Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2012272	01/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Care Of Thomasville	33650 Hwy 43, Thomasville, AL	

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 a review of the API (American Proficiency Institute) proficiency testing (PT) records and an interview with the Technical Consultant, the surveyor determined the laboratory failed to retain instrument printouts for one of three Chemistry /Endocrinology surveys performed in 2017. The findings include: 1. A review of the API PT records revealed the laboratory had failed to retain the instrument printouts for the Chemistry and Endocrinology testing performed on the 2017-Event #1 survey. 2. During an interview on 1/31/2018 at 11:30 AM, the Technical Consultant reviewed and confirmed she had been unable to locate the instrument printouts for the above survey. .
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I

	of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing records and an interview with the Technical Consultant, the surveyor determined the laboratory failed WBC differential (White Blood Cell) testing for three out of four consecutive testing events. These failures resulted in non-initial unsuccessful proficiency testing participation. The findings include: 1. Refer to D2130. .
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing records and an interview with the Technical Consultant, the surveyor determined the laboratory failed WBC differential (White Blood Cell) testing for three out of four consecutive testing events. These failures resulted in non-initial unsuccessful proficiency testing participation. The findings include: 1. A review of the API Hematology proficiency testing records revealed the following scores: A) Event #3-2016: WBC differential with a failing score of 40% B) Event #1-2017: WBC differential with a failing score of 27% C) Event #3-2017: WBC differential with a failing score of 0% (due to failure to submit results by the cut-off date specified by the proficiency testing provider) 2. In an interview on 1/31/2018 at 11:30 AM, the Technical Consultant reviewed and confirmed the above noted 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 reviews of analytical processes and procedures and an interview with the Technical Consultant, the laboratory failed to: 1. Ensure proficiency testing results were entered correctly and before the cut-off date specified by the proficiency testing provider to prevent failing Hematology scores (Refer to D2016 and D2130.) 2. Ensure data generated during the initial installation procedures for the Siemens Dimension XPAND Plus Chemistry analyzer verifying the manufacturer's performance specifications was documented as reviewed and approved by the Laboratory Director; and ensure the reference ranges were verified for the laboratory's patient population. (Refer to D5421.) 3. Follow the manufacturer's instructions to calibrate the Medonic M Series Hematology analyzer every six months (Refer to D5437.) 4. Ensure a calibration verification was performed every six months on all analytes that are calibrated with less than three calibrators (Sodium, Potassium and Chloride) (Refer to D5439.) 5. Ensure two levels of quality control (QC) were within acceptable ranges to assure the quality of laboratory services before patient testing was performed on the Medonic Hematology and the Dimension Chemistry analyzers. (Refer to D5481.) 6. Implement effective timely quality assessment reviews to identify and correct problems identified in the analytical systems (D5791). .
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 a review of the installation and validation records for the Siemens Dimension XPAND Plus Chemistry analyzer and an interview with the Technical Consultant, the surveyor determined the laboratory failed to ensure data generated during the initial installation procedures was reviewed and approved as verification of the manufacturer's performance specifications before patient testing began. The laboratory further failed to ensure the reference ranges were verified for the laboratory's patient population. The findings include: 1. A review of the installation and validation records for the Dimension XPAND Plus Chemistry analyzer revealed no documentation of review and approval by the Laboratory Director (as indicated by a signature and date) on the initial verification procedures performed on 6/6 and 6/7/2016. The laboratory further failed to ensure the reference ranges in use were verified and approved for the laboratory's patient population. 2. Patient Chemistry and Endocrinology testing on this analyzer began in June 2016. 3. During an interview and review of these records on 1/31/2018 at 12:00 PM, the Technical Consultant confirmed the above noted 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 reviews of the Medonic Hematology analyzer calibration records and the Procedure Manual, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to perform one of two calibrations in 2017, as required by the manufacturer. The findings include: 1. A review of the Medonic CDS M Series Procedure Manual revealed, "...CALIBRATION: Calibration must be performed upon setup of the instrument and then at a minimum of every six months...". 2. A review of the Medonic Hematology analyzer records revealed calibrations were performed on 1/27/2016, 7/15/2016, and 7/20/17 (one year after the previous calibration). There was no documentation of a calibration performed in early 2017. 3. During an interview on 1/31/2018 at 12:50 PM, the Technical Consultant stated she believed the laboratory had missed the first calibration in 2017, and further confirmed calibrations should be performed every six months. 4. This is a previously cited deficiency. .
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 reviews of the calibration procedure and a lack of calibration verification records for Sodium (Na), Potassium (K), and Chloride (Cl) on the Siemens Dimension

