| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 14D1026302 | 12/06/2023 |
| **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 |
|---|---|
| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>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<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory and proficiency testing (PT) records and interview with the technical consultant (TC); the laboratory failed to test PT samples by personnel who routinely perform oxyhemoglobin testing on the ACL Avoximeter 1000e (Serial Number: 6804) in the laboratory for six out of six events in 2022 and 2023. Findings Include: 1. Review of the laboratory's "Cath Lab Quality Plan" it's stated, under Proficiency Testing (PT), The educational purpose and documentation of proficiency is best served by a rotation that allows all Testing Personnel to be involved in the proficiency testing program." 2. Review of the American Proficiency Institute (API) PT attestation statements for oxyhemoglobin testing in calendar years 2022 and 2023 found TP #1 performed six of six PT events. 3. On survey date 12-06-2023, at 5:17 pm the TC confirmed eleven of twelve TP who were authorized to perform oxyhemoglobin testing failed to participate in PT for six of six PT events in 2022 and 2023. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>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:<br>Based on review of laboratory records and interviews with testing personnel (TP) and the technical consultant (TC); the laboratory a) failed to retain all quality control (QC) and required daily optical filter printouts for oxyhemoglobin testing on the ACL Avoximeter 1000e and b) failed to retain all QC and required daily electronic simulator printouts for Activated Clotting Time (ACT) testing on the i-Stat analyzer for 24 of 24 months in 2022 and 2023 as required per 493.1105. a) Findings Include: 1. Review of the "ACL Avoximeter 1000e" Policy and Procedure Manual, under "Quality Control", stated, "Two QC filters are provided for verification of the calibration of the instrument. Automatic QC lockout requires that both filters be run every 8 hours of patient testing and documented on the QC filter log sheet." 2. Review of QC and daily optical filter performance records for oxyhemoglobin testing found no instrument QC or optical filter performance printout records were retained for eight of eight testing dates (02/18/2022, 06/23/2022, 08/28/2022, 10/17/2022, 03/07/2023, 06/23/2023, 09/19/2023, 11/16/2023) reviewed in the years of 2022 and 2023. 3. Interview with TP #1 on 12-6-2023 at 12:01 pm, stated the laboratory disposed of the QC and daily optical filter performance result printouts performed on the Avoximeter analyzer for oxyhemoglobin testing. b) Findings include: 1. Review of the "I-STAT Celite Activated Clotting Time" Policy and Procedure Manual, under "Quality Control", stated, "The I-STAT System daily quality control is an electronic internal simulator." 2. Review of QC and electronic stimulator performance records for ACT testing on the i-Stat analyzer found no instrument QC or electric stimulator printout records were retained for eight of eight testing dates (02/24/2022, 06/22/2022, 08/26 /2022, 10/17/2022, 03/17/2023, 06/23/2023, 09/18/2023, 11/13/2023) reviewed in the years of 2022 and 2023. 3. Interview with TP #1 on 12-6-2023 at 12:01 pm, stated the laboratory disposed of the QC printouts performed on the i-Stat analyzer for ACT testing. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory policies and procedures, the laboratory's Individualized Quality Control Procedure (IQCP), record review, review of manufacturer package inserts, lack of documentation, interviews with testing personnel (TP) (as defined on the CMS-209 (Laboratory Personnel Report) signed by the laboratory director (LD) on 12/01/2023) and the technical consultant (TC), and email correspondences with the TC; the laboratory: a) failed to ensure reagents, kits, and supplies are not used when they have exceeded their expiration date (see D5417); b) failed to perform calibration verifications every six months for oxyhemoglobin testing performed on the ACL Avoximeter 1000e analyzer used for oxyhemoglobin testing (see D5439); c) failed to ensure results of quality control (QC) materials meet the laboratory and manufacturer's policies and procedures for acceptability before reporting patient test results (see D5481 and D5445); d) failed to retain all printouts and transcribed result data for oxyhemoglobin testing on the ACL Avoximeter 1000e (see D5789); and e) |

