| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 21D1082260 | 09/06/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Kp Holy Cross Cardiology And Vascular | 1400 Forest Glen Road Ste 300, Silver Spring, MD | |

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 |
|---|---|
| **D3009** | FACILITIES<br>CFR(s): 493.1101(c)<br><br>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Code of Maryland Regulations (COMAR), review of the laboratory's procedure, and interview with the technical consultant (TC), the laboratory failed to be in compliance with COMAR 10.10.06.06(B)(6)(a)(ii) regulations for performing quality control (QC) on single-use test devices at least weekly when patient testing was performed. Findings: 1. COMAR 10.10.06.06(B)(6) states that "A licensee shall ensure that quality control testing for a quantitative test system is performed and documented using at least two levels of control material before patient testing ...At least weekly for each lot of single-use test device used for patient testing." 2. The laboratory performed testing using an Abott i-STAT analyzer which fit the criteria for a single-use test device. 3. Section 6.2.1 of the laboratory procedure titled "i-STAT Portable Clinical Analyzer POCT" stated that "QC is performed once every 30 days, with the receipt of every new shipment of test cartridges, and when training a new test performer." 4. During the survey on 09/06 /2023 at 12:40 PM, the TC confirmed that the laboratory was not performing QC on the i-STAT at least weekly when patients were run as required by COMAR. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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:<br>Based on review of the procedure manual and interview with the technical consultant (TC), the laboratory failed to establish written procedures for assessing testing personnel (TP) and TC competency. Findings: 1. The laboratory's "Point of Care Quality Assurance Policy" stated that competency would be assessed initially, at six-months, and then annually. 2. There were no procedures describing the six procedures required for assessing competency of TP: 1) Direct observation of routine patient test performance, 2) Monitoring the recording and reporting of test results, 3) Review of intermediate test results or worksheets, quality control records, proficiency testing (PT) results, and preventive maintenance records, 4) Direct observations of performance of instrument maintenance and function checks, 5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external PT samples, and 6) Assessment of problem solving skills. 3. There were no procedures describing the competency assessment of the TC based on their regulatory responsibilities. 4. During the survey on 09/06/2023 at 12:40 PM, the TC confirmed that there was no procedure detailing how to perform competency assessments for the TP and TC. |
| **D5301** | TEST REQUEST<br>CFR(s): 493.1241(a)<br><br>The laboratory must have a written or electronic request for patient testing from an authorized person.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of instrument results and interview with the technical consultant (TC), the laboratory failed to use written or electronic requests for patient testing. Findings: 1. The laboratory performed testing using an Abbott i-STAT handheld analyzer. 2. Results from three patients were observed directly from the i-STAT analyzer: accession numbers 96331495 tested on 08/31/2023, 51216899 tested on 06 /19/2023, and 14195998 tested on 06/08/2023. 3. During the survey on 09/06/2023 at 12:30 PM, the TC confirmed that there were no written or electronic requisitions for the testing performed on the three patients. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the procedure manual and interview with the technical consultant (TC), the procedure manual failed to include instruction for cartridge storage at room temperature, how to document critical value reporting, and how to perform new lot verifications for i-STAT cartridges. Findings. 1. The laboratory performed coagulation and chemistry testing using an Abbott i-STAT analyzer. 2. The cartridges that were used for testing were stored in the refrigerator and once removed, could be stored at room temperature for 14 days. Though documented on the cartridge packaging, there was no procedure stating that cartridges were only stable for 14 days at room temperature and that the new expiration date of 14 days was to be written on the cartridge packaging when removed from the refrigerator for room temperature storage. 3. The laboratory's procedure titled "i-STAT Portable Clinical Analyzer POCT" stated that "Critical values are to be given verbally to the physician immediately." There was no procedure for how to document notification of critical values to the physicians. 4. The laboratory performed verifications on new lot numbers of cartridges that were documented on the "i-STAT New Cartridge Lot Verification Form - Point of Care." There were no procedures explaining how to perform the new lot verification, what the acceptability criteria was, and how to document the results on the lot verification form. 5. During the survey on 09/06/2023 at 12:40 PM, the TC confirmed that the procedure manual failed to include instructions for storing cartridges at room temperature, documentation of notification of critical values to physicians, and how to perform and document verification of new cartridge lots. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of temperature records and interview with the technical consultant (TC), the laboratory failed to ensure it had access to temperature data for the refrigerator that stored supplies required for testing. Findings: 1. The laboratory used the refrigerator for storing the quality control and cartridges used for testing on the i-STAT analyzer. 2. The refrigerator was remotely monitored by the TempTrak system and the laboratory did not have a record of daily temperatures. 3. During the survey on 09/06/2023 at 10:40 AM, the TC confirmed that laboratory staff did not have access to the TempTrak data. The TC stated that laboratory staff would be notified if there was an alarm, but did not know at what temperature the alarm sounded and if the acceptable temperature range was suitable for storage of the i-STAT reagents and supplies. |

