Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1026302	06/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cgh Medical Center-Cath Lab	100 E Lefevre Rd, Sterling, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to establish and follow written policies and procedures to assess employee competency for the following position: *Technical Consultant (TC) Findings: 1. Review of Laboratory Personnel Report (FORM CMS 209) revealed that there was a total of 1 TC listed on the form. 2. Review of personnel records revealed that there was no documentation to show that the laboratory director assessed the competency of the TC based on the responsibilities of the position of TC. 3. During survey date 06/21/18 at 11:00 AM, the TC confirmed the surveyor's findings.
D5303	TEST REQUEST CFR(s): 493.1241(b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to have a written or electronic authorization within 30 days of the oral test request. Findings: 1. Review of the laboratory's procedures manaul reveatled that there were no written procedures that described how tests are ordered. 2. During survey date 06/21/18 at 10:30 AM, the

	surveyor asked testing personnel how Activated Clotting Times are ordered. Testing personnel told the surveyor that the doctor will give them a verbal order. 3. Review of 4 patients tests records revealed that there was no written or electronic test request for 4 of 4 patients' test records reviewed. 4. During survey date 06/21/18 at 1:00 PM, the technical consultant confirmed the surveyor's findings.
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 and interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct problems as specified in 493.1289 for Activated Clotting Time. Findings: 1. Review of the laboratory's procedures manual revealed that the procedures did not include all the required information for preanalytic, analytic, and postanalytic test performance. See tag D5403 2. Review of laboratory records revealed that the laboratory did not perform all verification procedures that demonstrate that it can obtain performance specifications comparable to those established by the manufacturer. See tag D5421 3. Review of the laboratory's procedures manual revealed that there were no instructions that described how Quality Control of the test is performed. See D 5441 4. There was no documentation to show Quality Assessments (QA) were performed. See tag D5791
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 and interview, the procedure manual did not include the following: (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) The reportable range for test results for the test system as established or verified in 493.1253. (3) Control procedures. (4) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (5) 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. (6) Description of the course of action to take if a test system becomes inoperable. Findings: 1. The laboratory's procedures manual did not include requirements for specimen referral. When the surveyor asked testing personnel what would happen to the patient if their test system were to become inoperable, she was told that they would send the specimen to the OR for testing. There were no procedures for referral of patient's specimens for testing by other laboratories. 2. The laboratory did not verify its reportable range for Activated Clotting Time; and the procedures manual did not include its reportable range. 3. The laboratory's procedure manual did not include control procedures. The technical consultant told the surveyor that the laboratory performed 2 levels of liquid control material each shift of testing. However Review of 4 patient tests results revealed that there was no documentation to show QC performance for 3 of 4 dates where patients' specimens were assayed and reported. 4. There was no procedure that describes corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. 5. There were no procedure that describes 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. 6. There were no procedures that described the course of action to take if a test system becomes inoperable. 7. During survey date 06/21/18 at 11:00 AM, the technical consultant confirmed the surveyor's 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: Based on review an interview, the laboratory failed to do the following before reporting patient test results: *Demonstrate that it can obtain performance specification comparable to those established by the manufacturer. Findings: 1. Review of laboratory records revealed that there was no documentation to show that the laboratory demonstrated the accuracy of the Istat analyzer for Active Clotting Times. 2. Review of laboratory records revealed that there was no documentation to show that the laboratory demonstrated the Precision of the analyzer. 3. Review of laboratory records revealed that there was no documentation to show that the laboratory demonstrated the Reportable range of test results for the test system. 4. Review of laboratory records revealed that there was no documentation to show that

	the laboratory verified that the manufacturer's reference intervals are appropriate for the laboratory's patient population. 5. During survey date 06/21/18 at 1:00 PM the surveyor reviewed 4 patients' test results. Four of 4 patients' specimens were tested and reported prior to verification of the Istat analyzer. 6. During survey date 06/21/18 at 1:30 PM, the technical consultant confirmed the surveyor's findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to have control procedures that monitor the accuracy and precision of the complete analytic process. Findings: 1. Review of the laboratory's procedures manual revealed that there was no written procedure that described how quality control (QC) of the test is performed. The technical consultant stated that the laboratory performs 2 levels of QC material each day patient testing is performed. 2. Review of 4 patients' test records revealed that there was no documentation to show QC performance for 2 of 4 days when patients' specimens were tested and reported. 3. During survey date 06/21/18 at 2:00 PM, the technical consultant confirmed the surveyor's findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings: 1. Review of the laboratory's procedures manual revealed that there were no procedures that describe how the laboratory assesses its testing practices for the Activated Clotting Time using the Istat. 2. There was no documentation to show that the laboratory performed quality assessments of it testing. The technical consultant stated that the laboratory performs Quality Control (QC) each day it performs and reports patients' test results. However, surveyor review of patient testing revealed that

