Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0436489	07/27/2018
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: A. Based on review of laboratory records and personnel interviews; the laboratory failed to enroll and maintain enrolment in proficiency testing (PT) for the regulated analytes; infectious mononucleosis, syphilis serology and hCG. Findings Include: 1. Review of American Proficiency Institute (API) PT records revealed that the laboratory failed to enroll in PT for the regulated analytes; infectious mononucleosis and syphilis serology when the laboratory switched PT providers after event 1 of 2017. 2. Interview with testing personnel (TP) #1 confirmed on 7-26-2018, at 10:30 am, the laboratory performs infectious mononucleosis testing using the Clearview Mono test kit with serum and syphilis serology with ASI rapid plasma reagin card test kit. 3. On survey date 7-27-2018, at 2:00 pm, it was confirm that that the lab had not enroll in PT testing for infectious mono and syphilis serology since 1st quarter 2017. B. Based on review of laboratory records, direct observations, and personnel interviews; the laboratory failed to maintain enrollment for the regulated analyte serum human chorionic gonadotropin (hCG). 1. Review of API PT records found the laboratory discontinued enrollment for qualitative serum hCG in the second event of 2018. 2. Review of the qualitative serum hCG testing log found testing was still being performed by the laboratory, as recent as 07-12-2018. 3. Review of the API 2018 PT

	event schedule for qualitative serum pregnancy (Chemistry-Core) states PT results were due June 8, 2018 when the laboratory was still performing patient testing. 4. Direct observation during a tour of the laboratory facility on 7-26-2018, at 10:30am, with TP #1, identified Clearview qualitative serum hCG kits used for qualitative serum pregnancy testing. 5. TP#1 confirmed on 7-26-2018, at 1:30pm, the laboratory is still performing qualitative serum hCG till the kits expire.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of laboratory records and personnel interviews; the laboratory failed to test American Proficiency Institute (API) proficiency testing (PT) samples by personnel who routinely perform testing in 2017 through 2018. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the policy, "Proficiency Testing Policy", which states, "All personnel will be involved in the testing of the proficiency samples. Testing is to be performed with the laboratory's regular workload, by personnel who routinely perform the testing, using the methods of testing normally used for patient testing." 2. Review of API PT records found no documentation of testing personnel (TP) #1 performing core chemistry, hematology /coagulation, or immunology proficiency testing from event 2 of 2017 through event 2 of 2018. 3. On survey date 07-26-2018, at 1:00 pm, TP #1 confirmed 1 of 3 TP who were authorized to perform laboratory testing failed to participate in API PT in 2017 through 2018.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of laboratory records and personnel interviews; the laboratory failed

	to successfully participate in proficiency testing (PT) for calcium and PO2 in the specialty of chemistry. Findings include: 1. Review of the CASPER Report 0096D, American Association of Bioanalysts (AAB) and American Proficiency Institute (API) PT records, and interview with testing personnel (TP) #1, on 7-26-2018 2016, at 1:00 pm, confirmed that the initial unsuccessful PT performance for calcium occurred during chemistry 3, 2016 and event 2 of 2017. See D2096. 2. Review of the CASPER Report 0096D, American Proficiency Institute (API) PT records, and interview with testing personnel (TP) #1, on 7-26-2018 2016, at 1:00 pm, confirmed that the initial unsuccessful PT performance for PO2 blood gas occurred during chemistry event 1 of 2018 and event 2 of 2018. See D2096.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to perform and document a corrective action for unsatisfactory performance for bilirubin direct, in event 1 of 2018. Findings include: 1. Review of American Proficiency Institute (API) proficiency testing (PT) records for event 1 of 2018, Core Chemistry found no documented review and corrective action for the direct bilirubin failure, 50%. 2. During the survey on 07-26-2018, at 1:00 PM, TP#1 confirmed the laboratory failed to document a corrective action for the bilirubin results.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: A. Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to successfully participate in the testing of proficiency testing (PT) samples under the specialty of chemistry for total calcium. Findings include: 1. Review of the CASPER report 0096D revealed that the initial unsuccessful PT performance occurred during the American Association of Bioanalysts (AAB) PT event 3 of 2016 and the American Proficiency Institute (API) event 2 of 2017, as listed below. ROUTINE CHEMISTRY EVENT -3, 2016 Calcium, total 60% Unsatisfactory EVENT -2, 2017 Calcium, total 0% Unsatisfactory 2. Further review of AAB and API PT records confirmed the unsuccessful performance for total Calcium for two of three events (Event 3 2016 and Event 2 2017). 3. During the survey on 07-26-2018, at 1:00 PM, TP#1 confirmed the unsuccessful PT performance

