Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0436489	12/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cairo Diagnostic Center	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
D5012	SYPHILIS SEROLOGY CFR(s): 493.1207 If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory records, patient test results, manufacturer's package inserts, lack of documentation, and interview with the laboratory technical consultant (as listed on the CMS-209 - Laboratory Personnel Form on 12/13/2023); the laboratory failed to ensure two levels of qualitative quality control materials were run each day of patient testing for Syphilis Rapid Plasma Reagin (RPR) Card Testing prior to reporting of patient results (see D5449). In addition, the laboratory failed to follow their RPR Card Test procedure regarding the frequency of a) verifying rocker rotations; b) frequency of verifying the needle weekly for proper volumetric delivery; and c) the frequency of which to run controls (see 5401). The laboratory also failed to follow the manufacturer's package insert for RPR regarding allowing all reagents and samples to warm to the provided room temperature prior to use (see D5411). Lastly, the laboratory failed to document a patient RPR test result for one of nine patients (see D5789).
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on record review, lack of documentation, and interview with the technical consultant (TC), the laboratory failed to meet the criteria for acceptability of quality control (QC) results prior to reporting patient test results for one of six patients reviewed for prothrombin time (PT) testing (see D5481).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and records, and interview with the laboratory's technical consultant (TC); the laboratory failed to follow their Syphilis Rapid Plasma Reagin (RPR) procedure regarding a) the frequency of verifying the rocker rotations; b) the frequency of verifying the needle weekly for proper volumetric delivery; and c) the frequency of which to run controls as required by 493. 1251. Findings include: 1. Review of the "Rapid Plasma Reagin" (RPR) Procedure Manual revealed the procedure stated: a) "The rotator should be checked daily to see that it rotates at 100 +/- 3 rpm [rotations per minute]; adjust as needed. Record the observed rate on speed." Upon review of patient log sheets, six of nine patients tested for RPR from 12/17/2021 to the survey date of 12/13/2023 did not have documentation of rotator speed correlating with their date of testing recorded on the patient log sheet. Patient Identification: Date of testing: 133390 12/17/2021 135778 06 /28/2022 7734 08/18/2022 59136 10/24/2022 4321 03/13/2023 7894 03/20/2023 b) "Check needle weekly for volumetric delivery (60drips/ml [milliliter]) and record on the A.C. worksheet." Upon review of patient log sheets, six of nine patients tested for RPR from 12/17/2021 to the survey date of 12/13/2023 did not have documentation of needle volume dispenses within one week of their date of testing recorded on the log sheet. Patient Identification: Date of testing: 133390 12/17/2021 135778 06/28/2022 7734 08/18/2022 59136 10/24/2022 4321 03/13/2023 7894 03/20/2023 c) "Reactive and non-reactive, minimally reactive and reactive control is tested with each batch of patient specimens." Upon review of patient log sheets, three of nine patients tested for RPR from 12/17/2021 to the survey date of 12/13/2023 had no quality control testing documented for the dates testing was performed. Patient Identification: Date of testing: 135778 06/28/2022 7734 08/18/2022 7894 03/20/2023 2. Interview with the laboratory's TC on 12/13/2023 at 04:26 pm confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and records, the manufacturer's package

	insert, and interview with the laboratory's technical consultant (TC); laboratory failed to follow the manufacturer's package insert for the Syphilis Rapid Plasma Reagin (RPR) Card Test in regard to allowing all reagents and samples to warm to the provided room temperature prior to use, as required by 493.1252. Findings include: 1. Review of the Arlington Scientific, Inc. (ASI) RPR Card Test manufacturer's package insert, under Preparation For The Assay, stated, "Allow all reagents and samples to warm to room temperature (20-30 C) before use." Upon review of a) patient logs sheets, the documented range of acceptable temperature was recorded as 20-25 C and b) the laboratory's procedure manual's documented range of acceptable temperature was recorded as 23-30 C. 2. Upon review of patient log sheets, five of nine patients tested for RPR from 12/17/2021 to the survey date of 12/13/2023 did not have documentation of provided room temperature correlating with their date of testing recorded on the patient log sheet. Patient Identification: Date of testing: 133390 12/17 /2021 135778 06/28/2022 7734 08/18/2022 59136 10/24/2022 4321 03/13/2023 7894 03/20/2023 3. Interview with the laboratory's TC on 12/13/2023 at 04:26 pm confirmed the above findings.
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 review of patient test results, laboratory quality control (QC) records, and interview with the laboratory technical consultant (TC); the laboratory failed to ensure two levels of quality control (QC) materials were ran each day for Rapid Plasma Reagin (RPR) serology testing on three out of nine patients before reporting patient test results, as required per 493.1256. Findings include: 1. RPR serology testing reports logs were reviewed from 12/17/2021 to the date of the survey (12/13/2023). 2. Review of three of nine patient test reports for RPR serology testing found no quality control testing was documented for the test dates performed. Medical Record Number: Test Date: 135778 06/28/2022 7734 08/18/2022 7894 03/20/2023 3. During survey date 12/13/2023, at 02:41 pm, the TC confirmed the surveyors' findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the technical consultant (TC), the laboratory failed to meet the criteria for acceptability of quality control (QC) results prior to reporting patient test results for one of six patients reviewed for prothrombin time (PT) testing using the Sysmex CA-600 (serial Number: 12733), as required per 493.1256. Findings include: 1. Review of quality

	control results on the dates of six patients was performed. Medical Record Number (MRN): Date of Testing: 1011 11/01/2023 37962 08/04/2023 7490 10/10/2022 63307 03/16/2023 1011 02/23/2022 6851 10/14/2022 2. Review of MRN 6851, patient test report date of 10/14/2022, found the following: a. Patient was tested for PT, result 16.6 seconds. b. Review of QC data for patient test report date of 10/14/2022 shows PT Ci-Trol Level 1 (lot number: 564813) QC did not meet the limits of acceptability and was outside the acceptable range. There was no documentation of corrective action. c. PT Ci-Trol QC Level 1, was 10.7 seconds and the acceptable range was 9.6 to 10.4 seconds. 3. During survey date 12/13/2023 at 04:26 pm, the laboratory TC confirmed the survey findings.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory's technical consultant (TC); the laboratory failed to document a patient Rapid Plasma Reagin (RPR) test result for one of nine patients tested for RPR from 12 /17/2021 to the survey date of 12/13/2023, as required per 493.1283. Findings Include: 1. Review of patient test reports revealed one of nine reported Rapid Plasma Reagin (RPR) tests was not documented on the patient testing worksheet in which quality control results and maintenance/function tests are recorded each day of patient RPR testing. Patient Identification Testing Date 7894 03/20/2023 2. Interview with laboratory's TC on 12/13/2023 at 2:41 pm confirmed these findings.