Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227307	06/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Premier Healthcare Associates, Inc	7702 E Parham Road - Suite 101, Richmond, VA	

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
D0000	An announced CLIA validation survey was conducted at Premier Healthcare Associates, INC on June 1, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include the Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems.
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation, and an interview, the laboratory failed to ensure hematology Complete Blood Count (CBC) PT module results were returned to American Proficiency Institute (API) within the program's deadline for one (1) of four (4) events reviewed. Findings include: 1. Review of the laboratory's API hematology PT documentation (2020 Event 3, 2021 Events 1-3), a total of 4 events, revealed that the laboratory failed to submit and received failure to participate scores for the following CBC module: Hematology 2021 Event 2: receiving 0% scores for Cell Identification (Lymphocyte, Monocyte, Granulocyte), Red Blood Cell Count, White Blood Cell Count, Platelet Count, Hemoglobin, and Hematocrit. API noted: "Failure to participate" on the PT results. 2. An exit interview with the general supervisor on 6/1/22 at approximately 3:30 PM confirmed the above findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)

	The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, procedures, and interviews, the laboratory failed to document evaluation of non-graded PT results per established policy for hematology and immunology analyte challenges on two (2) of four (4) American Proficiency Institute (API) testing events reviewed. Findings include: 1. Review of the laboratory's procedure manual revealed a Quality Assurance policy that stated, "When a PT challenge receives a score of non-graded, we will conduct a self-evaluation of performance". 2. Review of the laboratory's API PT documentation (2020 Event 3, 2021 Events 1-3), a total of 4 events, revealed no evaluation or verification of accuracy for the non-graded responses for the following 4 analyte challenge samples: 2020 Hematology Module Event 3 - Blood Cell ID one (1) of five (5) responses (BCI-11), Urine Sediment 1 of two (2) responses US-06; API 2021 Immunology Module Event 1 - Anti-CCP 2 of 2 responses (CCP-01 and CCP-02). The inspector requested to review evaluation documentation for the non-graded analyte challenges BCI-11, US-06, CCP-01 and CCP-02 outlined on the 2 PT events listed above. No additional documentation was available for review. 3. An exit interview with the general supervisor on 6/1/22 at approximately 3:30 PM confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of analyzers' user guides, maintenance records, tour, review of policies, hematology calibration records, chemistry calibration verification records, lack of documentation, and interviews, the laboratory failed to: 1. document required monthly maintenance protocols for the Beckman Coulter DxH 520 hematology analyzer for six (6) of the twenty-four (24) months reviewed (timeframe: June 2020 to the time of the inspection June 1, 2022) - Cross Reference D5429 A; 2. document required monthly maintenance protocols for the Beckman Coulter AU480 chemistry analyzer for one (1) of 6 months reviewed in calendar year 2020 and failed to document required quarterly maintenance tasks for five (5) of the (8) quarters during the 24 months reviewed - Cross Reference D5429 B; 3. document required monthly maintenance protocols for the TOSOH A1A 360 chemistry analyzer for thirteen (13) of 24 months reviewed - Cross Reference D5429 C; 4. document annual function checks for centrifuge revolutions per minute for the urinalysis Thermo Biofuge centrifuge serial number (SN 41329853) in calendar year 2021 - Cross Reference D5435; 5. document every 6 months calibration procedures for Complete Blood Count testing on the Beckman Coulter DxH 520 hematology analyzer during the 24