	for Calcium, total. B. Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to successfully participate in the testing of proficiency testing (PT) samples under the specialty of chemistry for PO2 Blood Gas. Findings include: 1. Review of the CASPER report 0096D revealed that the initial unsuccessful PT performance occurred during the American Proficiency Institute (API) PT event 1 of 2018 and event 2 of 2018, as listed below. ROUTINE CHEMISTRY EVENT -1, 2018 PO2 Blood Gas 40% Unsatisfactory EVENT -2, 2018 PO2 Blood Gas 60% Unsatisfactory 2. Further review of API PT records confirmed the unsuccessful performance for PO2 Blood Gas for two consecutive events (Event 1 2018 and Event 2 2018). 3. During the survey on 07-26-2018, at 1:00 PM, TP#1 confirmed the unsuccessful PT performance for PO2 Blood Gas.
D2105	ENDOCRINOLOGY CFR(s): 493.843(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to perform and document a corrective action for unsatisfactory performance of quantitative human chorionic gonadotropin (hCG) in event 2 of 2018. Findings include: 1. Review of American Proficiency Institute (API) proficiency testing (PT) records for event 2 of 2018, Core Chemistry, found no documented review and corrective action for the quantitative human chorionic gonadotropin (hCG) failure, 20%. 2. During the survey on 07-26-2018, at 1:00 PM, TP#1 confirmed the laboratory failed to document corrective action for the quantitative hCG failure.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory records and personnel interviews; the laboratory failed to retain all quality control records for blood gas testing. Findings Include: 1. Review of patient test results for blood gas testing on the Siemens RAPIDPoint 500 analyzer found no quality control records were retained for 3 of 3 testing dates reviewed. Patient Identification Test Date P1 11-09-2017 P2 12-14-2017 P3 01-30-2018 2. Interview on 7-27-2017 at 2:00 pm, the laboratory representative confirmed the laboratory failed to have documented control records for the Siemens RAPIDPoint 500 analyzer for 3 of 3 dates reviewed.
D3037	RETENTION REQUIREMENTS

	CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory records and personnel interviews; the laboratory failed to retain proficiency testing (PT) documentation for American Association of Bioanalysts (AAB), event 1 of 2017. Findings Include: 1. Surveyor requested at 1:00 pm, on 7-26-2018, with testing personnel (TP) #1, PT records for AAB PT event 1 of 2017. 2. Review of the PT records found no documentation was available for AAB PT event 1. 3. During the survey on 7-27-2018, at 2:00 pm, the above findings were confirmed by the laboratory representative.
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 review of laboratory records and personnel interviews; the laboratory failed to perform bi-annual method accuracy evaluations for 25-hydroxyvitamin D (25-OH-D) testing in 2017 and 2018. Findings Include: 1. Review of the laboratory testing volume documentation from June 1, 2017 through May 31st, 2018 found the laboratory performed 567 tests for 25-hydroxyvitamin D (25-OH-D). 2. Review of testing records show that the laboratory had not performed twice per year verification for the analyte, 25-hydroxyvitamin D (25-OH-D). 3. Interview with testing personnel (TP) #1, on 7-26-2018, at 1:30 pm confirmed the laboratory failed to perform bi-annual method accuracy verifications for 25-hydroxyvitamin D (25-OH-D) in 2017 and 2018.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and personnel interviews; the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. Findings Include: 1. The laboratory failed to have procedures in place for blood gas and H. pylori testing. See D5401. 2. The laboratory failed to include control procedures and corrective actions to take when controls fail to meet the laboratory's criteria for acceptability for prothrombin time testing on the Sysmex CA-620 analyzer. See D5403. 3. The laboratory failed to demonstrate it can obtain performance specifications for quantitative human chorionic gonadotropin, vitamin D,

	vitamin B12, and folate on the Siemens Dimension analyzer, prothrombin time testing on the Sysmex CA-620, and blood gas testing on the Siemens RAPIDPoint 500 prior to patient testing. See D5421. 4. The laboratory failed to perform calibration verifications as required for the Siemens RAPIDPoint 500 analyzer for blood gas analytes (PH, PO2, PCO2) in 2017 through 2018. See D5439. 5. The laboratory failed to ensure positive and negative control materials were ran each day of testing prior to reporting patient test results for infectious mononucleosis, qualitative serum human chorionic gonadotropin, and H. pylori testing. See D5449. 6. The laboratory failed to establish statistical parameters for coagulation controls used on the Sysmex CA-620 analyzer. See D5469. 7. The laboratory failed to ensure control materials for Vitamin B12 testing met the laboratory's criteria for acceptability before reporting patient test results for 3 of 5 patient test dates reviewed. See D5481. 8. The laboratory failed to perform and document corrective actions for quality control failures in chemistry testing in 2018. See D5783.
