

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1106904	(X3) Date Survey Completed 01/27/2021
Name of Provider or Supplier Southern Urology	Street Address, City, State 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 January 26, 2021 through January 27, 2021 at Southern Surgical and Medical Specialists, CLIA ID # 19D1106904. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS form, personnel records, and interview with personnel, the laboratory failed to ensure the Laboratory Director assessed competency for one (1) of two (2) General Supervisors reviewed. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed the Technical Consultant and Technical Supervisor were listed as the laboratory's General Supervisors. 2. Review of personnel records for the Technical Supervisor revealed the laboratory did not have a documented competency assessment for her duties as General Supervisor. 3. In interview on January 26, 2021 at 10:45 am, the Technical Consultant confirmed the Laboratory Director did not perform a competency assessment for the Technical Supervisor for her duties as General Supervisor.</p>
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in</p>

paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's directory of services manual, manufacturer's requirements, and interview with personnel, the laboratory failed to ensure written instructions for providers related to room temperature stability requirements for Sensitive Estradiol specimens were complete. Findings: 1. Review of the laboratory's Directory of Services manual revealed the following serum stability requirements for Sensitive Estradiol: Sensitive Estradiol: "Maximum Transport Time (Stability) to Lab: 24 hours RT" 2. Review of the Access Sensitive Estradiol manufacturer package insert revealed the following specimen stability requirements: "Serum: Room Temperature 8 hours" 3. In interview on January 27, 2021 at 8:33 am, the Technical Consultant stated the specimen stability requirements for Estradiol listed in the Directory of Services manual was a typo.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have a complete Complete Blood Count (CBC) policy for flags. Findings: 1. Review of the laboratory's policies and procedures revealed the following procedure was not included: a) Flag Policy for Complete Blood Counts (CBC), to include actions to take for manufacturer's histogram flags 2. In interview on January 27, 2021 at 8:33 am, the Technical Consultant confirmed the laboratory's current laboratory policy did not specify what is done for CBC flags.

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 direct observation by surveyor, review of the manufacturer's instrument manual, laboratory's policies, patient test reports, and interview with personnel, the laboratory failed to follow the manufacturer's instructions for flags appearing on Complete Blood Counts (CBC) for five (5) of five (5) patients reviewed. Findings: 1. Direct observation by surveyor during the laboratory tour on January 26, 2021 at 9:17 am revealed the laboratory utilizes the Sysmex XP 300 for CBC testing. 2. Review of the laboratory's CBC policy revealed the following: a) " If you have trouble obtaining results due to platelet clumping or if you want to confirm results, send specimen out to the reference lab for a manual differential or slide review." b) "For troubleshooting

specifics, refer to Sysmex XP-300 Instructions for Use." c) "When megakaryocytes are present, perform a WBC and PLT estimate." 3. Review of the Sysmex XP 300 instrument manual under "8.3 Histogram flags" section revealed "When the histogram flags are displayed, perform analysis again. If afterwards the flags are still displayed, the sample is considered to correspond to one of the following." 4. In interview on January 27, 2021 at 8:55 am, the Technical Consultant stated the laboratory follows their error message policy for CBC flags other than "AG" flags. The Technical Consultant further stated the "AG" flag has a canned comment. The Technical Consultant stated the laboratory typically sees "AG" flags. The Technical Consultant stated the laboratory previously repeated samples that had an "AG" flag; however the laboratory no longer repeats the testing, instead uses the canned comment. 5. Further review of the Sysmex XP 300 instrument manual under "8.3 Histogram flags" section revealed for "AG" flags the following actions: "Probable sample cause: Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction (reference): Check smear, etc." 6. Review of the laboratory's "Data Analysis and Remedial Actions" policy under "Error detected in reported patient results (in-house)" section revealed the following actions: a) "Notify physician verbally, note date, time, and initial of testing personnel" b) "Note date, time and initial of testing personnel on the original report" c) "Do not change original copy" d) "If necessary, retest sample if sample is still viable for testing" e) "If necessary, call patient back for new specimen" f) "Issue a corrected report" 7. Further review of the laboratory's "Data Analysis and Remedial Actions" policy revealed the policy did not include written instructions of actions to take for manufacturer's CBC flags. 8. Review of random selection of patient instrument printouts and patient final reports from December 2020 and January 2021 revealed the following five (5) patients with "AG" flags were reported without following manufacturer requirements: a) December 1, 2020 : Patient 141349 b) December 8, 2020: Patient 56912 c) January 22, 2021: Patient 117952 d) January 22, 2021: Patient 110704 e) January 25, 2021: Patient 67521 The identified patient final reports revealed the following comment for platelet "AG" flags: "Platelet clumps flagged. Platelet count reported may be falsely decreased."