	month review timeframe - Cross Reference D5437; 6. perform every 6 month chemistry calibration verification studies per established policy for Beckman Coulter AU480 analytes Albumin, Urease, Calcium, Cholesterol, Chloride, Creatinine, Glucose, Potassium, Sodium, Total Protein, Triglyceride, CO2, Alkaline Phoshatase, Alanine Transaminase, Aspartate Aminotransferase, Creatine Kinase, Total Bilirubin, High-density Lipoprotein and TOSOH A1A 360's Prostate Specific Antigen in calendar years 2020 and 2021 - Cross Reference D5439.
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: A. Based on review of analyzer's user guide, available maintenance records, lack of documentation, and an interview, the laboratory failed to document required monthly preventative maintenance protocols for the hematology analyzer for six (6) of the twenty-four (24) months reviewed (timeframe: June 2020 to the time of the inspection June 1, 2022). Findings include: 1. Review of the laboratory's Beckman Coulter DxH 520 hematology procedures and maintenance guidelines revealed the following two required monthly maintenance protocols (outlined in "Hematology Maintenance Binder"): Perform Bleach Cycle, Clean the WBC Bath Filter. 2. Review of the laboratory's available DxH 520 maintenance log records from June 2020 to 6/1/22 revealed lack of documentation for: Monthly Task "Perform bleach cycle" - in November 2021, January 2022; Monthly Task "Clean WBC Bath Filter" - in July, September, October, and December of calendar year 2020, November 2021, and January 2022. A total of 6 months lacked documentation of one (1) or both of the 2 monthly maintenance tasks as outlined above during the 24 months reviewed. The inspector requested to review additional documentation of monthly maintenance for the 6 months noted. No records or corrective action documentation was available for review. 3. An exit interview with the general supervisor on 6/1/22 at approximately 3: 30 PM confirmed the above findings. B. Based on review of analyzer's user guide, available maintenance records, lack of documentation, and an interview, the laboratory failed to document required monthly maintenance protocols for the Beckman Coulter AU480 chemistry analyzer for 1 of 6 months reviewed in calendar year 2020 and failed to document AU480 quarterly maintenance tasks for five (5) of the (8) quarters reviewed during timeframe of June 2020 to the time of the inspection June 1, 2022. Findings include: 1. Review of the laboratory's AU480 chemistry analyzer procedures and maintenance guidelines revealed the following required maintenance protocols (outlined in "Chemistry AU480 Maintenance Binder"): Monthly - replace ISE tubing; Quarterly - clean the air filters, inspect DI water and sample probe filters (replace if needed), replace the Wash Solution Roller pump tubing, check ISE Reference Electrode and add solution, manually clean the drain well, back up parameters every three months. 2. Review of the laboratory's available maintenance log records from June 2020 to 6/1/22 revealed lack of documentation for monthly AU480 maintenance in August 2020. The inspector noted that the laboratory documented the 6 required quarterly tasks outlined above on June 2020, November 2020, and July 2021. The inspector requested to review documentation of the monthly maintenance August 2020 and additional documentation of the quarterly maintenance performed in calendar year 2020 (September), calendar year 2021 (March, September,

	December), and in March 2022. No additional records or corrective action documentation was available. 3. An exit interview with the general supervisor on 6/1 /22 at approximately 3:30 PM confirmed the above findings. C. Based on review of analyzer's user guide, available maintenance records, lack of documentation, and an interview, the laboratory failed to document required monthly maintenance protocols for the TOSOH A1A 360 chemistry analyzer for thirteen (13) of 24 months reviewed during timeframe of June 2020 to the time of the inspection June 1, 2022. Findings include: 1. Review of the laboratory's A1A 360 chemistry analyzer procedures and maintenance guidelines revealed the following four required monthly maintenance protocols (outlined in "Chemistry TOSOH Maintenance Binder"): Clean sample sampling area with ethanol; Clean diluent and wash reservoirs; Rinse reservoirs with reagent grade type 1 water; Clean the wash probe. 2. Review of the available maintenance log records from June 2020 to 6/1/22 revealed lack of documentation for the monthly A1A 360 maintenance in the following months: 2020: June, July, August, September, October, November, December; 2021: July, November, December; 2022: January, February, March. A total of 13 months lacked monthly maintenance documentation. The inspector requested to review additional documentation of the monthly maintenance. No additional records or corrective action documentation was available for review. 3. An exit interview with the general supervisor on 6/1/22 at approximately 3:30 PM confirmed the above findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a tour, maintenance logs, lack of documentation, and interviews, the laboratory failed to document function checks for centrifuge revolutions per minute (RPM) for the Thermo Biofuge urinalysis centrifuge in calendar year 2021. Findings include: 1. During an entrance interview tour with the laboratory's General Supervisor (GS) on 6/1/22 at approximately 10:30 AM, the inspector noted a Thermo Biofuge centrifuge serial number (SN 41329853) in use for urine microscopy specimen processing. The inspector inquired regarding the protocol for verification of the RPM of the centrifuge. The GS stated at approximately 10:40 AM, "Checks for 1,500 to 2,100 RPM are done annually by H & M Sales and Service as part of our quality assurance policy." 2. Review of the laboratory's maintenance documentation revealed no records of RPM verifications for the Biofuge centrifuge outlined above for the urine setting of 1,500 to 2,100 RPM. The laboratory GS logged into the H & M Service's record site and printed the following two documents: 12/02/20 SN 41329853 centrifuge speed verified by tachometer 2100 RPM, 02/03/22 SN 41329853 centrifuge speed verified by tachometer 2100 RPM. The inspector requested to review a centrifuge verification record for calendar year 2021. No documentation was available. 3. An exit interview with the GS on 6/1/22 at approximately 3:30 PM confirmed the above findings.

