Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2043109	04/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Spring Creek Urology Specialists Llc	1020 Riverwood Ct Ste 330, Conroe, TX	

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	The laboratory was found out of compliance with the following CONDITION LEVEL DEFICIENCIES: D6108- 42 C.F.R. 493.1447 Condition: Technical Supervisor high complexity D6141- 42 C.F.R. 493.1459 Condition: General Supervisor high complexity Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor's observations on 04/07/2022 at 1120 hours in the laboratory, review of the laboratory's client instructions, review of establishment studies for the microbial urine panel laboratory developed polymerase chain reaction (PCR) test performed on the QuantStudio 12K Flex instrument and staff interview it was determined the laboratory failed to document monitoring of conditions for specimen

	transportation from outlying provider facilities. Findings included: 1. Surveyor's observations on 04/07/2022 at 1120 hours in the laboratory revealed multiple coolers used for transportation of urine samples from outside providers to the laboratory. 2. Review of laboratory's client instructions revealed: "Transport: Utilize cooled transport (i.e., cold packs in a cooler to maintain temperature between 2C -8C) to store samples in transit." 3. Review of the laboratory's establishment studies for the microbial urine panel laboratory developed PCR test performed on the QuantStudio 12K Flex instrument (placed in service in January 2022) revealed: "Urine samples collected for urinary tract infection microbiota testing are stable at refrigerated temperature for future analytical processing up to 5 days." 4. The laboratory was asked to provide documentation for verification of transport conditions (temperature and presence of cooler ice pack at receipt) and no such documentation was provided. 5. In an interview on 04/07/2022 at 1120 hours in the laboratory the Technical Supervisor (as described on submitted Form 209, signed by Laboratory Director on 04 /07/2022) stated that the technicians verify the presence of ice packs visually but there is no documentation of their observations or of monitoring of sample's temperature at receipt. This confirmed the findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and establishment studies for its own laboratory developed microbial urine panel on the Biorad CFX 96 Touch polymerase chain reaction (PCR) analyzer and staff interview it was determined the laboratory failed to address specimen stability and interfering substances, 2 of 7 components of establishment studies for a laboratory developed test (LDT). Findings included: 1. Review of the laboratory's records revealed the Biorad CFX 96 Touch PCR analyzer was used by the laboratory from February of 2021 to January of 2022. 2. Review of the laboratory's establishment studies for its own laboratory developed microbial urine panel tested on the Biorad CFX 96 Touch PCR analyzer revealed there was no documentation of studies for specimen stability or interfering substances, 2 of 7 components of establishment studies for a LDT. 3. The laboratory was asked to provide the complete establishment studies and no such documents were available for review. 4. In an interview on 04/07/2022 at 1400 hours in the reception area the Laboratory Director stated that a total of 4060 patient samples were processed by the laboratory per year. Furthermore, in the same interview the Technical Supervisor (as described on submitted Form 209, signed by Laboratory Director on 04/07/2022) confirmed the above findings.
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 data provided by the laboratory director, review of the laboratory's quality control (QC) records for the laboratory developed polymerase chain reaction (PCR) urine panel tested on the Biorad CFX 96 Touch instrument from February of 2021 to January of 2022, review of laboratory's Individualized Quality Control Plan (IQCP) establishment studies for said panel and staff interview it was determined the laboratory failed to document complete Risk Assessment (RA) and Quality Control Plan (QCP) as part of the Individualized Quality Control Plan (IQCP) for this panel. Findings included: 1. An interview with the Laboratory Director at 1400 hours in the reception area revealed the laboratory performed testing on 4060 patient urine samples per year. 2. Review of the laboratory's QC records for the laboratory developed PCR urine panel tested on the Biorad CFX 96 Touch instrument from February of 2021 to January of 2022 revealed the laboratory was performing QC once each week of testing. 3. Review of laboratory's Individualized Quality Control Plan (IQCP) establishment studies for the the said panel revealed the studies were incomplete, and were missing the following components: a. There was no documentation of RA evaluation by the laboratory for either of the pre-analytic, analytic, post-analytic test phases, environmental factors or personnel factors that may affect test performance. b. There was no documentation of QCP establishing the new frequency of QC for said panel. 4. In an interview on 04/07/2022 at 1430 hours in the reception area the Technical Supervisor (as described in the CMS Form 209 signed by laboratory director on 04/07/2022) confirmed the findings.
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 random review of the laboratory's test rejection/issue log for January to March of 2022, review of patient reports and staff interview it was determined the laboratory failed to include documentation of information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability

	/testing on final patient report for 6 of 6 rejected samples. Findings included: 1. Review of the laboratory's test rejection/issue log for January to March of 2022 revealed the following patient samples were rejected: Subject No. 11-03/07/2022 Sample collected: 03/07/2022 Date received: 03/09/2022 Date processed: 03/09/2022 Rejected due to: "Sample eluate failed due to gelling" Corrective action: "Sent sample for culture" Subject No. 13-03/10/2022 Sample collected: 03/10/2022 Date received: 03/10/2022 Date processed: 03/11/2022 Rejected due to: "Sample eluate failed due to gelling" Corrective action: "Sent sample for culture" Subject No. 19-03/02/2022 Sample collected: 03/02/2022 Date received: 03/02/2022 Date processed: 03/03/2022 Rejected due to: "Sample eluate failed due to gelling" Corrective action: "Sent sample for culture" Subject No. 15-03/03/2022 Sample collected: 03/03/2022 Date received: 03/03/2022 Date processed: 03/03/2022 Rejected due to: "Sample eluate failed due to gelling" Corrective action: "Sent sample for culture" Subject No. 14-03/08/2022 Sample collected: 03/08/2022 Date received: 03/08/2022 Date processed: 03/08/2022 Rejected due to: "Sample eluate failed due to gelling" Corrective action: "Sent sample for culture" Subject No. none-03/29/2022 Sample collected: 03/29/2022 Date received: 03/30/2022 Date processed: 03/30/2022 Rejected due to: "Sample lid was not on properly/leakage" Corrective action: none 2. The laboratory was asked to provide final patient reports for the above rejected samples and no such documentation was available for review. 3. In an interview on 04/07/2022 at 1610 hours in the reception area the Technical Supervisor (as described in the CMS Form 209 signed by laboratory director on 04/07/2022) stated that the laboratory notified the provider of the rejection, but did not generate a final report for the rejected samples documenting sample disposition and/or notification to provider. This confirmed the findings.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Laboratory Personnel Report (CLIA), Form 209, review of personnel records and staff interview it was determined the Laboratory Director failed to ensure one of one Technical Supervisor/General Supervisor had the appropriate education for the represented position(s). Refer to D6108 and D61041.
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 review of the laboratory's submitted Laboratory Personnel Report (CLIA), Form 209, review of personnel records and staff interview it was determined the

	laboratory failed to have one of one Technical Supervisor who meets the qualification requirements of the position. 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 review of the laboratory's submitted Laboratory Personnel Report (CLIA), Form 209, review of personnel records and staff interview it was determined the laboratory failed to have one of one Technical Supervisor who meets the qualification requirements of the position. Findings included: 1. Review of the laboratory's submitted Laboratory Personnel Report (CLIA), Form 209 revealed the laboratory employed one Technical Supervisor. 2. Review of personnel records revealed that the laboratory's Technical Supervisor completed a Doctorate of Philosophy (PhD) in Biomedical Sciences from the Royal Melbourne Institute of Technology on December 13, 2017. 3. Further review of the records revealed there was no documentation of a foreign equivalency evaluation of the diploma. 4. In an interview on 04/07/2022 at 1110 hours in the reception area the Technical Supervisor (as described in the CMS Form 209 signed by laboratory director on 04/07/2022) confirmed the findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, review of submitted Laboratory Personnel Report (CLIA), Form 209, and staff interview it was determined the laboratory's technical supervisor failed to document semiannual competency assessment for one of three testing personnel within the first year of employment. Findings included: 1. Review of personnel records and submitted Form 209 revealed that one of the laboratory's testing personnel hired in March of 2021 and promoted to the current Technical Supervisor position in March of 2022 had no documentation of semiannual competency assessment within the first year of employment. This former testing person had only the Annual Competency assessment performed on 03/01 /2022. 2. Review of the submitted personnel Form 209 revealed the laboratory currently employed only one technical supervisor. 3. In an interview on 04/07/2022 at 1110 hours in the reception area the Technical Supervisor (as described in the CMS Form 209 signed by laboratory director on 04/07/2022) confirmed the findings.
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 review of the laboratory's submitted Laboratory Personnel Report (CLIA), Form 209, review of personnel records and staff interview it was determined the laboratory failed to have one of one General Supervisor who meets the qualification requirements of the position. 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 review of the laboratory's submitted Laboratory Personnel Report (CLIA), Form 209, review of personnel records and staff interview it was determined the laboratory failed to have one of one General Supervisor who meets the qualification requirements of the position. Findings included: 1. Review of the laboratory's submitted Laboratory Personnel Report (CLIA), Form 209 revealed the laboratory employed one General Supervisor. 2. Review of personnel records revealed that the laboratory's General Supervisor completed a Doctorate of Philosophy (PhD) in Biomedical Sciences from the Royal Melbourne Institute of Technology on December 13, 2017. 3. Further review of the records revealed there was no documentation of a foreign equivalency evaluation of the diploma. 4. In an interview on 04/07/2022 at 1110 hours in the reception area the Technical Supervisor (as described in the CMS Form 209 signed by laboratory director on 04/07/2022) confirmed the findings.