| | |
|---|---|
| | failed to ensure value assignment sheets provided by the manufacturer's package insert were accurately transfer to the laboratory's working QC log sheets (see D5791). |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, record review, and an email correspondence with the technical consultant (TC), the laboratory failed to ensure reagents, kits, and supplies are not used when they have exceeded their expiration date as required per 493.1252 for a) 34 out of 96 quality control (QC) performances on the ACL Avoximeter 1000e and b) 6 out of 62 QC performances on the i-Stat analyzer. a) Findings include: 1. Upon review of the "ACL Avoximeter 1000e" Policy and Procedure Manual, under "Quality Control", it's stated, "Verify that the QC material is stored according to the manufacturer's recommendation and is not expiration criteria." 2. On 12/11/2023 at 09:10 am, QC record review, the surveyors observed 8 of 24 months reviewed ran with expired Level 2 (Lot #: 14962) QC on the ACL Avoximeter 1000e analyzer used for oxyhemoglobin testing: Month/Year: QC Expiration: Number of times QC run: October 2022 09/30/2022 4 November 2022 09/30/2022 4 December 2022 09/30/2022 4 January 2023 09/30/2022 5 February 2023 09/30/2022 4 March 2023 09/30/2022 4 April 2023 09/30/2022 5 May 2023 09/30/2022 4 Total QC runs performed after expiration on the ACL Avoximeter: 34 out of 96. 3. An email correspondence with the TC on 12/13/23 at 3:30 pm confirmed the above findings. b) Findings include: 1. Upon review of the laboratory's i-Stat Activated Clotting Time (ACT) procedure manual, under Liquid Controls Level #1 & #2 (Abbott ISTAT ACT Controls), it's stated, "Do not use after expiration date printed on the box or vials." 2. On 12/11/23 at 11:05 pm, during QC record review, the surveyors observed 3 of 31 months reviewed ran with expired Level 1 (Lot #: 261134) and Level 2 (Lot #: 271134) QC (both with expirations of 02/28/2022) on i-Stat analyzer #1 (Serial Number: 397750) used for Activated Clotting Time testing: Date QC Ran: QC Expiration: Number of times QC run: 03/24/2022 02/28/2022 2 (Levels 1 & 2) 04/08 /2022 02/28/2022 2 (Levels 1 & 2) 05/16/2022 02/28/2022 2 (Levels 1 & 2) Total QC runs performed after expiration on i-Stat analyzer #1 for ACT: 6 out of 62. 3. An email correspondence with the TC on 12/13/23 at 3:30 pm confirmed the above findings. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, record review, lack of documentation, and an interview with the technical consultant (TC); the laboratory failed to perform calibration verifications every six months as required per 493.1255, for oxyhemoglobin testing performed on the ACL Avoximeter 1000e analyzer in 2020 through 2023. Findings Include: 1. Upon review of the laboratory's procedure for the ACL Avoximeter 1000e: i. Under Calibration Verification, it's stated, "Calibration Verification must be performed: 1. Every six months by using RNA CVC 223 kit." ii. Under Materials and Equipment Required, it's stated, "Cal Verification 223". 2. The calibration verification records for oxyhemoglobin testing on the Avoximeter (Serial Number: 6804) identified calibration verifications were not performed in 2020 through the date of the survey, 12/06/2023. 3. In an interview with the TC conducted on 12/06/2023 at 3:05 pm, the TC confirmed the above findings. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Part 1: Based on review of laboratory policies and procedures, the Individualized Quality Control Plan (IQCP), record review, and interview with the technical consultant (TC); the laboratory failed to perform control procedures specified by the laboratory for oxyhemoglobin testing on the ACL Avoximeter 1000e from January of 2022 though the survey date of 12/07/2023. Findings include: 1. Upon record review, there is an absence of consistency regarding the quality control (QC) to be performed for oxyhemoglobin testing on the ACL Avoximeter 1000e between the laboratory's procedure manual, the IQCP, and the observed practice of performing QC: i. The laboratory's ACL Avoximeter 1000e procedure manual states: a. Under Quality Control Weekly, "Two levels of liquid QC are performed weekly to verify calibration of the system." The procedure also walks through the steps to perform Level 1 and Level 3 QC. b. Under Materials and Equipment Required: -Level 1 QC -Level 3 QC ii. The laboratory's IQCP states: a. "QC will include: External QC (Level 1 and Level |

