Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1077508	10/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Quality Care	2075 Pleasant Plains Ext, Jackson, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of package inserts, staff interviews, review of patient test reports, the Centers for Medicare and Medicaid Services regulated analytes, proficiency testing records and interview with the laboratory liaison, the laboratory failed to enroll in proficiency testing for viral antigen detection in 2020 and 2021. The findings include: 1. Observation of the laboratory on 10/6/21 at approximately 8:40 am revealed the BinaxNOW test kit in use for patient testing. 2. Review of the package insert for the BinaxNOW RSV kit revealed the test is waived when used for patients under the age of five. The package insert indicated the test is a qualitative RSV antigen detection. 3. Staff interviews on 10/6/21 at approximately 9: 00 am revealed testing is performed on patients five and older, resulting in a laboratory developed high complexity test system. 4. Review of patient test reports revealed the modified test was used for patient testing in 2020 and 2021. 5. Review of the CMS regulated analyte list revealed that direct viral antigen detection is a regulated analyte. 6. Review of the 2020 and 2021 proficiency testing records revealed no enrollment or participation in proficiency testing for the viral antigen

	detection. 7. Interview with the laboratory liaison on 10/6/21 at approximately 5:00 pm confirmed the laboratory was not enrolled in proficiency testing for viral antigen detection in 2020 and 2021.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation of the laboratory, record review, and staff interviews, the laboratory failed to report negative SARS-CoV-2 test results to public health authorities in 2020 and 2021. The findings include: 1. Observation of the lab on 10/6 /21 at approximately 9:00 am revealed the Accula and QuickVue test kits in use for patient testing for SARS-CoV-2. 2. Review of records for reporting of SARS-CoV-2 results to public health authorities revealed that the laboratory does not report negative SARS-CoV-2 results. For dates selected (10/2/20, 12/10/20, 6/19/21, and 9/24/21) only positive results were reported. 185 of 231 results were not reported. 3. Interview with the lab director on 10/6/21 at approximately 1 pm confirmed negative patient test results have not been reported to public health authorities since 10/1/20.
D5010	VIROLOGY CFR(s): 493.1205 If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: The laboratory failed to establish performance specifications for use of the laboratory modified, high complexity Respiratory Syncytial Virus test. (Refer to D5423)
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by:

	Based on review of final patient test reports, patient test management (PTM) documents, and staff interview, the laboratory quality assessment process was ineffective in correcting problems with units of measure on the final patient Complete Blood Count (CBC) test reports. The findings include: 1. Review of the final CBC patient test report for account number 362012 revealed no units of measure for Neut, Baso, Mono, and MPV. 2. Review of PTM documents dated 9/30/21 that included the same patient revealed a check mark for units of measure and no corrective action performed. 3. Interview with the laboratory liaison on 10/6/21 at approximately 5:00 pm confirmed the laboratory quality assessment process was ineffective when it did not detect and correct problems with units of measure on the final CBC report.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation of the laboratory, staff interview, review of package insert, document request, patient test reports and staff interview the laboratory failed to establish performance specifications for the use of the BinaxNOW Respiratory Syncytial Virus (RSV) test in patients five and older. The findings include: 1. Observation of the laboratory on 10/6/21 at approximately 8:40 am revealed the use of BinaxNOW kit for the detection of RSV. 2. Interview with the lead laboratory testing person on 10/6/21 at approximately 9:00 am revealed the laboratory used the BinaxNOW test for performing RSVon patients five and older. 3. Review of the BinaxNOW RSV product package insert revealed the following: "ATTENTION: Do not use RSV test in patients five years or older." "Any modifications by the laboratory to this test system or FDA cleared test system instructions will result in the test no longer meeting the requirements for waived categorization." 4. Request for establishment of performance specifications documents for the use of the BinaxNOW RSV test in patient five or older on 10/6/21 at approximately 9:00 am revealed no documents were available. 5. Review of patient test reports from dates spanning from 1/1/2020 to 10/7/2021 revealed approximately 542 of 813 total RSV tests were performed on patients five and older using the BinaxNOW RSV. 6. Interview with the laboratory liaison on 10/6/21 at approximately 5:00 pm confirmed the laboratory failed to establish performance specifications for the use of the BinaxNOW RSV test in patients five and older.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed

	specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on observation of the laboratory, record review, and staff interview, the technical consultant failed to include blind testing as part of competency assessment for seven of twelve competencies performed for testing person number seven in 2020 and 2021. The findings include: 1. Observation of the laboratory on 10/6/21 at 8:40 am revealed the following moderately complex test systems in use for patient testing: Biosite Triage Meter used for performing Troponin, Myoglobin, Creatine Kinase MB (CKMB), and D-Dimer, a microscope on the counter in use for patient Wet Prep Microscopy, and a Beckman Coulter DXH520 used for performing complete blood counts (CBCs). 2. Review of testing personnel competency records for testing person number seven, revealed blind testing was not included as part of competency as follows: a. Biosite triage meter for competency performed on 3/9/20 and 12/3/20. b. Wet Prep Microscopy for competency done on 12/3/20 and 9/30/21. c. Complete Blood Count instrument for competency done on 3/9/20, 12/3/20, and 9/30/21. 3. Interview with the laboratory liaison on 10/6/21 at approximately 12:00 pm confirmed the technical consultant failed to include blind testing as part of competency assessment for testing person number seven for seven of twelve competencies performed in 2020 and 2021.
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 observation of the laboratory, record review, and staff interview, the technical consultant failed to assess problem solving skills as part of competency assessment for three of twelve competencies performed on testing person number seven in 2020 and 2021. The findings include: 1. Observation of the laboratory on 10/6 /21 at 8:40 am revealed a microscope on the counter in use for performing moderately complexity testing for patient Wet Prep Microscopy. 2. Review of testing personnel competency records for testing person number seven revealed problem solving skills were not included as part of Wet Prep Microscopy competency for three of twelve competencies performed (4/15/20, 12/3/20, and 7/30/21). 3. Interview with the laboratory liaison on 10/6/21 at approximately 5:00 pm confirmed the technical consultant failed to include assessment of problem solving skills as part of competency assessment for testing person number seven for three of twelve competencies performed for Wet Prep Microscopy in 2020 and 2021.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of previous survey notes, request for training documents and staff interviews the technical consultant failed to evaluate testing personnel performance for the use of a new Complete Blood Count (CBC) instrument in 2020. The findings include: 1. Observation of the laboratory on 10/6/21 at approximately 8:40 am revealed a Beckman Coulter DxH520 in use for performing patient testing for CBCs. 2. Review of survey notes from the previous survey performed on 8/8/18 revealed a Drew 3 instrument in use for performing CBCs. 3. Request for training and assessment documents for use of the new instrument on 10/6 /21 at approximately 1:30pm revealed no documents were available. 4. Interview with the lead laboratory testing person on 10/6/21 at approximately 1:30 pm confirmed the technical consultant failed to ensure testing personnel were trained and evaluated prior to the use of a new CBC instrument in 2020. Use of the new instrument for patient testing began around August 2020.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: The laboratory director failed to meet the education and experience requirements for directing high complexity testing. (Refer to D6078).
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b) (1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience

	directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of package inserts, staff interviews, review of personnel records and interview with the laboratory liaison, the laboratory director failed to meet the education and experience requirements for directing high complexity testing. The findings include: 1. Observation of the laboratory on 10/6/21 at approximately 8:40 am revealed the BinaxNOW test kit in use for patient testing. 2. Review of the package insert for the BinaxNOW RSV kit revealed the test is waived when used for patients under the age of five. 3. Staff interviews on 10/6/21 at approximately 9:00 am revealed testing performed on patients five and older, resulting in a laboratory developed high complexity test system. 4. Review of lab director qualifications revealed the director of the laboratory did not meet high complexity personnel requirements. 5. Interview with the laboratory liaison on 10/6/21 at approximately 5:00 pm confirmed that the laboratory director failed to meet the education and experience requirements for directing high complexity testing.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: The laboratory testing personnel failed to meet the requirements for performing high complexity testing. (Refer to D6171)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of

biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of package inserts, staff interviews, review of personnel records and interview with the laboratory liaison, six of eight testing personnel (TP) failed to meet the high complexity testing personnel requirements for performing the laboratory modified, high complexity Respiratory Syncytial Virus (RSV) test. The findings include: 1. Observation of the laboratory on 10/6/21 at approximately 8:40 am revealed the BinaxNOW test kit in use for patient testing for RSV. 2. Review of the package insert for the BinaxNOW RSV kit revealed the test is waived when used for patients under the age of five. 3. Interview with the laboratory lead on 10/6/21 at approximately 9:00 am revealed testing on the BinaxNOW RSV kit was used for testing patients five and older, resulting in a laboratory developed high complexity test system. 4. Review of TP records revealed

	six of eight laboratory TP did not meet high complexity personnel requirements. 5. Interview with the laboratory liaison on 10/6/21 at approximately 5:00 pm confirmed that six of eight TP failed to meet the requirements for performing high complexity testing.