

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0665218	<b>(X3) Date Survey Completed</b>  02/26/2020
<b>Name of Provider or Supplier</b>  Perry Medical Clinic Pc	<b>Street Address, City, State</b>  401 Northwood Drive, Centre, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the environmental logs and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to review the instrument manufacturer's required environmental parameters and establish an acceptable range for room temperature, and failed to document the actual freezer temperatures for more than two years since the previous survey on 11/29/2017. The findings include: 1. A review of the 2018-2020 environmental logs revealed the testing personnel had utilized a vaccine refrigerator temperature log each day of patient testing, however, the records failed to specify an acceptable range for room temperature, and failed to specify the actual freezer temperatures (testing personnel had checked a box for less than or equal to -17 degrees C [Celsius]). 2. During an interview on 2/26/2020 at 4:00 PM, the surveyor reviewed the manufacturer's insert for BioRad Liquicheck Immunoassay controls (QC), which specified storage requirements of -20 to -70 degrees C. TP #1 confirmed checking a box for less than or equal to -17 degrees C did not document the QC was maintained at the required storage temperature of -20 degrees C or colder. 3. As the interview continued the surveyor and the testing personnel then reviewed the manufacturer's operating environmental requirements for analyzers in use, as follows: A) Tosoh AIA-360: Temperature 15-30 degrees C B) Beckman Coulter AcT diff 2: Temperature 16-35 degrees C C) Vital Envoy 500:</p>

Temperature 18-32 degrees C TP #1 reviewed and confirmed the manufacturer specified environmental parameters, however the laboratory had failed to collate this information and document the acceptable room temperature ranges on the environmental logs. .

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on reviews of the maintenance logs and maintenance procedures in the Operator's Manual for the DCA Vantage analyzer, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory: 1) failed to perform and document the weekly and quarterly maintenance with the frequency required by the manufacturer on the DCA Vantage analyzer (used for Urine Microalbumin/Creatinine testing); 2) failed to perform and document the six month decontamination maintenance on the Tosoh AIA-360; and 3) failed to document the quarterly and annual maintenance on the ISE (Ion-Selective Electrode) modules on the Vital Envoy 500. This was noted to occur for the last two years since the previous survey on 11/29 /2017. The findings include: 1. A review of the maintenance logs revealed no documentation of maintenance for the DCA Vantage (used for Urine Microalbumin /Creatinine, a non-waived moderate-complexity test). 2. A review of the Maintenance procedures on page 97 in the DCA Vantage Operator's Manual, revealed the following: "...Weekly Cleaning the on-board barcode reader window Cleaning the exterior Quarterly Removing and cleaning the cartridge spring and cartridge area Changing the air filter Optical Test" As needed procedures were also listed in the manual. 3. A review of the maintenance logs for the Tosoh AIA-360 revealed no documentation of the six-month decontamination and bottle filter change maintenance from November 2017 thru 2019. 4. A review of the maintenance logs for the Vital Envoy 500 revealed no documentation of quarterly maintenance (replace ISE tubing, and Sodium, Potassium and Chloride electrodes). The dates of the annual maintenance in 2018 and 2019 were not documented; this maintenance was performed during the service technician's annual PM (Preventative Maintenance) and included replacement of the ISE reference electrode. 5. During an interview on 2/26/2020 from 3:40-3:50 PM, the above records were reviewed with TP #1, who stated she replaced the ISE electrodes when the analyzer prompted the user, however she was unable to provide the surveyor with the specific dates. TP #1 stated she performed the maintenance for the Tosoh and Envoy 500, however she was "not good about documenting" it. Thus the above noted finding were confirmed. .

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a

minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of the calibration and calibration verification (C/V) records for the Tosoh AIA-360 and the Vital Envoy 500, a lack of C/V records for Urine Microalbumin/ Creatinine performed on the DCA Vantage, and interviews with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to perform calibration verifications at least every six months as per CLIA regulations. The findings include: 1. A review of the records for the Tosoh revealed PSA has a two-point calibration. The laboratory performed routine Chemistry testing on the Vital Envoy 500 which calibrated the electrolytes with two calibrators, and other tests with one multi-calibrator. Analytes calibrated with less than three calibrators must have a calibration verification (C/V) performed every six months. 2. A review of the Vital Envoy 500 C/V records revealed the following: A) C/V on 9/12/2017 (reviewed during the previous survey) B) C/V on 6/26/2018 (nine and a half months after the previous C/V) C) C/V on 5/14/2019 (ten and a half months after the previous C/V) D) C/V on 2/07/2020 (nine months after the previous C/V) 3. A review of the Tosoh AIA-360 C/V records revealed the following: A) C/V on 9/12/2017 (reviewed during the previous survey) B) C/V on 8/21/2018 (eleven months after the previous C/V) C) C/V on 5/14/2019 (eight months after the previous C/V) D) C/V on 2/07/2020 (nine months after the previous C/V) 4. During an interview on 2/26/2020 at 2:35 PM, the surveyor asked TP #1 how often PSA and Envoy 500 tests should have a calibration verification. TP #1 stated every six months. The surveyor then asked if the laboratory had performed two C/V in 2018 and 2019 on the above instruments. TP #1 stated she was unable to find the second C/V's performed in 2018, and she had missed the second C/V in 2019; it was not performed until 2/7/2020. The surveyor further confirmed no C/V was performed on Bilirubin in 2018 or 2019; Bilirubin required a separate C/V kit, and no C/V was performed until 2/7/2020. 5. During a later interview on 2/26/2020 at 3:45 PM, the surveyor confirmed the laboratory also utilized the DCA Vantage analyzer for Urine Microalbumin/Creatinine testing (a non-waived, moderate-complexity test). This test was calibrated using a calibrator card, and the laboratory had never performed C/V's on this test. 6. During the exit summation on 2/26/2019 at approximately 4:00 PM, the surveyor reviewed the deficiencies and also noted a lack of review and approval of the C/V data by the Laboratory Director or Technical Consultant to ensure no corrective actions or adjustment of reportable ranges were required. .

**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 a review of Proficiency Testing (PT) failures, a review of Quality Control (QC) records on the Vital Envoy 500, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure QC results were reviewed, and remedial actions implemented for negative biases noted in the Sodium and Chloride QC results. This was noted for two months in 2018-2019. The findings include: 1. A review of American Proficiency Institute PT results revealed on 9/11 /2018, the 2018 Event #3 PT survey was performed and received a failing score of 20% for Chloride; and on 1/30/19, the 2019 Event #1 PT survey was performed and received a failing score of 60% on Sodium. 2. A review of September 2018 and January 2019 QC records on the Vital Envoy 500 revealed negative biases in the Sodium and Chloride QC results. 3. During the exit summation at approximately 4:00 PM, the surveyor asked TP #1 if the Laboratory Director or Technical Consultant ever reviewed the QC data to determine if corrective actions are needed for shifts or trends. TP #1 stated they always made sure QC was "in", but if there was a problem they called the Vital QC service for direction. The surveyor explained there needed to be on-site review of the QC results over time to review for shifts and trends that might require corrective actions before a problem worsened. TP #1 stated no one was doing this. .

**D5481**

**CONTROL PROCEDURES**

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a lack of the quality control records for the DCA Vantage analyzer (used for Urine Microalbumin/ Creatinine, a non-waived moderate-complexity test), patient test volume records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure two levels of quality control (QC) were performed each day of patient testing for over two years since the previous survey on 11/29/2017. The findings include: 1. A review of the laboratory records revealed no documentation of QC for Urine Microalbumin/ Creatinine testing performed on the DCA Vantage. 2. During an interview on 2/26/2020 at 3:45 PM, the surveyor asked TP #1 if the laboratory performed external QC on the DCA Vantage Urine Microalbumin/ Creatinine cartridges. TP #1 stated, "No, we have never done that; it has an internal control. 3. As the interview continued, the surveyor and TP #1 reviewed the manufacturer's instructions in the DCA Vantage Operators's Guide on

page 83, which revealed, "QUALITY CONTROL ... Run controls under the following conditions: ... -when using a new shipment of reagents -when using a new lot number of reagent -each time a calibration card is scanned -whenever test results are in doubt - when training new operators All control results must be within acceptable ranges before any patient sample is tested and the results are reported. ..." 4. After review of the manufacturer's instruction for QC, TP #1 confirmed the laboratory had not followed this protocol. A review of the test volumes revealed the laboratory had performed 1010 Urine Microalbumin/ Creatinine patient tests in 2019, and about the same number in 2018, according to TP #1. 5. During the exit summation on 2/26/2019 at approximately 4:00 PM, the surveyor reviewed the deficiencies and explained CLIA regulations required two levels of acceptable QC each day of patient testing for moderate complexity tests. However, when using the DCA Vantage (since the manufacturer had less stringent requirements for QC than CLIA has) the Laboratory Director had the option of implementing an optional IQCP (Individualized Quality Control Plan), which must include a risk assessment, QC plan, and quality assurance plan for the Urine Microalbumin/ Creatinine testing. .

**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 a lack of quality assurance documentation and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. During an interview on 2/26/2020 at 3:50 PM, when asked if the laboratory had any documentation of quality assurance activities for the last two years, TP #1 stated "No". 2. In a review of the laboratory processes, the surveyor noted the following quality assurance problems: A) Problems with the ISE (Ion-Selective Electrodes) on the Vital Envoy 500: On 9/11/2018, the 2018 Event #3 survey was performed and received a failing score of 20% for Chloride; documented corrective action by TP #1 for this survey was "samples were on the analyzer too long". On 1/30/19, the 2019 Event #1 survey was performed and received a failing score of 60% on Sodium; documented corrective action by TP #1 for this survey was incorrect results written. There was no documentation of investigation of other factors that might have affected the electrolytes such as the negative bias in the electrolyte quality controls or lack of ISE maintenance (Refer to D5429 and D5441.) B) Failure to review the instrument manufacturer's required environmental parameters and establish an acceptable range for room temperature, and failure to document the actual freezer temperatures (Refer to D5413.) C) Failure to document required maintenance procedures on the Tosoh AIA-360 and DCA Vantage (Refer to D 5429.) D) Failure to perform calibration verifications every six months on the Tosoh AIA-360, the Vital Envoy 500, and Urine Microalbumin/ Creatinine performed on the DCA Vantage (Refer to D5439.) E) Failure to perform quality control on Urine Microalbumin/ Creatinine, a non-waived moderate-complexity performed on the DCA Vantage (Refer to D5481.) F) Lack of sufficient

personnel (Refer to D6028.) 3. During the exit summation on 2/26/2019 at approximately 4:00 PM, the surveyor reviewed and confirmed the above noted findings. .

**D6028**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(10)

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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on a review of the Testing Personnel listed on the Form CMS-209, a review of laboratory processes and test volumes, and an interview with Testing Personnel (TP) #1, the Laboratory Director failed to ensure the laboratory had sufficient staff available to perform and document required quality control, calibration verification, maintenance and quality assurance procedures for accurate and reliable test performance. The findings include: 1. A review of the Form CMS-209 (Laboratory Personnel Report) revealed three testing personnel (TP), with TP #1 and # 2 employed since the previous survey, and TP #3 recently hired, currently still in training. 2. A review of laboratory processes revealed many deficiencies related to a lack of staff, including: A) Failure to correctly document environmental and freezer temperatures (Refer to D5413) B) Failure to perform and document required maintenance procedures on the Tosoh AIA-360, the Vital Envoy 500, and the DCA Vantage with the frequency prescribed by the manufacturer (Refer to D5429) C) A) Failure to perform Calibration verifications every six months on the Tosoh AIA-360, the Vital Envoy 500, and Urine Microalbumin/ Creatinine performed on the DCA Vantage (Refer to D5439) D) Failure to perform and Quality Control procedures on the Urine Microalbumin/ Creatinine testing performed on the DCA Vantage (Refer to D5481.) E) Failure to perform routine Quality Assurance activities to ensure accurate and reliable test performance and implement corrective actions when required (Refer to D5791.) 3. During the exit summation on 2/26/2020 at approximately 4:00 PM, the surveyor reviewed the deficiencies and asked who was the primary TP in the laboratory, responsible for the above tasks. TP #1 stated she was; however her patient care responsibilities left little time for the extra lab duties. The surveyor reviewed information on the CMS-116 (CLIA Application for Certification): approximately 140,000 tests annually in six specialties / subspecialties. Considering the laboratory's testing volume and important tasks, which were not being performed, the surveyor determined the laboratory has insufficient staff to ensure accurate reliable test performance and quality of services provided. .

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**  
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:  
Based on reviews of environmental logs, quality control (QC) records, maintenance logs, calibration verification records, a lack of quality assurance reviews, and interviews with Testing Personnel (TP) #1, the surveyor determined the Technical Consultant (who also serves as the Laboratory Director) failed to adequately fulfill responsibilities to provide effective technical and scientific oversight of the laboratory. The findings include: 1. Refer to D6036, which includes requirements cited at D5413, D5429, D5439, D5441, D5481, and D5791. .

**D6036**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:  
Based on reviews of environmental logs, quality control (QC) records, maintenance logs, calibration verification records, a lack of quality assurance reviews, and interviews with Testing Personnel (TP) #1, the surveyor determined the Technical Consultant (who also serves as the Laboratory Director) failed to adequately fulfill responsibilities to provide effective technical and scientific oversight of the laboratory. The findings include: 1. A review of laboratory processes revealed the Technical Consultant had failed to provide effective technical and scientific oversight in the following areas: A) Failure to fully investigate electrolyte proficiency testing failures, determine the cause of the problem on the Vital Envoy 500, and implement corrective actions (Refer to D5791, D5429 and D5441.) B) Failure to review the instrument manufacturer's required environmental parameters and establish an acceptable range for room temperature, and failure to ensure testing personnel documented the actual freezer temperatures (Refer to D5413.) C) Failure to ensure TP performed and documented required maintenance procedures on the Vital Envoy 500, Tosoh AIA-360 and DCA Vantage (Refer to D 5429.) D) Failure to ensure TP performed calibration verifications (C/V) every six months on the Tosoh AIA-360, the Vital Envoy 500, and Urine Microalbumin/ Creatinine performed on the DCA Vantage; and ensure review and approval of the C/V data by the Technical Consultant to determine whether corrective actions or adjustment of reportable ranges were required. (Refer to D5439.) E) Failure to review requirements for quality control on Urine Microalbumin/ Creatinine, a non-waived moderate-complexity test performed on the DCA Vantage, and ensure TP performed QC each day of patient testing, or as per manufacturer's requirements after implementation of an IQCP (Individualized Quality Control Plan) (Refer to D5481.) F) Failure to ensure the laboratory employed a sufficient number of personnel to perform the above duties in a timely manner (Refer to D6028.) G) Failure to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems. (Refer to D5791.) 3. During the exit summation with TP #1 on 2/26/2019 at approximately 4:00 PM, the surveyor reviewed and confirmed the above noted findings. SURVEYOR ID #32558  
Licensure and Certification Surveyor