| | |
|---|---|
| | 2) performed per lot/shipment." b. "QC will include: External QC (Level 1 and Level 2) performed every 7 days." iii. Upon QC record review, the surveyor observed the laboratory performed and documented 3 levels of QC (Level 1, Level 2, and Level 3) weekly on the ACL Avoximeter QC log worksheets every month for the years reviewed, 2022 and 2023. 3. An interview with TC at 5:17 pm on 12/06/2023 confirmed the above findings. Part 2: Based on review of the laboratory's policies and procedures, record review, lack of documentation, and email correspondences with the technical consultant (TC); the laboratory failed to ensure results of quality control (QC) materials meet the laboratory and manufacturer's policies and procedures for acceptability before reporting patient test results on the ACL Avoximeter analyzer used for oxyhemoglobin testing. Findings include: 1. Upon review of the "ACL Avoximeter 1000e" Policy and Procedure Manual, under "Quality Control", it's stated, "Two levels of liquid QC are performed weekly to verify calibration of the system." 2. Upon QC record review, it was revealed that 3 out of 96 weeks of QC reviewed were not performed as required per the laboratory's policy and procedure manual. The missing QC runs were in the weeks of 01/07/2022, 02/25/2022, and 03/25/2022. 3. According to email correspondence on 12/13/2023 at 3:30 pm, the TC verified that there is no explanation as to the missing weeks of QC runs. Part 3: Based on review of the laboratory's policies and procedures, record review, lack of documentation, interview with the technical consultant (TC) and email correspondences with the TC; the laboratory failed to be able to correlate the lot number of QC with the lot number of Activated Clotting Time (ACT) cartridges performed on the i-Stat analyzer resulting in the inability to verify QC was run on the corresponding ACT cartridges prior to patient reporting for all ACT patient testing reviewed. Findings include: 1. Review of the laboratory's control records revealed a lack of documentation to enable correspondence of the lot number of QC being ran against the lot number of the testing cartridge for eight of eight patient testing dates reviewed for ACT testing on the i-Stat analyzer. 2. Upon review of the laboratory's i-Stat ACT procedure: i. Under Reagents, Supplies & Equipment, it's stated, "From each lot of I-STAT ACT test cartridges, two levels of controls are tested in duplicate. Perform a parallel reagent check by testing quality control from the previous lot numbers. Perform QC on the old cartridge lot number along with the new cartridge lot number and record results." ii. Under Quality Control, it's stated, "Liquid control solution(s) Level #1 and #2 for verification of cartridges are tested for each new lot number and /or shipment of cartridges received." 3. Upon review of the laboratory's i-Stat ACT Individualized Quality Control Procedure (IQCP), it's stated "QC will include: External QC (Level 1 and Level 2) performed per lot/shipment." 4. A lack of documentation revealed that no QC was being performed on each lot of i-Stat ACT test cartridges upon receipt; the two levels of controls are not being tested in duplicate; and no parallel reagent check is being performed upon receipt of new i-Stat ACT cartridges. 5. According to email correspondence on 12/08/2023, at 1:54 pm, the TC verified that a lack of documentation was present to identify which cartridge lot was being used at the time QC was performed for 31 out of 31 QC runs reviewed for i-Stat analyzer #1 (Serial Number (S/N): 397750) and 4 out of 4 QC runs reviewed for i-Stat analyzer #2 (S/N: 436792). Analyzer 1 (S/N: 397750) Analyzer 2 (S/N: 436792) 2021 2022 2023 2023 08/03/2021 01/21/2022 01/20/2023 08/25/2023 09/03/2021 02/22/2022 02/20/2023 09/29/2023 10/08/2021 03/24/2022 03/17/2023 10/27/2023 11/08/2021 04/08/2022 04/24/2023 11/14/2023 12/08/2021 05/16/2022 05/26/2023 06/17/2022 06/27/2023 07/20/2022 07/10/2023 08/19/2022 07/18/2023 09/21/2022 08/18/2023 10/21/2022 08/25/2023 11/15/2022 09/29/2023 x2 12/21/2022 10/27/2023 11/14/2023 6. An interview with the TP #1 at 12:07 pm on 12/06/2023 confirmed the above findings regarding verification of cartridges being tested with two levels of QC upon receipt of a new lot and / or shipment. |

