Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2286056	03/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cooper Univ Healthcare	400 Nj - 38, Moorestown, NJ	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Technical Supervisors (TS) the PM lacked a Quality Control (QC) procedure for Manual Urine Microscopic (MUM) tests from 5/1/24 to 3/5/25. The findings include: 1. There was no procedure for performing QC for MUM tests on each day of patient testing. 2. The TS confirmed on 3/5/25 at 1:25 pm, the PM lacked a QC procedure for MUM tests.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of Abbott piccolo xpress analyzer Performance Specification (PS) records and interview with the Techincal Supervisor (TS), the laboratory failed to ensure that all PS records were adequate for all analytes run on the Abbott piccolo xpress Analyzer from May 2025 to 3/5/25. The findings include: 1. There was no documented evidence that Normal Patient Range was verified. 2. The TS confirmed on 3/5/25 at 11:30 am that the laboratory failed to ensure that all PS records were adequate.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Technical Supervisors (TS), the laboratory failed to perform and document QC for Manual Urine Microscopic (MUM) tests on each day of patient testing from 5/1/24 to 3/5/25. The finding includes: 1. There was no documented evidence testing personnel (TP) performed and documented QC for MUM tests on each day of patient testing. 2. The TS confirmed on 3/5/25 at 1:30 pm, TP did not perform and document QC for MUM tests.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on the lack of Quality Control Verification (QCV) records and interview with the Technical Supervisor (TS), the laboratory failed to verify commercially assayed

	QC material with each new lot and/or shipment used on the i-Stat analyzer for Chemistry and Blood gas testing from May 2024 to 3/5/25. The finding includes: 1. There were no QCV records available for review for the i-Stat analyzer. 2. The TS confirmed on 3/5/25 at 12:20 pm, the assayed values of QC material were not verified before patient testing.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on survey review of the Procedure Manual (PM) and interview with the Technical Supervisors (TS), the Laboratory Director (LD) failed to ensure that approved procedures for the use of the Sysmex BeyondCare Quality Monitor (BCQM) was available to all testing personnel from 5/1/24 to 3/5/25. The findings include: 1. The laboratory could not provide approved procedures for the use of the Sysmex BCQM. 2. The TS confirmed on 3/5/25 at 11:00am, approved procedures for the Sysmex BCQM was not available for review.