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 records and interview with laboratory personnel; the laboratory failed to have procedures for blood gas and H. pylori testing. Findings Include: 1. Review of laboratory's policy and procedure manual found the laboratory failed to have procedures in place for blood gas testing on the Siemens RAPIDPoint 500 analyzer and H. pylori testing using the Alere Clearview H. pylori test kit. 2. On survey date 7-26-2018, at 3:30 pm, testing personnel (TP) #1 confirmed no written procedures were available for review for blood gas testing on the Siemens RAPIDPoint 500 analyzer or H. pylori testing using the Alere Clearview H. pylori test kit.
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 laboratory records and interview with laboratory personnel; the laboratory failed to include all required components of the test procedure for prothrombin time testing on the Sysmex CA-620 analyzer. Findings Include: 1. Review of laboratory's policy and procedure manual identified the policy, "Coagulation Quality Control Policy", which failed to indicate the control procedures (including how the laboratory establishes the control mean values and the laboratory's criteria for acceptability) and the corrective action to take when control results fail to meet the laboratory's criteria for acceptability. 2. On survey date 7-27-2018, at 2:00 pm, the laboratory representative confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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: A. Based on review of laboratory records and personnel interviews; the laboratory failed to demonstrate it can obtain performance verification data for quantitative human chorionic, vitamin D, vitamin 12, folate, blood gases, and prothrombin time prior to patient testing. Performance verification studies were not done in house at the Cairo laboratory. Findings Include: 1. During tour of the laboratory facility on 7-26-2018, at 10:30 am, testing personnel confirmed the laboratory added 4 new analytes (quantitative human chorionic gonadotropin, vitamin D, vitamin B12, and folate) in September of 2017 to the test menu for the Siemens Dimension EXL 200 analyzer. 2. Review of verification of performance documentation for quantitative human chorionic gonadotropin, vitamin D, vitamin B12, and folate found no analysis of data showing that accuracy, precision and reportable range had been verified to demonstrate comparable performance results to those established by the manufacturer. 3. On survey date 07-27-2018, at 2:00 pm, the above findings were confirmed by a laboratory representative. B. Based on review of laboratory records and personnel interviews; the laboratory failed to demonstrate it can obtain performance specifications for blood gas testing on the Siemens RAPIDPoint 500 analyzer prior to patient testing. Findings Include: 1. During tour of the laboratory facility on 7-26-2018, at 10:30 am, testing personnel (TP) #1 confirmed the laboratory was performing blood gas testing using the Siemens RAPIDPoint 500 analyzer. 2. Review of verification of performance documentation for blood gas testing found no analysis of data showing the accuracy, precision, and reportable range had been verified. Therefore, it cannot be verified that the blood gas instrument results were acurate and reliable. 3. On survey date 07-26-2018, at 11:15 am, TP#1 confirmed the verification of performance study was performed at Massac Memorial Hospital in Metropolis, IL and not in house at Cairo as it should be, and by its own testing personnel. C. Based

	on review of laboratory records and personnel interviews; the laboratory failed to demonstrate it can obtain performance specifications for prothrombin time testing on the Sysmex CA-620 analyzer prior to patient testing. Findings Include: 1. During tour of the laboratory facility on 7-26-2018, at 10:30 am, testing personnel (TP) #1 confirmed the laboratory was performing prothrombin time testing using a Sysmex CA-620 analyzer, which was put into use in July of 2017. 2. Review of verification of performance documentation for prothrombin time testing found no analysis of data showing that precision, accuracy and reportable range had been verified and compare to the manufacturer's established ranges. 3. On survey date 07-27-2018, at 2:00 pm, the above findings were confirmed by a laboratory representative.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with laboratory personnel; the laboratory failed to conduct calibration verifications as required for the Siemens RAPIDPoint 500 analyzer for blood gas analytes (PH, PO2, PCO2) in 2017 through 2018. Findings include: 1. Review of blood gas records found no documentation of completed calibration verification for the Siemens RAPIDPoint 500 analyzer since the start of patient testing in November of 2017. 2. Interview on 07-26-2018, at 3:30 pm, with testing personnel (TP) #1 confirmed the laboratory was unable to find any documented calibration verification records for the Siemens RAPIDPoint 500 analyzer.