D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, hematology calibration records, and an interview, the laboratory failed to document calibration procedures every six (6) months for Complete Blood Count (CBC) on the Beckman Coulter DxH 520 hematology analyzer during the review timeframe of January 2020 to the date of the inspection on June 1, 2022. Findings include: 1. Review of the laboratory's procedures revealed a Quality Assurance policy that stated "calibration frequency for CBC analyzer is at least once 6 months". 2. Review of the available Beckman Coulter DxH 520 hematology analyzer calibration documentation from calendar year 2020 to 6/1/22 revealed three calibration records: 1/12/20, 8/18/21, 3/3/22. The inspector requested to review additional calibration records. No additional calibration documentation was available for review. 3. An exit interview with the general supervisor on 6/1/22 at approximately 3:30 PM confirmed the above findings.
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 calibration verification records, procedures, analyzer operations' guides, lack of documentation, and interviews, the laboratory failed to perform chemistry calibration validation studies every six months in calendar years 2020 and 2021 per their policy for eighteen (18) Beckman Coulter AU480 analytes: Albumin (Alb), Urease (BUN), Calcium (Ca), Cholesterol (Chol), Chloride (Cl), Creatinine (Creat), Glucose (Glu), Potassium (K), Sodium (Na), Total Protein (TP), Triglyceride (Trig), Carbon Dioxide (CO2), Alkaline Phoshatase (ALP), Alanine Transaminase (ALT), Aspartate Aminotransferase (AST), Creatine Kinase (CK), Total Bilirubin (Tbili), High-density Lipoprotein (HDL); and TOSOH A1A 360's Prostate Specific Antigen (PSA). Findings include: 1. Review of the laboratory's available chemistry calibration verification documentation for the twenty-four months reviewed (June 2020 up to the date of the survey on 6/1/22) revealed documentation of the following calibration verification records for nineteen (19) test analytes: AU480 - Alb, BUN, Ca, Chol, Cl, Creat, Glu, K, Na, TP, Trig, CO2, ALP, ALT, AST, CK, Tbili, and HDL: dated on 10/21/20, 7/21/21, 3/16/22; A1A 360 - PSA: dated on 3/13/20, 1/15 /21, 5/20/22. One calibration verification study was performed in calendar year 2021 for each of the 18 AU480 test analytes outlined above. One calibration verification study for A1A 360 PSA analyte was performed in each calendar year of 2020 and 2021. 2. Review of the laboratory's procedure manual revealed the following policies: Calibration Verification Policy that stated, "A successful calibration verification confirms that the test system is providing accurate results for the analyte throughout the reportable range of the test. Tests are run on materials with known concentrations of the analytes in the same manner as patient specimens. Calibration verifications will be performed every six months for those analytes that are routinely calibrated with two or less calibrators". Quality Assurance Policy that stated, "QA to be sure calibration verification is done every 6 months on chemistry and immunoassay tests". 3. Review of the manufacturer's AU480 and A1A 360 operator's guide revealed a two-point calibration for the following nineteen (19) test analytes: ALB, BUN, Ca, Chol, Cl, Creat, Glu, K, Na, TP, Trig, CO2, ALP, ALT, AST, CK, Tbili, and HDL, and PSA. The inspector requested to review additional calibration verification for the above AU480 analytes in calendar year 2021 and for A1A PSA in 2020 and 2021. No additional documentation was available for review. 4. An exit interview with the general supervisor on 6/1/22 at approximately 3:30 PM confirmed the above findings.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on a review of procedures/policies, proficiency testing (PT) records, lack of documentation, and an interview, the laboratory director failed to ensure performance of remedial/corrective action was documented for 2020 Event 3 and 2021 Event 1 unsatisfactory hematology Eosinophil and Neutrophil Percent (%) analyte performance scores. Findings include: 1. Review of the laboratory's procedure manual revealed a Quality Assurance policy (section II Analytical/Proficiency Testing) that stated, "Ensure a review of all graded results is conducted and corrective active is documented by the lab supervisor, lad director, and lab techs." 2. Review of the laboratory's American Proficiency Institute (API) PT documentation: 2020 (Event 3)

