

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0313029	(X3) Date Survey Completed 10/25/2023
Name of Provider or Supplier Farragut Pediatrics	Street Address, City, State 11220 West Point Dr, Knoxville, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory liaison, the laboratory director and testing personnel failed to sign two of four PT attestation statements in 2022 and 2023. The findings include: 1. Review of the laboratory's proficiency testing records revealed the following: - Events not signed by laboratory director: 2022 2nd Event and 2023 2nd Event - Event not signed by testing personnel: 2023 2nd Event 2. Interview with the laboratory liaison on 10.25.2023 at 2:15 p.m. confirmed laboratory director and testing personnel failed to sign attestation statements for two of four PT events in 2022 and 2023.</p>
D3027	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1)</p> <p>Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test reports, lack of patient test requisitions and interview with the laboratory liaison, the laboratory failed to retain records of test requisitions for three of three patients reviewed in 2022 and 2023. The findings include: 1. Review</p>

of the patient test reports revealed the following: -patient number 6641 had documented test results for Complete Blood Count and Urine Microscopy on 06.27.2022 -patient number 7280 had documented test results for Complete Blood Count and Urine Microscopy on 09.11.2023 -patient number 6823 had documented test results for Complete Blood Count and Urine Microscopy on 10.07.2023 2. No patient test requisitions could be provided for surveyor review for the Complete Blood Counts and Urine Microscopy tests for patients 6641, 7280, and 6823. 3. Interview on 10.25.2023 at 2:15 p.m. with the laboratory liaison affirmed the laboratory documents patient orders on a charge sheet and once orders are completed and charges filed, charge sheets are shredded which confirmed the laboratory failed to retain records of test requisitions for three of three patients reviewed in 2022 and 2023.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of patient test reports, review of laboratory records and interview with the laboratory liaison, the laboratory failed to verify the accuracy of urine microscopic testing twice a year in 2022 and 2023. The findings include: 1) Observation of the laboratory on 10.25.2023 at 11:05 a.m. revealed a microscope on the counter in use for patient testing for urine microscopy. 2) Review of patient test reports revealed urine microscopic patient testing was performed in 2022 and 2023. 3) Review of the laboratory records revealed no documentation that twice per year verification of accuracy had been done for urine microscopy in 2022 or 2023. 4) Interview with the laboratory liaison on 10.25.2023 at 2:15 p.m. confirmed the laboratory performed urine microscopic testing and no records were present for verifying the accuracy twice a year in 2022 and 2023.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

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.

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 2023. The findings include: 1. Review of the laboratory procedure for urine microscopic testing revealed the procedure did not include the following; -step by step performance of the procedure, including interpretation of results -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 10.25.2023 at 2:15 p. m. confirmed the laboratory procedure for urine microscopic testing did not include all elements as required by the regulations.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
 Based on observation of the laboratory, observation of storage room, review of manufacturers' operator's manual and test kit cartridge packaging, lack of records, and staff interview, the laboratory failed to monitor humidity in the area where the Sight OLO-U1 Complete Blood Count (CBC) analyzer and test kit cartridges were in use for patient testing and the room temperature and humidity in the storage room where additional test kit cartridges were being stored on the date of the survey (10.25.2023). The findings include: 1. Observation of the laboratory on 10.25.2023 at 11:05 a.m. revealed the Sight OLO-U1 (serial # Q398) and OLO test kit cartridges (lot # 10059) in use for performing patient testing for CBC. 2. Observation of the storage room on 10.25.2023 at 11:20 a.m. revealed two additional boxes of OLO test kit cartridges (lot #10059) being stored. 3. Review of the manufacturers' operator's manual and OLO test kit cartridge packaging revealed the following humidity and storage temperature requirements: Sight OLO-U1 CBC analyzer: humidity 20%-80% OLO test kit cartridges: humidity 10%-80% OLO test kit cartridges: storage temperature 18C-26C 3. There were no records for humidity monitoring in the laboratory and no records for humidity and room temperature monitoring in storage room for surveyor review. 4. Interview with the laboratory liaison on 10.25.2023 at 11:30 a.m. confirmed the laboratory did not monitor the humidity in the area where the Sight OLO-U1 CBC analyzer and test kit cartridges were in use and room temperature and humidity in the storage room where additional OLO test kit cartridges were being stored on the date of the survey (10.25.2023).

D5449

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(3)(ii)(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--

At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the laboratory director, the laboratory failed to have reference material available for performance of urine microscopic testing on the day of the survey (10.25.2023). The findings include: 1. Observation of the laboratory on 10.25.2023 at 11:10 a.m. revealed a microscope on the counter in use for patient urine microscopic testing. There was no reference material noted in the laboratory. 2. Interview with the laboratory director on 10.25.2023 at 11:20 a.m. confirmed the laboratory failed to have reference material available for performance of urine microscopic patient testing in 2023.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual and interview with the laboratory liaison, the laboratory director failed to ensure job descriptions were present that outlined the duties and responsibilities of the laboratory director, technical consultant, clinical consultant, and testing personnel on the date of the survey (10.25.2023). The findings include: 1) Review of the laboratory procedure manual revealed no job descriptions were present for the laboratory director, technical consultant, clinical consultant, and testing personnel. 2) Interview with the laboratory liaison on 10.25.2023 at 2:15 p.m. confirmed the laboratory director failed to ensure job descriptions were present for the laboratory director, technical consultant, clinical consultant and testing personnel on the date of the survey (10.25.2023).