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:
A. Based on review of laboratory records and interview with laboratory personnel; the laboratory failed to ensure positive and negative control materials were ran each day of testing prior to reporting 5 of 5 patient test results for infectious mononucleosis. Findings include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "Clearview Mono Whole Blood, Serum, Plasma", which states the quality controls are to be ran as follows: "Quality control requirements must be performed in accordance with local, state and federal regulations or accreditation requirements. Minimally, Inverness Medical Professional Diagnostics recommends that a positive and negative external controls be ran with each new lot and with each new untrained operator." 2. Interview with testing personnel (TP) #1, at 10:30 am, on 07-26-2018 confirmed external quality control is only performed with each new lot of Alere Clearview Mono test kits and no Individual Quality Control Plan (IQCP) had been implemented. 3. Review of 5 of 5 patient test results found no daily positive and negative external quality control results were documented on the laboratory's quality control logs. Serum Mono Test a. Patient ID: P14, Test Date: 03-02-2018 b. Patient ID: P15, Test Date: 04-09-2018 c. Patient ID: P16, Test Date: 06-06-2018 d. Patient ID: P17, Test Date: 06-11-2018 e. Patient ID: P18, Test Date: 03-16-2018 4. During survey date 07-27-2016 at 2:00 pm, the laboratory representative confirmed daily external quality controls were not performed for the moderate complexity test, serum infectious mononucleosis. B. Based on review of laboratory records and interview with laboratory personnel; the laboratory failed to ensure positive and negative control materials were ran each day of testing prior to reporting 5 of 5 patient test results for H. pylori. Findings include: 1. Review of the laboratory's policy and procedure manual found no procedure manual for H. pylori testing. See D5401. 2. Review of the procedure manual for the Alere Clearview H. pylori test kit states the following: "It is recommended that a positive and negative external control be run once per kit and as deemed necessary by your internal laboratory procedures." 3. Interview with testing personnel (TP) #1, at 10:30 am, on 07-26-2018 confirmed external quality control is only performed with each new lot of Alere Clearview H. pylori test kits and no Individual Quality Control Plan (IQCP) had been implemented. 4. Review of 5 of 5 patient test results found no daily positive and negative external quality control results were documented on the laboratory's quality control logs. Serum H. pylori Test a. Patient ID: P19, Test Date: 05-31-2018 b. Patient ID: P20, Test Date: 06-26-2018 c. Patient ID: P21, Test Date: 07-12-2018 d. Patient ID: P22, Test Date: 04-20-2018 e. Patient ID: P18, Test Date: 03-16-2018 5. During survey date 07-27-2016 at 2:00 pm, the laboratory representative confirmed daily external quality controls were not performed for the moderate complexity test, serum H. pylori. C. Based on review of laboratory records and interview with laboratory personnel; the laboratory failed to ensure positive and negative control materials were ran each day of testing prior to reporting 3 of 3 patient test results for qualitative serum human chorionic gonadotropin (hCG). Findings include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "Clearview 25 HCG Combo" states the quality controls are to be ran as follows: "Laboratory policy is that external controls are ran with each new kit and each new operator as they are trained" 2. Interview with testing personnel (TP) #1, at 10:30 am, on 07-26-2018 confirmed external quality control is only performed with each new lot of Alere hCG combo kits and no Individual Quality Control Plan (IQCP) had been implemented. 3. Review of 3 of 3 patient test results found no daily positive and negative external quality control results were documented on the laboratory's quality control logs. Serum hCG Test a. Patient