| | |
|---|---|
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's records, review of package inserts, interviews testing personnel (TP), technical consultant (TC) and email correspondences with the TC; the laboratory failed to ensure results of quality control (QC) materials meet the laboratory and manufacturer's policies and procedures for acceptability before reporting patient test results on the ACL Avoximeter analyzer used for oxyhemoglobin testing. Findings include: 1. Review of 24 months of QC records for the ACL Avoximeter 1000e analyzer used for oxyhemoglobin testing revealed 5 of 96 weekly QC runs were out of range for Level 3 QC (Lot #: 15056) for oxyhemoglobin testing. The manufacturer's package insert reveals an acceptable range of oxyhemoglobin QC as 48.2% - 56.8%. 1. 01/21/2022 57.0% - (out of range) 2. 01/28 /2022 57.0% - (out of range) 3. 02/04/2022 57.0% - (out of range) 4. 02/11/2022 57.2% - (out of range) 5. 02/18/2022 57.2% - (out of range) 2. According to email correspondence on 12/13/2023 at 3:30 pm, the TC verified the above findings. |
| **D5789** | TEST RECORDS<br>CFR(s): 493.1283(b)<br><br>Records of patient testing including, if applicable, instrument printouts, must be retained.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records and interviews with testing personnel (TP) and the technical consultant (TC); the laboratory failed to retain all printouts and transcribed result data for oxyhemoglobin testing on the ACL Avoximeter 1000e for eight of eight patients reviewed in 2022 and 2023 as required per 493.1105. Findings Include: 1. Upon review of the laboratory's procedure for the ACL Avoximeter 1000e, under Results, it's stated, "A copy of the MACLAB documentation and a copy of the original printout from the Avoximeter will be mounted and scanned into the patient's [Electronic Medical Record] EMR." 2. Review of patient test results for oxyhemoglobin testing on the Avoximeter test system found no transcribed patient testing results or analyzer printouts were retained for eight of eight testing dates reviewed for oxyhemoglobin testing. Patient Identifier: Date of testing: 40362697 02 /18/2022 40392774 06/23/2022 40414590 08/28/2022 40429796 10/17/2022 40463808 03/07/2023 40496600 06/23/2023 40523391 09/19/2023 40537670 11/16 /2023 3. Interview with TP #1 on 12-6-2023 at 12:01 pm, stated they disposed of the patient test result printouts performed on the Avoximeter analyzer for oxyhemoglobin testing. 4. Interview with the TC on 12-6-2023, at 5:17 pm confirmed the above findings. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy and procedure manuals, record review, and interview the Technical Consultant (TC); the laboratory failed to ensure value assignment sheets, provided by the manufacturer's package insert, were accurately transcribed to the laboratory's working quality control (QC) log sheets, resulting in a) 34 out of 70 transcription errors for Activated Clotting Time (ACT) on the both i-Stat analyzers (Analyzer 1, serial number: 397750 & Analyzer 2, serial number: 436792) and b) eight out of eight transcription errors for oxyhemoglobin testing on the ACL Avoximeter. a) Findings include: 1. Upon review of the laboratory's procedure manual for the i-Stat Celite ACT, under "Control Target Values and Expected Ranges", it's stated, "Always be sure that the lot number printed on the value assignment sheet [VAS] matches the lot number on the label of the vial in use...." 2. Based on review of QC records and manufacturer package inserts for the controls on the i-Stat analyzer used for ACT; 34 out of 70 QC performances reviewed from 08/03/2021 through 11 /14/2023 were transcribed with