

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1082260	(X3) Date Survey Completed 03/27/2025
Name of Provider or Supplier Kp Holy Cross Cardiology And Vascular	Street Address, City, State 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory failed to ensure that all the testing personnel (TP) who tested patient samples performed the PT. Findings: 1. The laboratory currently has three TP listed on the "Laboratory Personnel Report" (CMS-209) who perform hematology and chemistry testing. 2. A review of hematology PT attestation worksheets from five PT events from 2023 through 2025 showed that PT was performed by the same TP in five of five events; and 3. A review of chemistry PT attestation worksheets from five PT events from 2023 through 2025 showed that PT was performed by the same TP in four of five events. 4. During an interview on 03/27/2025 at 2:00 PM, the TC confirmed that PT samples were not tested each year by all the staff who perform patient testing to ensure accurate and reliable patient test results.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory failed to ensure that the laboratory director (LD) or their designee and the individual testing the samples (TP) signed PT attestation statements, attesting to the routine integration of the PT samples into the patient workload using the laboratory's routine methods. Findings: 1. A review of hematology PT records for five PT events from 2023 through 2025 showed that the attestation statement for the 3rd event of 2023 for the activated clotting time (ACT) was not signed by the LD or their designee or the TP; and 2. A review of chemistry PT records for five PT events from 2023 through 2025 showed that the attestation statement for the 1st event of 2024 for "BloodGas1" was not signed by the LD or their designee. 3. During an interview on 03/27/2025 at 2:00 PM, the TC confirmed that not all of the PT attestation statements were signed by the LD, their designee, or the TP, attesting that PT specimens were run in the same way as patient samples.

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:
Note: This is a repeat deficiency. The laboratory was cited during the initial certification survey on 09/06/2023 for failing to establish written procedures for assessing testing personnel and technical consultant competency. The plan of correction stated that this would be corrected. Based on procedure manual and competency record review 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 "Point of Care Quality Assurance Policy" procedure, subsection "Competency Assessments" states that "Competency for performing POCT [point of care testing] will be assessed with initial training prior to performing any POCT. Competency for POCT will be re-assessed 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 an interview on 03/27/2025 at 2:00 PM, the TC confirmed that there was no procedure detailing how to perform competency assessments for the TP and TC.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score

for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory failed to verify the accuracy of hematology PT when the results were not evaluated by the PT provider because the laboratory submitted its PT results after the submission deadline. Findings: 1. The laboratory performs PT for prothrombin time/International Normalized Ratio (PT/INR) and activated clotting time (ACT) testing on the i-STAT blood analyzer. The PT provider issues a "Proficiency Testing Evaluation" sheet showing the grade the laboratory obtained for the PT event, and includes the "Status" (Pass/Fail) and "Comments." 2. The laboratory participates in three PT events a year for PT/INR. A review of hematology PT records from 2024 showed that the laboratory failed to submit their PT results before the PT provider's submission deadline in two of three events. 3. The "Comments" section of the "Proficiency Testing Evaluation" sheet for the second event in 2024 ("2024-Coag2") for PT/INR stated, "Excuse requested - instrument out of order" for samples PRC-6 through PRC-10. PT record review showed that the laboratory ran the PT on 06/25/2024 and documented the results on the PT provider's "Proficiency Testing Work Sheet," however the laboratory failed to perform a self-evaluation to verify the accuracy of the results; and 4. The "Comments" section of the "Proficiency Testing Evaluation" sheet for the third event in 2024 ("2024-Coag3") for PT/INR stated, "Excuse requested - out of reagent/on backorder" for samples PRC-11 through PRC-15. PT record review showed that the laboratory ran the PT on 10/15/2024 and documented the results on the PT provider's "Proficiency Testing Work Sheet," however the laboratory failed to perform a self-evaluation to verify the accuracy of the results 5. The laboratory participates in two PT events a year for ACT. A review of hematology PT records from 2024 showed that the laboratory failed to submit their PT results before the PT provider's submission deadline in one of two events. 6. The "Comments" section of the "Proficiency Testing Evaluation" sheet for the second event in 2024 ("2024-CoagQA2") for ACT stated, "Excuse requested - out of reagent /on backorder" for samples CT-4 through CT-6. PT record review showed that the laboratory ran the PT on 10/10/2024 and documented the results on the PT provider's "Proficiency Testing Work Sheet," however the laboratory failed to perform a self-evaluation to verify the accuracy of the results 7. During an interview on 03/27/2025 at 2:00 PM, the TC confirmed that the laboratory failed to verify the accuracy of hematology PT results which had not been evaluated by the PT provider.

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 procedure manual review and interview with the technical consultant (TC), the laboratory failed to ensure that the laboratory's procedure manual included a detailed procedure for performing proficiency testing (PT). Findings: 1. The "Point of Care Quality Assurance Policy" procedure, subsection "Proficiency Testing" includes information about subscribing to a PT provider, that PT samples should be tested in

the same manner as patient samples, that there should be no communication between departments or testing personnel (TP) about PT prior to submitting results, and that all relevant paperwork should be maintained for at least 2 years. 2. The laboratory's procedure did not instruct TP on how to perform the PT; that all TP should participate in the PT (cross-refer to D2007); that the TP and laboratory director must sign PT attestation statements, attesting to the routine integration of the PT samples into the patient workload using the laboratory's routine methods (cross-refer to D2009); how to perform a self-evaluation of PT when the results were not evaluated by the PT provider because the laboratory submitted its PT results after the submission deadline (cross-refer to D5215); or how to perform corrective actions for unsuccessful PT results. 3. During an interview on 03/27/2025 at 2:00 PM, the TC confirmed that the laboratory failed to have written procedures for all aspects of performing PT.

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:
Note: This is a repeat deficiency. The laboratory was cited during the initial certification survey on 09/06/2023 for failing to ensure that the technical consultant evaluated the competency of all testing personnel performing laboratory testing. The plan of correction stated that this would be corrected. I. Based on record review and interview with the technical consultant (TC), the TC failed to completely evaluate the competency of all testing personnel (TP), assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. Findings: 1. The laboratory currently has three TP listed on the "Laboratory Personnel Report (CLIA)" (CMS-209). During an interview on 03/27/2025 at 1:15 PM the TC stated that one of the three TP (TP #1) was recently trained and was not performing patient testing. The TC also stated that they performed competency assessments by requiring TP to take an online training module, "MAS I-STAT Learning System POC." 2. A review of competency assessment records from 2023 through 2025 showed that TP #2 had completed the online training module on 08/24/2023 and 10/23/2024 and that TP #3 had completed the online training module on 08/2023 and 08/15/2024. The training module did not include all six procedures required for assessing the competency of the TP. (cross-refer to D5209) 3. During an interview on 03/27/2025 at 2:00 PM, the TC confirmed that the competency assessments performed on the TP did not include all six procedures required for assessing the competency of the TP. II. Based on record review and interview with the technical consultant (TC), the laboratory director (LD) acting as the TC failed to perform and document competency reviews on the TC, based on the TC's position responsibilities. Findings: 1. A review of competency assessment records from 2023 through 2025 showed that there were no competency assessments performed on the TC for the duties they perform as TC. 2. During an interview on 03/27/2025 at 2:00 PM, the TC confirmed that the LD failed to perform competency assessments on the TC.