interview on May 23, 2024 at 5:09 p.m., the Technical Consultant confirmed the normal reference ranges in the laboratory policy did not match the normal reference ranges on the final patient test report as identified above.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to follow manufacturer's instructions for intended use of the quantitative beta human chorionic gonadotropin (hCG) test. Refer to D5411. 2. The laboratory failed to define acceptable room temperature and humidity limits within the manufacturers' required ranges for the main laboratory. Refer to D5413.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation, review of laboratory policies and records, as well as interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports for urinalysis testing included pertinent information. Refer to D5805.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to follow manufacturer's instructions for intended use of the quantitative beta human chorionic gonadotropin (hCG) test. Refer to D5411. 2. The laboratory failed to define acceptable room temperature and humidity limits within the manufacturers' required ranges for the main laboratory. Refer to D5413. 3. The laboratory failed to perform weekly maintenance as required by the laboratory on the Vitros XT 3400 analyzer for two (2) of thirty (30) weeks reviewed. Refer to D5429. 4. The laboratory failed to ensure the normal reference range on the final test report matched the normal reference range in the laboratory's policy for urinalysis testing. Refer to D5801.
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 personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5445.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5445.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(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 review of the CMS 209 (Laboratory Personnel Report) and personnel records as well as interview with laboratory personnel, the Technical Supervisor failed to ensure competency assessments for two (2) of two (2) laboratory testing personnel included review of quality control for microbiology testing. Findings: 1. Review of the laboratory's CMS 209 revealed the following testing personnel: Personnel 2 Personnel 3 (also serves as Technical Supervisor) Personnel 4 Personnel 5 2. In interview on May 24, 2024 at 4 p.m., the Technical Consultant stated only the Technical Supervisor, Personnel 4, and Personnel 5 perform microbiology testing. 3. Review of personnel records for the following personnel revealed annual competency assessments, but the laboratory did not have documentation to support review of quality control records: a) Personnel 4 - 2023 annual competency assessment missing disc susceptibility quality control b) Personnel 5 - 2024 annual competency assessment missing Uricult and disc susceptibility quality control 4. In interview on May 24, 2024 at 10:53 a.m., the Technical Consultant confirmed the laboratory could not provide documentation of review of quality control for annual competency assessment as identified above.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(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 review of the CMS 209 (Laboratory Personnel Report) and personnel records as well as interview with laboratory personnel, the Technical Supervisor failed to ensure competency assessments for one (1) of two (2) laboratory testing personnel included assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for microbiology. Findings: 1. Review of the laboratory's Laboratory Personnel Report revealed the following testing personnel: Personnel 2 Personnel 3 (also serves as Technical Supervisor) Personnel 4 Personnel 5 2. In interview on May 24, 2024 at 4 p.m., the Technical Consultant stated only the Technical Supervisor, Personnel 4, and Personnel 5 perform microbiology testing. 3. Review of personnel records for Personnel 5 revealed a 2024 annual competency assessment, but the laboratory did not have documentation to support blind sample testing for urine cultures and/or organism

	sensitivities. 4. In interview on May 24, 2024 at 4:19 p.m., the Technical Consultant confirmed Personnel 5 did not perform blind sample testing as identified above.