Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2057960	01/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Quality Care	15463 S First St, Milan, TN	

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**
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of 2021 and 2022 proficiency testing (PT) records and interview with the laboratory liaison, the laboratory failed to maintain records of testing personnel who performed wet prep proficiency testing in 2021 and 2022 for six of six events, failed to maintain proficiency testing evaluation reports for one of twelve events, and failed to maintain a paper trail for wet prep for six of six events. The findings include: 1. Review of proficiency testing (PT) records revealed the following: The testing person who performed the wet prep PT was not identified on the PT attestation statement for six of six PT events in 2021 and 2022. There was no performance evaluation report for 2022 event two for hematology (one of twelve PT evaluation reports). There was no paper trail for the wet prep PT for six of six events in 2021 and 2022. 2. Interview with the laboratory liaison on 01/17/2023 at 11:30 a.m. confirmed the survey findings. The laboratory liaison confirmed that the lab failed to maintain all PT records when it did not retain the attestation signature of the person

	who performed the wet prep PT, did not retain the 2022 event two PT evaluation report for hematology and failed to have a paper trail for the wet prep PT in 2021 and 2022.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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: Based on review of quality control (QC) records for the Triage meter, Complete Blood Count (CBC) quality control records and interview with the laboratory liaison, the laboratory failed to retain analytic records for a period of two years when it failed to identify the testing person who performed QC for the Triage meter on 07/20/21 (one of four dates reviewed) and failed to retain the CBC QC package insert for QC lot EX0422 (Low, Normal and High) in use on 05/05/22 (one of five master lots reviewed for CBCs). The findings include: 1. Review of QC for the Triage meter (used for performing cardiac testing) performed on 07/20/21 revealed no identity of the testing personnel who performed the QC. 2. Review of CBC quality control records revealed the package insert was not maintained for master control lot number EX0422 for the Drew 3 CBC instrument in use on 05/05/22. 3. Interview with the laboratory liaison on 01/17/23 at 3:00 pm confirmed the laboratory failed to retain analytic records to include the identity of the person who performed QC on the Triage meter on 07/20/21 and the CBC control package insert for QC lot EX0422 in use on 05 /05/22.
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 observation of the laboratory, review of the laboratory's procedures for the DxH 520 complete blood count (CBC) instrument and the laboratory's quality control policy, DxH 520 calibration records and quality control records, patient test records, and interview with the laboratory liaison, the laboratory failed to follow its' own policies for calibration verification, quality control after calibration has been performed, and performing quality control after reagent change in 2023 with patient testing performed. The findings include: 1. Observation of the laboratory on 01/17/23 at 8:00 am revealed the Beckman Coulter DxH 520 CBC instrument in use for patient testing for CBC. Testing person #1 was observed changing out a reagent on the instrument. When asked if he performed quality control after changing reagents, he stated that he did not. 2. Review of the manufacturer instructions for use that was used by the laboratory as part of its' procedures and the laboratory policy for quality control revealed the following: After calibration, the 2nd calibrator is performed to verify the instrument calibration. Controls are to be performed after change in reagent lot

	number and calibration of analyte. 3. Review of records for the calibration performed on 01/09/23 on the Beckman Coulter DxH CBC instrument and the laboratory's quality control records, revealed the laboratory did not run the 2nd calibrator to verify the instrument calibration and did not perform quality control after instrument calibration. 4. Review of patient test records revealed the following: Patient testing was performed on 01/09/23 (post calibration) at 8:54 am (Specimen ID # 000426185). A total of approximately 16 patients were reported on 01/09/23 before quality control was performed the next day. 5. Phone interview with the laboratory liaison on 01/23 /23 at 9:15 am confirmed the laboratory failed to follow its' own procedures for performing quality control after changing reagents, calibration of the instrument, and after changing reagents on the DxH 520 CBC instrument in 2023.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test records and the Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), procedure manual for the Beckman Coulter DxH 520 complete blood count (CBC) instrument, and interview with the laboratory liaison, the laboratory failed to ensure procedures for use of the DxH 520 CBC instrument were approved prior to patient testing in 2022, with approximately 3,830 patient CBCs performed since testing began on 07/01/22. The findings include: 1. Observation of the laboratory on 01/17/23 at 8:00 am revealed the Beckman Coulter DxH 520 CBC instrument (serial #BF030189) in use for patient testing. 2. Review of patient test records and annual test volumes as indicated on the Form CMS 116 revealed the first patient CBC performed on the DxH 520 was reported on 07/01/22, with approximately 3,830 patients reported since testing began. 3. Review of the operator's procedure manual for the Beckman Coulter DxH 520 CBC instrument revealed no approval by the lab director. 4. Interview with the laboratory liaison on 01/17/23 at 12:45 pm confirmed the laboratory uses the manufacturer operator's manual and also confirmed the lab director had not approved the procedures for use.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation of the laboratory and review of the Beckman Coulter DxH 520 complete blood count (CBC) instrument manufacturer instructions for use, and interview with the laboratory liaison, the laboratory failed to comply with manufacturer measuring range requirements for the DxH 520 CBC instrument for White Blood Cell analyte. The findings include: 1. Observation of laboratory on 01/17

