| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 10D2262698 | 06/12/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Careful Touch Llc | 1420 St Lucie West Blvd Ste 106, Port Saint Lucie, 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 |
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| **D0000** | Initial certification survey was conducted on 5/23/2023 to 6/12/2023 at Careful Touch LLC. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Conditions were not met: D 5400-Analytic Systems 493.1250 |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on observation and interview, the laboratory failed to complete the performance specifications for interfering substance and method comparison for Urinary Tract Infection (UTI) Microbiota with Antibiotic Resistance (Polymerase Chain Reaction) PCR before starting patient testing on 2/2/2023. (Refer to D5423) and failed to run external positive and negative controls for six (2/2/2023, 2/3/2023, 2/17/2023, 3/5 /2023, 3/20/2023 and 4/5/2023) out of six testing days for Molecular Designs Urinary Tract Microbiota with Antibiotic Resistance Markers Plus Panels (UTI PCR) for eight patients reviewed. (Refer to D5455) |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>Each laboratory that modifies an FDA-cleared or approved test system, or introduces |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview, the laboratory failed to complete the performance specifications for interfering substance and method comparison for Urinary Tract Infection (UTI) Microbiota with Antibiotic Resistance (Polymerase Chain Reaction)PCR before starting patient testing on 2/2/2023. Findings Included: The laboratory's policy for PCR Assays to Identify Pathogens revealed the following pathogen identified for PCR: Acinetobacter baumannii Bacteroides fragilis Candida albicans Candida dubliniensis Candida glabrata Candida krusei Candida parapsilosis Candida tropicalis Citrobacter freundii Citrobacter koseri Enterobacter cloacae Enterococcus spp. Escherichia coli Klebsiella aerogenes Klebsiella oxytoca Klebsiella pneumoniae Morganella morganii Mycoplasma genitalium Mycoplasma hominis Prevotella bivia Proteus mirabilis Pseudomonas aeruginosa Serratia marcescens Staphylococcus aureus Staphylococcus epidermidis Staphylococcus saprophyticus Streptococcus agalactiae (Group B) Streptococcus pyogenes (Group A) Ureaplasma urealyticum ABX Resistance Markers: Class A B-lactamase (blaKPC) Class A B-lactamase (CTX-M-Group 1) Class B metallo-B-lactamase (blaNDM) Vancomycin (vanA, vanB) Methicillin/Oxacillin (mecA) Review of Validation Memo- Interfering Substance Study for qPCR Assay for Detection of Pathogens in UTI specimens signed by laboratory director on 1/10/ 2023, read "UTI specimens spiked with potential inhibitory substances were tested and compared with the control sample with inhibitory substances. No inhibition was observed." There was no documentation of what inhibitory substances were used in the interfering substance testing. Review of Table 4 Method Comparison Table revealed there was no known negative or positive identification to what the 6 samples were. Review of eight Urinary Tract Microbiota Patient Reports revealed the following: i.) Patient 1 and Patient 2 were tested for UTI PCR on 2/2/2023. ii) Patient 3 was tested for UTI PCR on 2/3/2023. iii) Patient 4 was tested for UTI PCR on 2/7/2023. iv) Patient 5 was tested for UTI PCR on 3/5/2023. vi.) Patient 6 and Patient 7 were tested for UTI PCR on 3/20/2023. vii.) Patient 8 was tested for UTI PCR on 4/5/2023. The annual testing volume for PCR was 100 tests. On 5/24/2023 at 1:07 PM, the General Supervisor confirmed their validation was incomplete. |
| **D5455** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(v)(g)<br><br>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. |

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| | This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to run external positive and negative controls for six (2/2/2023, 2/3/2023,2/17/2023,3/5/2023,3/20/2023 and 4/5/2023) out of six testing days for Molecular Designs Urinary Tract Microbiota with Antibiotic Resistance Markers Plus Panels (UTI PCR). Findings Included: Review of External Quality Control Log-Qualitative Test revealed the following: a. On 2/3/2023 external positive (lot FG002365) and negative (lot FG001467) controls were run and listed as passed but no documentation of instrument printouts for controls passed. b. On 3/5/2023 external positive (lot FG002569) and negative (lot FG001467) controls were run and listed as passed but no documentation of instrument printouts for controls passed. c. There was no written documentation or instruments for external positive and negative controls for 2/2/2023,2/17/2023,3/20/2023 and 4/5/2023. Review of eight Urinary Tract Microbiota Patient Reports revealed the following: i.) Patient 1 and Patient 2 were tested for UTI PCR on 2/2/2023. ii) Patient 3 was tested for UTI PCR on 2/3/2023. iii)Patient 4 was tested for UTI PCR on 2/7/2023. iv) Patient 5 was tested for UTI PCR on 3/5/2023. vi.) Patient 6 and Patient # 7 were tested for UTI PCR on 3/20/2023. vii.) Patient 8 was tested for UTI PCR on 4/5/2023. Review of UTI WND ABX Plate Map it revealed the following: a. Plate Map on 2/3/2023 had no external positive and negative control map b. Plate Map on 2/17/2023 had no external positive and negative control map c. Plate Map on 3/5/2023 had no results for the external positive and negative control. d. Plate Map on 3//17/2023 had no external positive and negative control map. e. No plate map for 4/5/2023 and 2/2/2023 and 3/20/2023. Review of Molecular Designs Urinary Tract Infections Panels - General Information: Testing Policies Section: Quality Control effective date 1/17/2023 read, "External controls corresponding to each organism are available for each assay. These should be run with every lot/shipment and week the plates are in use or as dictated by appropriate regulatory bodies." Review of emails from the manufacturer dated 1/19/2023 at 11:54 AM, noted, "we need to run an external control at minimum of once a week for every week that we run a UTI assay for a patient." The annual testing volume for PCR was 100 tests. On 5/23/2023 at 2:30 PM, the General Supervisor stated the external controls were run monthly. |