	ID: P24, Test Date: 05-21-2018 b. Patient ID: P25, Test Date: 06-20-2018 c. Patient ID: P27, Test Date: 03-23-2018 4. During survey date 07-27-2016 at 2:00 pm, the laboratory representative confirmed daily external quality controls were not performed for the moderate complexity test, serum qualitative hCG.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with laboratory personnel; the laboratory failed to establish statistical parameters for coagulation controls used on the Sysmex CA-620 analyzer. Findings Include: 1. During tour of the laboratory facility on 7-26-2018, at 10:30 am, testing personnel (TP) #1 confirmed the facility began prothrombin time testing on the Sysmex CA-620 analyzer in July of 2017. 2. Review of the policy, "Coagulation Quality Control policy", states the following: - "Siemens Ci-trol Levels 1 & 3 are used" - "Each laboratory should establish a range for control values." 3. Surveyor requested data used to determine Siemens Dade Ci-Trol Coagulation control level 1 and level 3 for the respective lot #'s, 548042 and 548479 in use on the CA-620. TP#1 confirmed on 7-27-2018 at 11:00 am that the established control values were taken from the old coagulation analyzer and were not re-established when the new coagulation analyzer was put into use for patient testing. 4. During the survey on 7-27-2018 at 2:00 pm, the surveyor findings were confirmed by the laboratory representative.
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 review of laboratory records and interview with laboratory personnel; the laboratory failed to ensure control materials for Vitamin B12 testing met the laboratory's criteria for acceptability before reporting patient test results for 3 of 5 patient test dates reviewed. Findings include: 1. Review of the laboratory policy and procedure manual identified the policy, "Chemistry Quality Control", which stated the following quality control criteria for acceptability: "1. If either of the controls (level I,

	II, or II) exceed 3 SD from its respective mean, patient results will not be reported pending corrective action and the problem is resolved and documented. 2. If levels I, II, & III exceed 2SD of their respective means on the same side, patient results are held pending corrective action and the problem is resolved and documented. 3. If the range between levels in the current run exceeds 4SD, patient results are not reported until corrective action is taken and the problem is resolved and documented." 2. Review of patient testing records for Vitamin B12 testing on the Siemens Dimension found for 3 of 5 patient testing dates reviewed quality controls did not meet the laboratory's acceptability criteria. Patient Identification Test Date P5 04-11-2018 P37 04-06-2018 P38 05-08-2018 P39 06-18-2018 P9 07-20-2018 3. Review of quality control (QC) reports identified the following issues: Test Date QC Level 1 Level 2 Level 3 04-11-2018 157.00 (-4.1 SD) 135.00 (-7.2 SD) 610.00 (-1.9 SD) 04-06-2018 258.00 (-0.8 SD) 89.00 (-8.2 SD) 80.00 (-15.0 SD) 05-08-2018 300.00 (+0.5 SD) 465.00 (+0.1 SD) 200.00 (-12.1 SD) SD - Standard Deviation 4. On survey date 7-27-2018, at 2:00 PM, the laboratory representative confirmed the above findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory records and personnel interviews; the laboratory failed to document corrective actions for chemistry quality control failures in 2018. Findings Include: 1. Review of chemistry "QC Report" documentation from 02-26-2018 through 7-26-2018 identified multiple dates where quality control failures where not investigated and no corrective actions were taken. (04-11-2018, 05-08-2018, and 06-12-2018) Vitamin B12 Date QC Comment/Violation Outcome 04-11-2018 157.00 (-4.1 SD) Reran Control No rerun documented. 04-11-2018 135.00 (-7.2 SD) Reran Control No rerun documented. Folate 05-08-2018 0.00 (-4.7 SD) Reran Control No rerun documented. 04-11-2018 0.10 (-13.8 SD) Reran Control No rerun documented. Thyroid Stimulating Hormone 06-12-2018 0.0100 (-7.2 SD) Reran Control No rerun documented. Alkaline Phosphatase 06-12-2018 176.00 (-6.3 SD) Reran Control No rerun documented. 06-12-2018 213.0 (-30.2 SD) Reran Control 4 times Control values never acceptable and corrective action steps not followed as identified in the "Chemistry Quality Control" policy. 2. On survey date 7-27-2018, at 2:00 pm, the survey findings were confirmed by the laboratory representative.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with laboratory personnel; the technical consultant (TC) failed to provide the technical oversight in accordance with 493.1413. Findings Include: 1. The TC failed to ensure new testing personnel received bi-annual competency assessments for 3 of 3 testing personnel listed on the CMS-209. See D6053. 