reference ranges not correlating with the VAS provided by the manufacturer package insert. Level & Lot Number: VAS range: Transcribed range: Date(s) effected: Analyzer(s) effected: Level 1 - 261134 147 - 273 140 - 260 08/03/2021, 1 09/03/2021, 1 10/08/2021, 1 11/08/2021 1 Level 2 - 271134 420 - 780 357 - 663 08/03/2021, 1 09/03/2021, 1 10/08/2021, 1 11/08/2021 1 Level 1 - 261142 154 - 286 151 - 280 06/17/2022, 1 07/20/2022, 1 08/19/2022, 1 09/21/2022 1 Level 2 - 271142 427 - 793 431 - 800 06/17/2022, 1 07/20/2022, 1 08/19/2022, 1 09 /21/2022 1 Level 2 - 271148 392 - 728 431 - 800 10/21/2022, 1 11/15/2022 1 Level 1 - 261149 144 - 267 151 - 280 02/20/2023 1 03/17/2023 1 04/24/2023 1 05/26/2023 1 Level 2 - 271149 385 - 715 392 - 728 02/20/2023 1 03/17/2023 1 04/24/2023 1 05/26 /2023 1 Level 1 - 261160 154 - 286 151 - 280 08/25/2023 2 09/29/2023 2 10/27/2023 2 11/14/2023 2 Level 2 - 271158 389 - 722 361 - 670 08/25/2023 2 09/29/2023 2 10 /27/2023 2 11/14/2023 2 3. Interview with the TC on 12/06/2023 at 5:17 pm confirmed the above findings. b) Findings include: 1. Based on review of QC records and manufacturer package inserts for the controls on the ACL Avoximeter 1000e used for oxyhemoglobin testing; eight of the eight QC lot reviewed had manufacturer VASs that did not correlate with the reference ranges transcribed on the QC logs /worksheets effecting 97 of 97 weeks of QC reviewed from January 2022 to the date of the survey, 12/07/2023. Level & Lot Number: VAS range: Transcribed range: Weeks effected: Level 1 - 14866 87.3 - 96.3 89.2 - 98.2 01/07/2022 - 08/26/2022 (31 weeks) Level 1 - 24869 85.9 - 94.9 89.2 - 98.2 09/02/2022 - 07/28/2023 (48 weeks) Level 1 - 24872 87.4 - 96.4 89.2 - 98.2 06/02/2023 - 12/01/2023 (27 weeks) Level 2 - 14962 75.4 - 84.0 77.0 - 85.6 01/07/2022 - 05/26/2023 (70 weeks) Level 2 - 24966 74.2 - 82.8 77.0 - 85.6 06/02/2023 - 10/27/2023 (22 weeks) Level 2 - 34970 76.3 - 84.9 77.0 - 85.6 11/03/2023 - 12/01/2023 (5 weeks) Level 3 - 15060 48.2 - 56.8 50.9 - 59.5 01/07/2022 - 05/26/2023 (70 weeks) Level 3 - 35065 48.6 - 57.2 50.9 - 59.5 08/04 /2023 - 12/01/2023 (18 weeks) 2. Interview with the TC on 12/06/2023 at 5:17 pm confirmed the above findings. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, patient Cardiac Cath Lab Procedural Reports, and interview with the technical consultant (TC); the laboratory failed to include all the required components of a laboratory test report for eight of eight Avoximeter oxyhemoglobin test reports reviewed as per 493.1291. Findings Include: 1. Review of Cardiac Cath Lab Procedural Reports revealed eight of eight patient reports (46669, 75701, 42872, 26799, 72367, 71929, 82002, 97058) for oxyhemoglobin testing on the ACL Avoximeter 1000e analyzer failed to indicate: a) the test performed; b) the specimen source; c) the result interpretation; and d) any information regarding the disposition of the specimen. 2. On survey date 12-06-2023, at 5:17 pm, the TC confirmed the patient test reports failed to include all the required components of a laboratory test report on eight of eight test reports. |
| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Cardiac Cath Lab Procedural Reports and interview with the technical consultant (TC); the laboratory failed to provide pertinent reference intervals for oxyhemoglobin results on eight of eight patients as required by 493.1291. Findings Include: 1. Review of Cardiac Cath Lab Procedural Reports revealed eight of eight patient reports (46669, 75701, 42872, 26799, 72367, 71929, 82002, 97058) for oxyhemoglobin testing on the ACL Avoximeter 1000e analyzer found the laboratory failed to indicate the test reference range on the laboratory's test report. 2. On survey date 12-06-2023, at 5:17 pm, the TC confirmed the patient test reports failed to include all the required components of a laboratory test report, including a reference range on eight of eight test reports. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory documents, quality control (QC) records, Proficiency Testing (PT) records, lack of documentation, manufacturer's packet inserts, CMS-209 (Laboratory Personnel Report), interviews with testing personnel (TP) and the |

| | |
|---|---|
