Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0257916	08/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Piedmont Newnan Hospital Laboratory	745 Poplar Road, Newnan, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) complaint survey was completed on August 22, 2019. The laboratory was found not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 surveyor review of the laboratory's policy and procedures, College of American Pathologists (CAP) proficiency testing (PT) records, and interview with the blood bank supervisor (BBS), the laboratory failed to test proficiency testing samples in the same manner as patients' specimens for the specialty of Immunohematology. (Refer to D2006, D2009 and D2010)
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of

	this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of hematology proficiency test (PT) sample results and staff interview, the laboratory failed to test the PT samples it received from the PT testing program in the same manner it tested patient specimens. Findings include: 1. PT sample result review revealed 2018 Hematology PT sample FH13-07-B (Second Event) was examined twice on 5/15/2018. The analytes were all in normal range. 2. An interview with the hematology lead tech, in the hematology area of the laboratory, on 8/22/2019, at approximately 11:00 a.m., confirmed the aforementioned PT sample was examined in duplicate.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency test (PT) records and interview with the blood bank supervisor (BBS), the laboratory failed to attest the routine incorporation of the College of American Pathologists (CAP) proficiency testing (PT) samples into the patient workload for the specialty of Immunohematology. The findings include: 1. The laboratory did not have a signed attestation statement from the testing personnel - for PT event JAT-B2019 for the specialty of Immunohematology. 2. Testing personnel must attest that PT samples were performed accordingly to the guidelines set forth by the PT provider. 3. The laboratory supervisor confirmed on 08/22/19, at 11:30 AM, in the office, that the testing personnel failed to review and sign the PT attestation statements for the specialty of Immunohematology.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) documentation, testing worksheets, and an interview with the blood bank supervisor (BBS), the laboratory failed to test transfusion medicine proficiency testing (PT) samples the same number of times that it routinely tests patient samples. The findings include: 1. A review of PT records indicated the PT event JAT-18 was ran on 10/13/18 and 10/9/18 for confirmation. No patient samples were performed in duplicate on 10/13/18 and 10/9/18. Also, JAT-02 was performed on 2/20/19 at 17:51 and repeated the same day at 18:11 for confirmation. JAT-03 was performed on 2/20

	/19 at 19:49 and repeated the same day at 20:38 for confirmation. 2. CAP's Proficiency Test policy states, "Duplicate analyses are not permitted unless patient samples are tested in the same manner." Repeat analyses of PT samples is only acceptable if patient samples are treated in the same manner. 3. The BBS confirmed on 8/22/2019, at 11:30 AM, in the office, that the laboratory did not test PT samples the same number of times that it routinely tests patient samples.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor observation of the blood bank specimens and interview with the Blood Bank Supervisor (BBS), the laboratory failed to ensure that the appropriate staff responsible for collecting specimens labeled the tubes with the required information. The findings include: 1. The laboratory received and accepted a blood specimen (#W900567046) on 8/8/19, that did not have the collector's initials on the tube. 2. The laboratory did not document this in their specimen rejection log or corrective action log. 3. The BBS confirmed on 8/22/19, at 12:45 PM, in the laboratory, that the laboratory received and accepted a blood specimen that was missing the collector's initials on the tube.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Review of patient logs and staff interview revealed the laboratory did not follow the the quality assurance (QA) policy and procedure as required for logging patient specimens for testing. Findings include: 1. Review of the Alere Triage drug screen patient log revealed the required date of testing was not written on the log sheet for one patient in 22 days of testing for the month of August, 2019. 2. An interview with the chemistry lead tech, in the chemistry area of the laboratory, on 8/22/2019, at approximately 10:30 a.m., confirmed the missing date of testing for one patient for the month of August, 2019.
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 and review of the laboratory policy and procedure manual (SOP), the laboratory failed to follow the established policies and procedures as required. Findings include: 1. Review of the hematology SOP and observation during the laboratory tour revealed three patient hematology slides in the 2019 hematology slide tray did not have dates as required by the SOP procedure for blood smear preparation.. 2. An interview with the hematology lead tech, in the hematology area of the laboratory, at approximately 11:00 a.m. , on 8/22/2019, confirmed the aforementioned hematology slides were not labeled with a date as required by the hematology SOP. 37356 Based on surveyor review of the blood bank procedure manual and interview with the blood bank supervisor (BBS), the laboratory failed to follow their own quality control (QC) procedures for the Ortho Vision Analyzer for the specialty of Immunohematology. Also, the laboratory failed to follow their fresh frozen plasma (FFP) procedure for temperature ranges for the water bath in the blood bank. The findings include: 1. The laboratory procedure stated,"The Vision has been set up with a 26-hour maximum interval between QC events to allow flexibility in the morning schedule." 2. The manufacturer specification indicated that maximum intervals between QC's should be 24 hours. The laboratory did not have verification or correlation studies indicating that the QC continues to be effective at 26 hours. 3. The laboratory's FFP procedure requires thawing at 36C 1, however the water bath's acceptable range is 30-37C. 4. The BBS confirmed on 8/22/19, at 10:45 AM, in the laboratory, that the laboratory was not following their quality control procedure for the Ortho Vision Analyzer for the specialty of Immunohematology. Also, the BBS confirmed that the laboratory was not following their acceptable ranges for the water bath.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff

