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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 44D0309288 | (X3) Date Survey Completed 03/20/2024 |
| Name of Provider or Supplier Paul G Smith Jr Do Plc | Street Address, City, State 2121 North Ocoee Street Suite 101, Cleveland, TN | |
| 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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| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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) 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the laboratory liaison, the laboratory's procedure for urine microscopic testing did not meet the procedure manual requirements in 2024. The findings include: 1. Review of the laboratory procedure for urine microscopic testing, on the date of the survey (03.20.2024), revealed the procedure did not include the following; -reference intervals (normal values) -panic or alert values -protocol for how to quantitate and report microscopic elements -protocol for reporting panic or alert values 2. Interview with the laboratory liaison on 03.20.2024 at 12:00 p.m. confirmed the laboratory</p> |

procedure for urine microscopic testing did not include all elements as required by the regulations.