| | technical consultant (TC), email correspondence with the TC, patient reports, and employee competency assessments; the laboratory director (LD) failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: a) The LD failed to ensure all TP are participating in PT. See D6016. b) The LD failed to monitor the laboratory's analytical system policies and reported oxyhemoglobin and Activated Clotting Time (ACT) patient test results when controls were out of range or not performed. See D6022/D6025. c) The LD failed to ensure calibration verifications are being performed as required for ACL Avoximeter 1000e. See D6013. d) The LD failed to provide competency assessment for all testing procedures annually and ensure all employees maintained competency. See D6030. e) The LD failed to ensure patient reports include pertinent information required for interpretation. See D6026. |
| **D6013** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(ii)<br><br>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;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, lack of documentation, and an interview with the technical consultant (TC); the laboratory director failed to ensure calibration verifications are being performed every six months as required per 493.1255, for oxyhemoglobin testing performed on the ACL Avoximeter 1000e analyzer in 2020 through 2023. See D5439. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<br><br>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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory and proficiency testing (PT) records and interview with the technical consultant (TC); the laboratory director failed to ensure all testing personnel routinely perform oxyhemoglobin testing on the ACL Avoximeter 1000e (Serial Number: 6804) were performing PT for six out of six events in 2022 and 2023. See D2007. |
| **D6022** | LABORATORY DIRECTOR RESPONSIBILITIES<br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, record review, review of package inserts, lack of documentation, interview with testing personnel and the technical consultant, and an email correspondence with the technical consultant (TC), the laboratory director failed to: a) ensure reagents, kits, and supplies are not used when they have exceeded their expiration date as required per 493.1252. See D5417. b) ensure results of control materials met the laboratory's and manufacturer's test system criteria for acceptability prior to reporting patient test results. See D5445 /D5481. c) ensure value assignment sheets, provided by the manufacturer's package insert, were accurately transcribed to the laboratory's working quality control (QC) log sheets, resulting in inaccurate QC results. See D5791. |
| **D6025** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(7)<br><br>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)(7) Ensure that patient test results are reported only when the system is functioning properly.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, record review, review of package inserts, lack of documentation, interview with testing personnel and the technical consultant, and an email correspondence with the technical consultant (TC), the laboratory director failed to ensure patient test results are reported only when the system is functioning properly. See D5445/D5481. |
| **D6026** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(8)<br><br>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)(8) Ensure that reports of test results include pertinent information required for interpretation.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, patient results and interview with the technical consultant (TC); the laboratory director failed to ensure patient test reports included the pertinent information required for interpretation for eight of eight Avoximeter |

| | |
|---|---|
| | oxyhemoglobin test reports reviewed for testing as per 493.1291. See D5805 and D5807. |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of employee competency assessments and interview with the technical consultant (TC); the laboratory director a) failed to have competency assessments performed by a qualified TC for four of four individuals responsible for moderate complexity testing and b) failed to have competency assessments performed annually for both moderate complexity testing analyzers in use, including Activated Clotting Time (ACT) cartridges on the i-STAT analyzer and oxyhemoglobin testing on the ACL Avoximeter 1000e analyzer in 2021 and 2022. See D6046. |