2. The TC failed evaluate 3 of 3 TP prior to performing patient testing when new test methodologies in chemistry and new instrumentation for coagulation and blood gas testing were implemented. See D6055.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with laboratory personnel; the technical consultant (TC) failed to ensure semi-annual competency assessments were completed for 3 of 3 new testing personnel. Findings Include: 1. Review of the laboratory policy, "Competency Assessment for Laboratory Personnel", states "Employees will be assessed for competency within the first 6 months of employment and every year thereafter and whenever new procedures and methods are brought into the laboratory." 2. No competency assessment documentation was found for 3 of 3 new testing personnel (TP) listed on the CMS-209. 3. On survey date 07-26-2018, at 3: 35 pm, TP#1 confirmed no competency assessments had been completed for 3 of 3 TP identified on the CMS-209.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with laboratory personnel; the technical consultant (TC) failed to evaluate and document the performance of laboratory personnel for four new chemistry test methodologies and 2 new analyzers for Coagulation and Blood Gas testing prior to reporting patient test results. Findings Include: 1. Review of the laboratory policy, "Competency Assessment for Laboratory Personnel", states "Employees will be assessed for competency within the first 6 months of employment and every year thereafter and whenever new procedures and methods are brought into the laboratory." 2. No competency assessment documentation was found for 1 of 1 testing personnel (TP, TP#3) , listed on the CMS-209, who performs blood gas analysis on the Siemens RAPIDPoint 500, which was put into use for patient testing in November of 2017 . 3. No competency assessment documentation was found for 2 of 2 TP (TP#1 and TP#2), who perform prothrombin time testing on the Sysmex CA-620, which was put into use for patient testing in July

	of 2017. 4. No competency assessment documentation was found for 2 of 2 TP (TP#1 and TP#2), who test for the new analytes (folate, vitamin D, vitamin B12, and quantitative human chorionic gonadotropin) added in October of 2017 for patient testing on the Siemens Dimension analyzer. 5. On survey date 07-27-2018, at 2:00 pm, the laboratory representative confirmed the TC failed to evaluate and document the performance of 3 of 3 TP who perform testing with the new instrumentation and test methodologies utilized by the laboratory.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and interviews with laboratory personnel; the laboratory failed to employ testing personnel (TP) who meet the qualification requirements of 493.1423. Findings Include: 1. No degrees or transcripts were available for review for 1 of 3 TP listed on the CMS-209. See D6065. 2. No documentation of training was available for 1 of 3 TP listed on the CMS-209. See D6066.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with laboratory personnel; the laboratory failed to have qualifying documents for 1 of 3 testing personnel (TP) listed on the CMS-209. Findings Include: 1. No qualifying documents were available for review for TP#3. 2. On survey date 7-27-2018, at 2:00 pm, the surveyor findings were confirmed by a laboratory representative.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with laboratory personnel; the laboratory failed to have appropriate training documentation for 1 of 3 testing personnel (TP) listed on the CMS-209. Findings Include: 1. No training documentation was available for review for TP#3. 2. On survey date 7-27-2018, at 2: 00 pm, the surveyor findings were confirmed by a laboratory representative.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with laboratory personnel; the laboratory director (LD) failed to ensure a quality assessment program was established and maintained to assure the quality of laboratory services provided. Findings Include: 1. Review of the laboratory's policy and procedure manual failed to identify a documented quality assessment program. 2. On survey date 07-27-2018, at 2:00 pm, the laboratory representative confirmed no quality assessment program had been established, and ongoing problems were not assessed or resolved,