	interview, the laboratory failed to include all quality control (QC) policies and procedures as required. Findings include: 1. Hematology SOP review revealed the laboratory did not establish a policy and procedure for body fluid cell counts. 2. An interview with the hematology lead tech,in the hematology area of the laboratory, on 8 /22/2019, at approximately 11:00 a.m., confirmed there was not a QC policy and procedure for body fluid cell counts in the hematology SOP.
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 patient document review, manufacturer requirement review, and staff interview, the laboratory failed to follow manufacturer requirements to perform laboratory testing. Findings include: 1. Patient document review revealed the laboratory diluted lipase specimens for the following dates: 10/2/2018 -- patient specimen diluted 1:50 (one to fifty) and 1:100 (one to one hundred); 6/15/2019 -- patient specimen diluted 1:8, 1:10, 1:13. 2. Review of Vitros 5600 chemistry analyzer manufacturer requirements revealed the patient specimen should have a maximum dilution of 1:2 for accurate results. 3. Patient document review revealed the laboratory diluted a TSH (thyroid stimulating hormone) specimen (1:10) on 8/13/2019. 4. Review of Vitros 5600 chemistry analyzer manufacturer's requirements revealed the patient specimen should have a maximum dilution of 1:5 for accurate results. 5. An interview in the laboratory, with the chemistry lead tech, in the chemistry area of the laboratory, at approximately 10:00 a.m. ,on 8/22/2019, confirmed the aforementioned improper dilutions for lipase and TSH patient testing.
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 quality control (QC) document review, patient log review, laboratory policy and procedure manual (SOP) review, and staff interview, the laboratory failed to perform QC to monitor test performance with the frequency required in the SOP. Findings include: 1. QC document review and SOP review revealed external Fetal Fibronectin QC for Cassette Lot #K8010 was performed for the following dates: 1/13

	/2019 and 3/11/2019. 2. QC document review and SOP review revealed external Fetal Fibronectin QC for Cassette Lot #9054 was performed for the following dates: 6/24 /2019 and 8/4/2019. 3. SOP review revealed Fetal Fibronectin QC recommended frequency is once each time a new lot or new shipment of cassettes is received or every 30 days for an opened lot number of cassettes. 4. Cerebrospinal fluid (CSF) cell count patient log review revealed QC was not performed for CSF cell counts for 2018 and 2019 thus far. 5. An interview with the chemistry chief tech, on 8/22/2019, in the laboratory, at approximately 10:30 a.m., confirmed the lack of aforementioned external Fetal Fibronectin QC performance. 6. An interview with the Hematology lead tech, in the hematology area of the laboratory, on 8/22/2019, at approximately 11 a. m., confirmed the lack of QC for CSF cell counts for 2018 and 2019 thus far.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory maintenance records and interview with the blood bank supervisor (BBS), the laboratory failed to perform and document routine inspections of the audible alarm system of the temperature-controlled storage areas where blood and blood products are stored. The findings include: 1. The laboratory did not have a record indicating that regular inspections of the temperature alarm systems were being performed for the blood bank. 2. Refrigerators 24-2537 & 24-2536 had temperatures ranges of 1-6C, however blood reagents that had temperature requirements of 2-8C were also being stored in the refrigerators. 3. The BBS confirmed on 8/22/19, at 1:00 PM, in the laboratory, that the laboratory did not perform routine alarm system checks for temperature-controlled storage areas where blood and blood products are stored.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor review of blood bank procedures, the laboratory failed to provide comparison studies for the different methodologies currently in use for their Immunohematology assays. The findings include: 1. The laboratory did not have method comparison studies for the gel testing to Ortho Vision analyzer for the specialty of Immunohematology. 2. The laboratory uses both methods for antibody detection however failed to have a record of method comparison for the

	Immunohematology assays. 3. The BBS confirmed on 8/22/19, at 12:45 PM, in the laboratory, that the laboratory did not have a method a comparison study for gel testing to Ortho Vision analyzer for Immunohematology.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the chemistry policy and procedure manual and staff interview, the laboratory director (LD) failed to review the SOP with the frequency required. Findings include: 1. Review of the chemistry SOP revealed the LD had not performed a review since 1/27/2015. 2. The chemistry SOP established an LD review policy of every 2 years. 3. An interview with the chemistry lead tech, in the chemistry area of the laboratory, at approximately 10:30 a.m., in the chemistry department of the laboratory, confirmed the chemistry SOP had not been reviewed by the LD since 1/27 /2015 and that the SOP established an LD review policy of every 2 years.
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 observation and staff interview, the laboratory director (LD) failed to employ a sufficient number of testing personnel (TP) to properly supervise and accurately perform test and report test results as required. Findings include: 1. Observation during the laboratory tour revealed there was an inadequate number of TP in chemistry for the volume of testing performed. 2. An interview with the chemistry lead tech, in the chemistry area of the laboratory, at approximately 10:00 a. m., on 8/22/2019, confirmed there was inadequate staffing of TP in the chemistry department. 37356 Based on interviews with the blood bank supervisor (BBS) and testing personnel (TP), the laboratory director failed to employ a sufficient number of laboratory testing personnel for the specialties of Immunohematology and Routine Chemistry. The findings include: 1. An interview with the BBS revealed that one laboratory testing personnel is performing testing and performing supervisory duties for Routine Chemistry for the day shifts. Also, the blood bank has an interim supervisor and needs additional testing personal to assist with patient testing and the workload of the laboratory. 2. The BBS and TP confirmed on 8/22/19, at 1:00 PM, in the office, that the laboratory does not have an adequate number of testing personnel for the specialty of Immunohematology and Routine Chemistry.

D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual (SOP) and interview with testing personnel, the laboratory director (LD) failed to review and approve the procedure manual that monitors and evaluates the overall quality of the analytic systems within the laboratory. The findings include: 1. The blood bank procedure manual was not reviewed or approved by the laboratory director. Several procedures were last reviewed between 2013 to 2015 for the blood bank. 2. There was a laboratory director change in 2017 -however the current laboratory director has not reviewed or approved the SOP's for the laboratory. 3. An interview with the blood bank supervisor on 8/22/19, at 11:00 AM, in the office, confirmed that the laboratory director did not review or approve the procedure manual for the laboratory.