| **D6033** | TECHNICAL CONSULTANT-MODERATE COMPEXITY<br>CFR(s): 493.1409<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory documents, record review, review of manufacturer's package inserts, lack of documentation, quality control (QC) records, interviews with testing personnel (TP) and technical consultant (TC), and email correspondence with the TC; the TC failed to provide technical and scientific oversight of the laboratory in accordance with 493.1413 of this subpart. Findings include: a) The TC failed to monitor the laboratory's analytical system policies and reported oxyhemoglobin and Activated Clotting Time (ACT) patient test results when controls were out of range or not performed. See D6042. b) The TC failed to provide competency assessment for all testing procedures annually and ensure all employees maintained competency. See D6046. |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(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;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, record review, review of package inserts, lack of documentation, interview with testing personnel and the technical consultant (TC), and an email correspondence with the TC, the TC failed to: a) ensure reagents, kits, and supplies are not used when they have exceeded their expiration date as required per 493.1252. See D5417. b) ensure results of control materials met the laboratory's and manufacturer's test system criteria for acceptability prior to reporting patient test results. See D5481. c) ensure value assignment sheets, provided by the manufacturer's package insert, were accurately transcribed to the laboratory's working quality control (QC) log sheets, resulting in inaccurate QC results. See D5791. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of employee competency assessments and interview with the technical consultant (TC); the laboratory a) failed to have competency assessments performed by a qualified TC for four of four individuals responsible for moderate complexity testing and b) failed to have competency assessments performed annually for both moderate complexity testing analyzers in use, including Activated Clotting Time (ACT) cartridges on the i-STAT analyzer and oxyhemoglobin testing on the ACL Avoximeter 1000e analyzer in 2021 and 2022. a) Findings include: 1. Upon review of the laboratory's procedure for the i-Stat ACT, under Competency Assessment, the procedure states, "The Testing Personnel....will be assessed for competency initially at 6 months and annually by the Technical Consultant, as designated by the Laboratory Director." 2. Upon review of employee competency assessments, four of four testing personnel's (TP) (as identified on the CMS-209 Laboratory Personnel Form signed by the laboratory director 12/01/2023) competency assessments were not performed by a qualified TC. Testing Personnel: Individual performing competency: TP #4 TP #1 TP #5 TP #1 TP #7 TP #1 and TP #12 TP #12 TP #1 3. An interview with the TC at 5:17 pm on 12/06/2023 confirmed the findings. b) Findings include: 1. Upon review of employee competency assessments, the laboratory failed to have competency assessments performed annually for both moderate complexity testing analyzers in use in 2021 and 2022. Testing Personnel: Analyzer Competency Assessed: TP #4 None in 2021 / Only the i-Stat in 2022 TP #5 Only the i-Stat in 2021 / None in 2022 TP #7 None in 2021 / Only the i-Stat in 2022 TP #12 None in 2021 / Only the i-Stat in 2022 2. Upon review of the laboratory's procedure manual for ACL Avoximeter 1000e, under Competency, it's stated, "Operators that fail to meet competency requirements as assigned annually will be locked out of the system." 3. Upon review of the laboratory's procedure manual for i-Stat ACT, under Competency, it's stated, "Any operator who does not complete |

| | |
|---|---|
| | competency on a yearly basis will be locked out from using the Abbott I-STAT System." 4. According to email correspondence on 12/29/2023 at 3:55 pm, the TC verified the above findings. |