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 direct observation by surveyor, review of manufacturer requirements, and interview with personnel, the laboratory failed to monitor the room temperature where blood collection tubes are stored per manufacturer requirements. Findings: 1. Direct observation by surveyor during the laboratory tour on January 26, 2021 at 9:17 am revealed the laboratory did not monitor the temperature of the following rooms where blood collection tubes are stored: a) Storage room: BD Vacutainer K2EDTA blood collection tubes, Lot # 0281109, Quantity: 1000 tubes (10 packs) b) Phlebotomy Room: BD Vacutainer SST blood collection tubes, Lot 0212641, Quantity: 2400 tubes

(24 packs) BD Vacutainer SST blood collection tubes, Lot 0316770, Quantity 400 tubes (4 packs) BD Vacutainer SST blood collection tubes, Lot 0158819, Quantity 100 tubes (1 pack) BD Vacutainer K2EDTA blood collection tubes, Lot 072508, Quantity: 360 tubes Vacuette blood collection tubes, Lot B20043OH, Quantity: 400 tubes BD Vacutainer Serum blood collection tubes, Lot 0086408, Quantity: 12 tubes Vacuette Sodium Citrate blood collection tubes, Lot 454322, Quantity: 39 tubes BD Vacutainer SST blood collection tubes, Lot 0158819, Quantity: 120 tubes BD Vacutainer K2EDTA blood collection tubes, Lot 0072508, Quantity 40 tubes 2. Review of the manufacturer requirements revealed the following: a) BD Vacutainer blood collection tubes: storage requirement 4-25 degrees Celsius b) Vacuette blood collection tubes: storage requirement 4-25 degrees Celsius 3. In interview on January 26, 2021 at 9:35 am, the Technical Consultant stated the laboratory does not monitor the temperature of the storage and phlebotomy rooms.

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 patient final test reports, test menu, and interview with personnel, the laboratory failed to include the name and address where testing was performed on patient urine culture and sensitivity final test reports for five (5) of five (5) patients reviewed. Findings: 1. Review of random selection of the following five (5) patient final test reports for urine culture and sensitivity from December 2020 through January 2021 revealed the laboratory did not include the laboratory's name and address on the final reports: Patient 73976E Patient 54287E Patient 85391 Patient 149156 Patient 58692 2. In interview on January 27, 2021 at 9:00 am the Technical Consultant confirmed the patient final test reports for urine culture and sensitivity did not include the name and address of the laboratory performing testing. 3. Review of the laboratory's test menu revealed the laboratory performs 5,472 urine culture and sensitivity tests annually.

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:

	<p>Based on direct observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to ensure written instructions for providers related to room temperature stability requirements for Sensitive Estradiol specimens were complete. Review to D5317. 2. The laboratory failed to follow the manufacturer's instructions for flags appearing on Complete Blood Counts (CBC) for five (5) of five (5) patients reviewed. Refer to D5411. 3. The laboratory failed to monitor the room temperature where blood collection tubes are stored per manufacturer requirements. Refer to D5413</p>
<p>D6031</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D5401.</p>
<p>D6098</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8)</p> <p>The laboratory director must ensure that reports of test results include pertinent information required for interpretation.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports included required pertinent information. Refer to D5805.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.</p>