	/23 at 8:00 am and review of the DxH 520 instructions for use revealed the following: Reportable ranges posted on the DxH 520 CBC instrument: White Blood Cell (WBC) 0.20-102 x10. Manufacturer measuring range as stated in the instructions for use were 0.2-100 x 10. The limits posted on the instrument exceeded the manufacturer measuring range for the WBC analyte. 2. Interview with laboratory liaison on 01/17 /2023 at 12:30 pm confirmed the limits that were posted on the front of the DxH 520 instrument were the limits the laboratory used for their reportable range and that they exceeded the manufacturer ranges.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on review of a calibrator package insert, calibration records and interview with the laboratory liaison, the laboratory failed to ensure it did not use expired calibrator on 05/23/2022. The findings include: 1. Review of the calibrator package insert for Lot EX0422-CAL revealed the calibrator lot had an expiration date of 05/05/22. 2. Review of calibration records revealed calibration performed on 05/23/22 using the expired calibrator. 3. Interview with the laboratory liaison on 01/17/23 at 3 pm confirmed the laboratory failed to ensure expired calibrator was not used on 05/23 /2022.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of laboratory, review of the Beckman Coulter (BC) DxH 520 complete blood count (CBC) instrument validation records, patient test records and annual test volumes, and interview with laboratory liaison the laboratory failed to perform normal range studies to verify the manufacturer's ranges that were being used by the laboratory with the first patient tested on 07/01/22 with approximately 3,830 patients reported since testing began. The findings include: 1. Observation of the laboratory on 01/17/23 at 8 am revealed the BC DxH 520 CBC instrument (serial #BF030189) in use for performing patient testing. 2. Review of DxH 520 CBC instrument validation records revealed no normal range study had been performed as of the date of the survey on 01/17/23. 3. Review of patient test records and annual test volumes as indicated on the Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) revealed the first patient CBC on the BC DxH 520 CBC instrument was

	performed on 07/01/22 with approximately 3,830 patients reported since testing began. 4. Interview with laboratory liaison on 01/17/2023 at 12:30 pm confirmed the laboratory uses the manufacturer normal range and did not validate those ranges with patient testing beginning on 07/01/22.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare & Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), Aspen Web 116, interview with testing person number one, review of Aspen Web 116, and interview with the laboratory liaison, the laboratory director failed to ensure compliance with 493.51 which requires notification to HHS or designee of changes in specialties with six months of the change. The findings include: 1. Review of the Form CMS-116 submitted as part of the survey process revealed the laboratory was not performing urine microscopy. 2. Review of Aspen Web 116 reveled urinalysis was listed as a specialty, and there was no evidence in Aspen Web 116 that the state agency had been notified of the change in specialties. 3. During an interview with testing person number one on 01/17/23 at 8:30 am, testing person number one stated the lab did not perform urine microscopic procedures. He further stated that he was unsure when the lab stopped performing urine microscopics, but the lab was not performing them when he hired on in early 2020. 4. Interview on 01/17/23 at 9:30 am with the laboratory liaison confirmed the lab director failed to ensure the state agency was notified of the change in specialties within six months of the change.
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: Based on review of the the laboratory's quality assessment policy, review of testing personnel records, staff interview and email communication, the technical consultant failed to follow the laboratory's procedures for competency assessment in 2020, 2021, and 2022. The findings include: 1. Review of the laboratory's quality assessment policy revealed the following: "Training/competency will be performed and documented by the technical consultant initially, at 6 months, and annually

	thereafter." 2. Review of testing personnel records revealed the following: Testing person number one did not have documented initial training/competency, six month competency or annual competency in 2021 for performance of wet prep procedures. Testing person number three did not have documentation of initial training training /competency for performance of complete blood count, chemistry tests performed on the Triage meter, or wet preps. 3. Interview with the laboratory liaison on 01/17/23 at 3 pm confirmed the survey findings. 4. Subsequent email communication from the laboratory liaison on 01/23/23 at 2:44 pm revealed that testing person number three began working at the Milan laboratory location in November 2022. The email further confirmed there was no documentation of initial training for the testing being performed which included wet prep, complete blood count on the Beckman Coulter DxH 520 and cardiac and D-dimer testing performed on the Triage meter.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of testing personnel records, and interview with the laboratory liaison, the technical consultant failed to include problem solving as part of competency assessment in 2020, 2021 and 2022 for complete blood count (CBC) instruments and wet prep for testing person number two. The findings include: 1. Review of testing personnel records revealed problem solving was not included as part of competency assessment for testing person number two as follows:Drew 3 CBC instrument for competencies performed on 04/15/20, 05/26/21, and 04/27/22. DxH 520 CBC instrument for competency performed on 06/30/22. Wet Prep competency performed on 04/15/20, 04/15/21 and 04/12/22. 2. Interview with the laboratory liaison on 01/17/23 at 3 pm confirmed the technical consultant failed to include problem solving as part of competency assessment for CBC instruments in 2020, 2021 and 2022, and failed to include problem solving as part of competency assessment for wet prep in 2020, 2021, and 2022 for testing person number two.