	XPAND Plus Chemistry analyzer, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to perform a calibration verification for these tests every six months in 2017 as required. The findings include: 1. A review of the Dimension XPAND Plus calibration procedures revealed the electrolytes (Na, K, and Cl) are calibrated automatically using two on-board calibrators (Standards A and B). 2. Whenever any analyte is calibrated with less than three calibration points, a calibration verification is required every six months. 3. During an interview on 1/31 /2018 at 4:35 PM, the Technical Consultant was asked if she had records of electrolyte calibration verifications performed since the installation of the new Dimension in June 2016. After review of the Dimension calibration procedures, the Technical Consultant stated she had not realized any of the tests used less than three calibrators. She had failed to ensure the laboratory performed calibration verifications for Na, K and Cl as required. Thus the above noted findings were confirmed. 4. This is a previously cited deficiency. .
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 reviews of the quality control (QC) records for the Siemens Dimension EXPAND Plus Chemistry analyzer and the Medonic Hematology analyzer, and interviews with the Technical Consultant, the surveyor determined the laboratory failed to ensure at least two levels of QC were run and within acceptable limits before testing patient specimens. This was noted on many days in many months of QC performed in 2016-2017. The findings include: 1. A review the 2017 Hematology cumulative QC reports revealed multiple days in four out of eight months reviewed when QC was outside acceptable ranges on days of patient testing. Some examples of this practice include: A) 02/06/17: Low (L), Normal (N), and High (H) QC out-13 patient CBC's tested B) 02/16/17: N and H QC out-13 patient CBC's tested C) 02/17 /17: L, N, and H QC out-17 patient CBC's tested D) 02/24/17: L, N, and H QC out-13 patient CBC's tested E) 02/27/17: L and H QC out-21 patient CBC's tested F) 05/01 /17: N and H QC out-14 patient CBC's tested G) 05/02/17: N and H QC out-16 patient CBC's tested H) 05/03/17: N and H QC out-18 patient CBC's tested I) 05/04/17: N and H QC out-20 patient CBC's tested J) 06/07/17: L, N, and H QC out-9 patient CBC's tested K) 06/08/17: L, N, and H QC out-5 patient CBC's tested L) 06/19/17: L, N, and H QC out-6 patient CBC's tested M) 06/20/17: L, N, and H QC out-6 patient CBC's tested N) 06/27/17: L and H QC out-29 patient CBC's tested O) 12/23/17: L and N QC out-5 patient CBC's tested 2. A review of three months of the 2016-2017 Chemistry QC data and Levi-Jennings reports revealed multiple days of patient testing when at least one level of two QC was outside acceptable ranges as follows: A) 08/05 /16: Alkaline Phosphatase QC 1 out; 43 patient tests performed B) 08/08/16: Alkaline Phosphatase QC 1 out; 28 patient tests performed C) 08/19/16: BUN, ALT and AST QC 2 out; 21 patient tests on each analyte performed D) 08/29/16: Calcium QC 2 out; 14 patient tests performed E) 02/15/17: BUN QC 2 out; 12 patient tests performed F) 02/22/17: Glucose QC 2 out; 15 patient tests performed G) 11/02/17: Calcium QC 1 out; 12 patient tests performed H) 11/09/17: Calcium QC 2 out; 13 patient tests performed I) 11/10/17: Calcium QC 2 out; 17 patient tests performed G) 11/14/17: Cholesterol QC 1 out; 13 patient tests performed G) All days of patient testing in