	there was no documentation to show QC performance for 2 of 4 days when patients' results were reported. See tag D5441 3. During survey date 06/21/18 at 2:00 PM, the technical consultant confirmed the surveyor's findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review and interview, the laboratory director failed to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics for its Istat analyzer prior to patients' testing. 1. Review of verification records revealed that there was no documentation to show that the laboratory director reviewed, evaluated, and approved verification data prior to patient testing. Records show that all testing personnel were not included in the verification process (operator variance). The technical consultant stated that he performed all testing for the verification of the Istat analyzer for Activated Clotting Time. 2. Review of 4 patients' test records revealed that blood gas results were reported for 4 of 4 patients records reviewed. 3. During survey date 06/21/18 at 2:00 PM, the technical consultant confirmed the surveyor's findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory director failed to ensure that the quality control program is established and maintained. Findings: 1. There was no written procedure that describes the number, type, and frequency the laboratory tests control materials. 2. Review of 4 patients' test records revealed that there was no documentation to show that quality control was performed on the dates when 2 of 4 patients' test results were reported. 3. During survey date 06/21/18 at 2:00 PM, the technical consultant confirmed the surveyor's findings.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory director failed to ensure that quality control (QC) and quality assessment (QA) programs are established and maintained. Findings 1. There was no written procedure that describes the number, type, and frequency the laboratory tests control materials for its Activated Clotting Time testing. 2. Review of 4 patients' test records revealed that there was no documentation to show that quality control was performed on the dates when 2 of 4 patients' test results were reported. 3. There was no documentation to show that the laboratory performed QA of its test system. 4. During survey date 06/21/18 at 2:00 PM, the technical consultant confirmed the surveyor's findings.
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 and interview, the laboratory director did not specify, in writing, the responsibilities and duties of each consultant and each person, identifying which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen testing or results reporting, and whether consultant or director review is required prior to reporting patient test results. Findings: 1. Review of the laboratory's procedures manual revealed that there was a personnel chart that list personnel in the hospital. Further review revealed that there was no documentation to show that the laboratory director assigned, in writing personnel to their position in the laboratory, and listed their responsibilities and duties for the following positions in the laboratory: a. Laboratory Director b. Clinical Consultant c. Technical Consultant 2. Review of Laboratory Personnel Report (FORM CMS 209), that was collected during the survey revealed the laboratory director was also listed as the Clinical Consultant. One person was listed as the technical consultant; and 9 other individuals were listed as testing personnel. 3. Review of personnel records revealed that there was no documentation to show that the position of technical consultant was assigned to anyone. 4. During survey date 06 /21/18 at 11:00 AM, the technical consultant confirmed the surveyor's findings.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review and interview, the laboratory director failed to ensure that the quality control (QC) program is established and maintained. Findings: 1. There was no written procedure that describes the number, type, and frequency the laboratory tests control materials. 2. Review of 4 patients' test records revealed that there was no documentation to show that quality control was performed on the dates when 2 of 4 patients' test results were reported. The technical consultant stated that QC is performed each day of patients' testing. There was no documentation to show that the technical consultant reviewed QC records. 3. During survey date 06/21/18 at 11:00 AM, the technical consultant confirmed the surveyor's findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review and interview, the technical consultant (TC) failed to be responsible for evaluating the competency of all testing personnel, assuring that staff maintained their competency to perform tests procedures and report test results promptly, accurately and proficiently. Findings: 1. Review of the laboratory's procedures manual revealed that there were procedures that described the process for training and assessing testing personnel competency. 2. Review of personnel records revealed that there was documentation to show that 9 if 9 testing personnel were trained to test patients' specimens for Activated Clotting Times (ACT). However, there was no documentation to show that competency assessments were performed for 9 of 9 testing personnel listed on Laboratory Personnel Report (FORM CMS 209). 3. During survey date 06/21/18 at 11:00 AM, the technical consultant confirmed the surveyor's findings.