	and 2021 (Events 1-3), a total of 4 events, revealed no corrective action documented for the following unsatisfactory scores: 2020 Event 3- Eosinophil % scored as 40% (unsatisfactory), three (3) of five (5) challenges were unacceptable (DXH-12, DXH-13, DXH-14); 2021 Event 1- Eosinophil % scored as 40% (unsatisfactory), 3 of 5 challenges were unacceptable (Eosinophil DXH-01, DXH-02, DXH-05) and Neutrophil scored as 60% (unsatisfactory) with two (2) of 5 unacceptable (DXH-02, DXH-04). The inspector requested to review corrective/remedial action for the unsatisfactory PT performances outlined above. No documentation was available for review. 3. An exit interview with the general supervisor on 6/1/22 at approximately 3: 30 PM confirmed the above findings
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, procedures, quality assurance (QA) records, calibration records, analyzer operation guides, maintenance records, Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the laboratory director, during the twenty-four month review timeframe of June 2020 to 6/1/22, failed to ensure that the laboratory: 1. adhered to established QA policies for PT evaluation of non-graded results - Cross reference D5213; 2. adhered to QA policy to perform of every six month hematology analyzer calibrations- Cross reference D5437; 3. adhered to QA policy to perform of every six month chemistry calibration verification - Cross reference D5439; 4. performed remedial/corrective action documentation for unsatisfactory hematology Eosinophil and Neutrophil Percent (%) analyte performance scores - Cross reference D6091 5. documented/retained personnel competency documentation - Cross reference D6101.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must 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 Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the laboratory director (LD) failed ensure that an annual competency assessment for the dual assignments of General Supervisor/Technical Supervisor /Testing Personnel for Personnel A was documented in calendar year 2021. (See Personnel Code Sheet.) Findings include: 1. Review of the CMS 209 form on 6/1/22 at approximately 10 AM revealed that the LD identified Personnel A as responsible for the duties General Supervisor (GS), Technical Supervisor (TS), and as a moderate /high complexity testing personnel (TP) during calendar year 2021 and year to date

	2022. 2. Review of the laboratory personnel files revealed that Personnel A's file lacked competency assessment documentation for the role of GS, TS, and TP in calendar year 2021. The inspector requested to review the documentation. No record was available for review. The GS stated on 6/1/22 at approximately 1 PM, "we are in the process of updating our competency assessments for all roles". 3. An exit interview with the GS on 6/1/22 at approximately 3:30 PM confirmed the above findings.