	November 2017: HDL and Triglyceride QC 1 out; 191 patient tests performed on each analyte H) All days of patient testing in November 2017: Glucose and Total Protein QC 1 and QC 2 out; 210 patient tests performed on each analytes 4. During an interview on 1/31/2018 at 4:15 PM, the days of QC outages were reviewed with the Technical Consultant who stated she lived out of town and usually could only review the laboratory records once a month. The Technical Consultant was then asked if corrective action was performed on days when the laboratory failed to ensure two levels of QC were within acceptable ranges. The Technical Consultant stated when she had questioned the previous Testing Personnel (who resigned on 11/24/2017), the personnel stated she had not performed patient tests on days when QC was out. 5. As the interview continued, the Technical Consultant was asked to check their records to ensure patient testing was not performed. Office staff checked patient results in the APEX Laboratory Information System and the Greenway Success Electronic Health Record and provided the patient test counts incorporated above. Thus the above noted findings were confirmed. .
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 review of quality assurance documentation and an interview with the Technical Consultant and the Testing Personnel, the laboratory failed to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. A review of quality assurance documentation revealed the laboratory routinely performed monthly quality assurance activities, however the reviews were inadequate to discover and correct problems in the following areas: A.) Review of proficiency testing records to ensure analyzer printouts of the results were retained (Refer to D2015.) B.) Review of proficiency testing records and procedures to ensure results were entered correctly and before the cut-off date specified by the proficiency testing provider to prevent failing Hematology scores (Refer to D2016, D2130 and D6017.) C.) Review of installation records for the Siemens Dimension XPAND Plus Chemistry analyzer to ensure data generated during the initial installation procedures verifying the manufacturer's performance specifications was reviewed and approved by the Laboratory Director; and ensure the reference ranges were verified for the laboratory's patient population. (Refer to D5421 and D6013.) D.) Review of Hematology records and requirements to ensure the Medonic was calibrated every six months as required by the manufacturer. (Refer to D5437.) E.) Review of calibration and calibration verification procedures (C /V) to ensure a C/V was performed every six months on all analytes that are calibrated with less than three calibrators (Refer to D5439.) F.) Review of daily Chemistry and Hematology quality control (QC) data to ensure at least two levels of QC were within acceptable ranges each day of patient testing (Refer to D5481.) 2. During the exit summation on 1/31/2018 at 4:50 PM, these concerns were reviewed and discussed with the Technical Consultant and the Testing Personnel. 3. Failure to implement effective timely quality assurance reviews is a previously cited deficiency. .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of installation and validation documentation for the Siemens Dimension XPAND Plus Chemistry analyzer and an interview with the Technical Consultant, the surveyor determined the Laboratory Director failed to document his review and approval of the initial validation procedures as verifying the manufacturer's performance specifications for the analyzer, before patient testing began. The findings include: 1. A review of the installation and validation records for the Dimension XPAND Plus Chemistry analyzer revealed no documentation of review and approval by the Laboratory Director (as indicated by a signature and date) on the initial verification procedures performed on 6/6 and 6/7/2016. Patient Chemistry and Endocrinology testing on this analyzer began in June 2016. 2. During an interview and review of these records on 1/31/2017 at 12:00 PM, the Technical Consultant confirmed she was unable to find any documentation the data had been reviewed or approved.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing records and an interview with the Technical Consultant, the surveyor determined the Laboratory Director failed to ensure Hematology results for one of three 2017 surveys were submitted within the timeframes specified by the proficiency testing program. The findings include: 1. A review of the results from the 2017-Event #3 Hematology survey revealed 0% (percent) scores for all analytes due to failure to participate. 2. During an interview on 1/31/2018 at 11:30 AM, the Technical Consultant reviewed and confirmed the above noted findings. .
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 proficiency testing, quality control (QC), calibration verification records, installation and validation records for the Dimension XPAND Plus Chemistry analyzer, and inadequate timely quality assurance reviews, and interviews with the Technical Consultant, the surveyor determined the Technical Consultant failed to adequately fulfill her responsibilities to provide effective technical and scientific oversight of the laboratory. The findings include: 1. Refer to D6036. .
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 proficiency testing, quality control (QC), calibration verification records, installation and validation records for the Dimension XPAND Plus Chemistry analyzer, and inadequate timely quality assurance reviews and interviews with the Technical Consultant, the surveyor determined the Technical Consultant failed 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.) Review proficiency testing records to ensure Hematology analyzer printouts of the results were retained (Refer to D2015.) B.) Review proficiency testing records and procedures to ensure results were entered correctly and before the cut-off date specified by the proficiency testing provider to prevent failing Hematology scores (Refer to D2016 and D2130.) C.) Review installation records for the Siemens Dimension XPAND Plus Chemistry analyzer to ensure data generated during the initial installation procedures verifying the manufacturer's performance specifications was reviewed (as indicated by a signature and date); and ensure the reference ranges were verified for the laboratory's patient population. (Refer to D5421) D.) Review Hematology records and requirements to ensure the Medonic was calibrated every six months as required by the manufacturer. (Refer to D5437.) E.) Review calibration and calibration verification procedures (C/V) to ensure a C/V was performed every six months on all analytes that are calibrated with less than three calibrators (Refer to D5439.) F.) Review daily Chemistry and Hematology quality control (QC) data to ensure at least two levels of QC were within acceptable ranges before patient testing was performed (Refer to D5481 and D6042.) G.) Implementation of effective quality assessment reviews to identify and correct problems identified in the analytical systems. (Refer to D5791.) 2. During the exit summation on 1/31/2018 at 4:50 PM, these concerns were reviewed and discussed with the Technical Consultant and the Testing Personnel. When asked how long she had been the Technical Consultant (TC) for this laboratory, the TC stated she had been coming to the laboratory approximately once a month since September 2016. Thus the above noted findings were confirmed. .
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for

	acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on reviews of the quality control (QC) records for the Siemens Dimension EXPAND Plus Chemistry analyzer and the Medonic Hematology analyzer, and interviews with the Technical Consultant, the surveyor determined the Technical Consultant failed to ensure a quality control protocol was followed by the testing personnel to ensure the accuracy and quality of patient test results in 2016 and 2017. The findings include: 1. Refer to D5481. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor