| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 34D1105426 | 11/16/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Carolina Urology Healthcare, Pllc | 1021 Beaman Street, Clinton, NC | |

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 |
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| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods<br><br>This STANDARD is not met as evidenced by:<br>Based on review of 2019, 2020 and 2021 American Proficiency Institute (API) proficiency testing (PT) records and interview with TC #2(technical consultant) 11/16 /21, the laboratory failed ensure all testing personnel (TP) who routinely test patient samples participated in PT. Findings: Review of 2019 and 2020 API PT records revealed one TP, who is no longer employed, performed 4 of 6 PT events. Review of 2021 APT PT records revealed TP #4 (TC #2) performed 3 of 3 PT events. Review of 2019, 2020 and 2021 API PT records revealed TP #3, hired in July of 2019, did not participate in PT events for 2019, 2020 and 2021. Interview with TC #2 at approximately 1:00 p.m. confirmed PT was not performed by all TP who routinely test patient samples. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) |

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| | The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedure manual and interview with TC #2 11/16/21, the laboratory procedure manual failed to include a procedure for the performance of qualitative semen analysis and failed to include a procedure for entering test results in the patient record for qualitative semen analysis, prostate specific antigen (PSA) and testosterone (T). 1. The laboratory procedure manual failed to include a procedure for the performance of qualitative semen analysis. Findings: Review of laboratory procedure manual revealed no documentation of a procedure for the performance of qualitative semen analysis. Interview with TC #2 at approximately 10:30 a.m. confirmed the laboratory did not have a procedure for the performance of qualitative semen analysis. 2. The laboratory procedure manual failed to include a procedure for entering test results in the patient record for qualitative semen analysis, PSA and T testing. Review of laboratory procedure manual revealed no documentation of a procedure for entering test results in the patient record for qualitative semen analysis, PSA and T testing. Interview with TC #2 at approximately 1:00 p.m. confirmed the laboratory did not have a procedure for entering test results in the patient record for qualitative semen analysis, PSA and T testing. |
| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of package insert for PSA reagent, review of random patient test reports and interview with TC #2 11/16/21, the test reports for PSA failed to include the assay method as required for interpretation. Findings: Review of package insert for PSA, ST A1A-PACK PA, revealed "Because of differences in reagent specificity and assay methods, the concentration of PSA in a given specimen may vary with devices from different manufacturers. Values obtained with different assay methods cannot be used interchangeably. It is mandatory that results reported by the laboratory to physicians include the identity of the assay used." Review of random patient test reports for PSA testing on 11/02/21 and 11/11/21 revealed no identity of the assay used for PSA testing. Interview with TC #2 at approximately 1:30 p.m. confirmed the test reports did not include the identity of the assay used for PSA testing. She stated she was not aware that it should be included on patient test reports. |
| **D6004** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(a)(b) |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of personnel records, review of personnel competency records and interview with TC #2 11/16/21, the laboratory director (LD) failed to ensure that TC duties were performed by personnel meeting the qualifications of a TC. Findings: Review of personnel records revealed TP #3 does not meet the educational requirements to serve as a TC for the laboratory and is not delegated by the LD to perform competency assessments of TP. Review of personnel competency records revealed TP #3 assessed the competency of TP #4 (TC#2) in 2019, 2020 and 2021. Interview with TC #2 at approximately 1:30 p.m. confirmed TP #3 assessed her competency in 2019, 2020 and 2021. She stated she assesses the competency of TP #3 and TP #5 and they can assess her competency as a TP. |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>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;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedures, review of personnel records and interview with TC #2 11/16/21, the LD failed to establish a competency procedure for assessing the duties and responsibilities of TC #2 and failed to perform a competency assessment for the duties and responsibilities of TC #2. 1. The LD failed to establish a competency procedure for assessing the duties and responsibilities of TC #2. Review of laboratory procedures revealed no documentation of a competency procedure for assessing the duties and responsibilities of TC #2. Interview with TC #2 at approximately 1:30 p.m. confirmed the laboratory procedures failed to include a competency procedure for the assessment of her duties and responsibilities as TC. She stated the laboratory was unaware that she would have to serve as a TC in order to review competency of TP. And because they were not aware of this a competency procedure had not been established. 2. The LD failed to perform a competency assessment for the duties and responsibilities of TC #2. TC #2 assumed TC |

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| | responsibilities in October of 2020. Review of personnel competency records revealed no documentation of a competency assessment of TC #2 for her duties and responsibilities as TC. Interview with TC #2 at approximately 1:30 p.m. confirmed the she did not have her competency assessed for her duties and responsibilities as TC since she assumed the position in October of 2020. She stated they were unaware that she would have to serve as a TC in order to review competency of TP. And because they were not aware of this a competency assessment had not been performed. |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of testing personnel (TP) competency records, review of laboratory policies, and interview with TC #2 11/16/21, the LD failed to specify in writing the responsibilities and duties of TC #2. Review of TP competency records revealed TC #2 reviewed the competency of TP #1 and TP #3. Review of laboratory policies revealed no documentation the LD had specified in writing the responsibilities and duties of TC #2. Interview with TC #2 at approximately 11:00 a.m. confirmed she reviewed competency of TP #1 and TP #3. She also confirmed the LD did not specify in writing her responsibilities and duties as TC. |