

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0436489	(X3) Date Survey Completed 02/27/2020
Name of Provider or Supplier Cairo Diagnostic Center	Street Address, City, State 13289 Kessler Rd, Cairo, IL	
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
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory technical supervisor (TS); the laboratory failed to perform bi-annual method accuracy evaluations for pinworm examinations in 2018 and 2019. Findings Include: 1. Review of the laboratory's test menu identified the test "Pinworm Exam". 2. Review of proficiency testing documentation found no evidence of bi-annual method accuracy evaluation for pinworm examinations in 2018 and 2019. 3. Interview with the TS on 02-27-2020, at 2:30 pm, confirmed that the laboratory failed to perform bi-annual method accuracy verifications for pinworm examinations in 2018 through 2019.</p>
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</p>

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 laboratory records and interview with the laboratory's technical supervisor (TS); the laboratory failed to outline all components of a test procedure for pinworm examinations. Findings Include: 1. Review of the policy and procedure manual identified the procedure, "Pinworm Examination", which failed to have the following required components of a test procedure: a. Requirements for patient preparation, collection, labeling, storage, preservation, transportation, processing, acceptability, and rejection b. Step-by-step performance of the procedure, including test calculations and interpretation of results. c. Microscopic examination, including the detection of inadequately prepared slides. d. The reportable range for test results for the test system as established or verified in 493.1253. e. Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. f. Control procedures. g. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. h. Limitations in the test methodology, including interfering substances. i. Reference intervals (normal values). j. The laboratory's system for entering results in the patient record and reporting patient results including panic values. k. Description of the course of action to take if a test system becomes inoperable. 2. During survey date 02-27-2020, at 2:30 pm, the above findings were confirmed by the TS.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the technical supervisor (TS); the laboratory failed to have a reliable system to ensure that pinworm examination test results are accurately transferred to the final report destination. Findings include: 1. Review of the patient test log for pinworm examinations revealed the laboratory failed to ensure 1 of 3 patient test results made it to the final report destination (the patient chart). a. Patient ID: P10 sample collected on 10-29-2019 2. On survey date 02-27-2020, at 2:30 pm the above findings were confirmed by the TS.

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 review of laboratory records and interview with the technical supervisor (TS); the laboratory failed to include all the required components of a laboratory test report for 2 of 2 patient test reports reviewed for pinworm examinations. Findings Include: 1. Review of 2 of 2 patient test reports for pinworm examinations found the laboratory failed to indicate the name and address of the testing laboratory and for 1 of 2 of the patient test reports failed to indicate the test report date. Patient Identification Test Date P8 12-09-2019 P9 Unknown, Collected on 10-21-2019 2. On survey date 02-27-2020, at 2:30 pm, the TS confirmed the above findings.