| | |
|---|---|
| **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>Based on review of the procedure and interview with the technical consultant (TC), the laboratory did not perform two levels of quality control (QC) each day of patient testing as described in paragraph (d)(3) of this section and did not establish an Individualized Quality Control Plan (IQCP) to reduce the frequency of QC testing performed on the Abbott i-STAT analyzer. Findings: 1. The requirement is to perform two levels of QC for quantitative procedures each day of patient testing unless an IQCP has been established. 2. The laboratory's procedure titled "i-STAT Portable Clinical Analyzer POCT" stated that "QC is performed once every 30 days, with the receipt of every new shipment of test cartridges, and when training a new test performer." 3. During the survey on 09/06/2023 at 12:40 PM, the TC confirmed that the laboratory had started, but not completed an IQCP to reduce the frequency of performing QC testing for the i-STAT analyzer. |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of instrument results and interview with the technical consultant (TC), the laboratory failed to ensure it had a manual or electronic system in place to record and report patient test results. Findings: 1. The laboratory performed testing using an Abbott i-STAT handheld analyzer. 2. The TC stated that all results from the i-STAT analyzer were transmitted to a middleware for storage. The middleware was currently not linked to the electronic medical record (EMR). 3. Results from three patients were observed directly from the i-STAT analyzer: accession numbers 96331495 tested on 08/31/2023, 51216899 tested on 06/19/2023, and 14195998 tested on 06/08/2023. 4. Results from the three accession numbers were not found in the EMR or the middleware so that there was no way view the results unless someone |

| | |
|---|---|
| | scrolled through each individual test on the i-STAT analyzer. 5. During the survey on 09/06/2023 at 12:40 PM, the TC confirmed that the three patient results were only available on the analyzer and could not be viewed within the EMR. |
| **D5813** | TEST REPORT<br>CFR(s): 493.1291(g)<br><br>The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of instrument results, review of the procedure, and interview with the technical consultant (TC), the laboratory failed to document notification to the physician when critical test values were obtained. Findings: 1. The laboratory performed testing using an Abbott i-STAT handheld analyzer. 2. Section 9.5 of the procedure titled "i-STAT Portable Clinical Analyzer POCT" stated that "Critical values are to be given verbally to the physician immediately" and listed the critical value for INR (international normalized ratio) as "Greater than 4.4." 3. Results from three patients observed directly from the i-STAT analyzer were not available in the EMR system (cross-refer to tag D5801 for details). 4. Accession number 14195998 was tested on 06/08/2023 and had a result of 7.6 for INR. There was no documentation that the physician was notified of the critical value or even received the test result at all. 5. During the survey on 09/06/2023 at 12:40 PM, the TC confirmed that physician notification of patient test results with critical values was not being documented. |
| **D6015** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)<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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to ensure it was enrolled in an approved PT program prior to resuming patient testing. Findings: 1. The laboratory performed coagulation and chemistry testing using an Abbott i-STAT analyzer and was enrolled in approved PT programs for 2022. 2. From 10/2022 through 02/06/2023 patient testing was temporarily suspended. 3. There were no PT records for 2023. 4. During the survey on 09/06/2023 at 10:15 AM, the TC confirmed that the laboratory had not enrolled in PT for 2023 until 08/2023 even though patient testing resumed in 02/2023. |
| **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 lot verification forms, review of quality control (QC) records, and interview with the technical consultant (TC), the TC failed to ensure that quality control QC results that were outside the manufacturer's acceptable range were able to be recognized as failed on the i-STAT analyzer and that corrective actions were documented. Findings: 1. The laboratory performed coagulation and chemistry testing using an Abbott i-STAT handheld analyzer. 2. When QC samples were tested, the analyzer notified the testing person (TP) whether the QC passed or failed. 3. All QC results were electronically transmitted through a middleware program to a spreadsheet. The spreadsheet was formulated with the acceptable QC ranges for each lot number and would flag any results that fell outside of the acceptable QC range. 4. The procedure titled "i-STAT Portable Clinical Analyzer POCT" stated that for QC the TP should "Compare results to the value assignment sheet ranges. If results are all within range, use cartridges as needed. Do not test patients until both levels of QC have passed for the specific test." The TC stated that the TP did not refer to the value assignment sheet ranges because acceptable ranges should be programmed into i-STAT analyzer. 5. The laboratory performed verifications on new lots of cartridges that were documented on the "i-STAT New Cartridge Lot Verification Form - Point of Care" (form). 6. The form for lot number R23110 for the ACT cartridge showed a level 2 QC result of greater than 1000 that was tested on 06/13/2023. The TC confirmed that the acceptable range for that lot was 389-722. 7. It was discovered that the result was flagged in the middleware spreadsheet, but the handheld analyzer showed that the QC passed. There were no corrective actions or repeat QC testing documented. 8. During the survey on 09/06/2023 at 12:40 PM, the TC confirmed that the TP did not verify the QC results against the manufacturer's acceptable range as it should have been programed into the i-STAT analyzer, that the failed QC results obtained on 06/13/2023 during the lot verification was not recognized as failed by the i-STAT analyzer even though it was flagged on the middleware spreadsheet, and that corrective actions were not documented. |
| **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 personnel records and interview with the technical consultant (TC), there was no documentation that competency assessment of the testing personnel (TP) had been performed. Findings: 1. The Laboratory Personnel Report (form CMS-209) listed three TP. 2. During the survey on 09/06/2023 at 12:40 PM, the TC confirmed that there was no documentation that competency assessments had been performed for the three TP. |