Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0314910	05/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ronald L Terhune Md Family Practice	740 Bartlett Rd, Memphis, 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
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 review of the Centers for Medicare and Medicaid Services Casper Report 155 (CMS 155) and the laboratory's 2017 and 2018 proficiency testing performance evaluation reports provided to the surveyor by the laboratory's proficiency testing program, the laboratory failed to maintain satisfactory performance for the hemoglobin analyte in 2017 event three and 2018 event one, resulting in the first unsuccessful occurrence. (Refer to D2130).
D2128	HEMATOLOGY CFR(s): 493.851(e)

	(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing performance evaluation reports provided to the surveyor by the laboratory's proficiency testing provider (American Academy of Family Physicians (AAFP)), the laboratory's proficiency testing records, and interview with testing personnel number one, the laboratory failed to obtain appropriate training and employ the technical assistance necessary to correct proficiency testing failures in 2017 and 2018. The findings include: 1. Review of the laboratory's proficiency testing performance evaluation report for 2017 event three revealed unsatisfactory scores for the following analytes as follows: Red blood cell - samples SYX-13 and SYX-14 graded as "Fail" resulting in an overall score of 60%. Hematocrit - sample numbers SYX-13 and SYX-14 graded as "Fail" resulting in an overall score of 60% 2. Review of the laboratory's proficiency testing records revealed no performance evaluation records were available for the 2017 event three, and 2018 event one. 3. Interview with testing personnel number one on May 18, 2018 at 4:00 pm confirmed the laboratory did not have and had not reviewed the performance evaluation reports for 2017 event three, 2018 event one, and failed to perform corrective action for unsatisfactory proficiency testing results for 2017 event three and 2018 event one.
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 review of the Centers for Medicare and Medicaid Services (CMS) Casper Report 155 and review of the laboratory's proficiency testing performance evaluations provided to the surveyor by the laboratory's proficiency testing provider, the laboratory failed to maintain satisfactory performance for the hemoglobin analyte for two consecutive events resulting in the first unsuccessful occurrence. The findings include: 1. Review of the CMS 155 report revealed the following unsatisfactory scores for the hemoglobin analyte: 2017 event 3 = 60%, 2018 event 1 = 60%. 2. Review of the laboratory's proficiency testing 2017 event three performance evaluation summary report revealed sample numbers SYX-13 and SYX-14 were scored as "Fail" resulting in a score of 60% for the hemoglobin analyte. 3. Review of the laboratory's proficiency testing 2018 event one performance evaluation summary report revealed sample numbers SYX-1 and SYX-5 were scored as "Fail" resulting in a score of 60% for the hemoglobin analyte.
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 observation of the laboratory's control vials for the Sysmex XP-300 complete blood count instrument, review of the package insert for the Sysmex Eightcheck-3WP X-tra controls, and interview with testing personnel number one, the laboratory failed to ensure controls were not used past their expiration date in 2018. The findings include: 1. Observation on May 18, 2018 at 9:00 am of the laboratory's control vials in use for the Sysmex XP-300 revealed no dates for when the controls were opened or corrected expiration dates. 2. Review of the package insert for the Sysmex Eightcheck-3WP X-tra controls revealed the following statement related to control stability: "Unused material from open vials should be discarded after 14 days. Do not add residual to a new vial." 3. Interview with testing personnel number one on May 18, 2018 at 9:00 am confirmed the controls were not labeled with open dates or corrected expiration dates and the laboratory failed to ensure controls were not used past their expiration date in 2018.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the Sysmex XP-300 Complete Blood Count (CBC) Quick Guide instructions for use, the laboratory's instrument maintenance records for the Sysmex XP-300 for 2016, 2017 and 2018, and interview with testing personnel number one, the laboratory failed to follow manufacturer's instructions for recording, retaining, and determining acceptability of background counts for the Sysmex XP-300 CBC instrument in 2016, 2017, and 2018. The findings include: 1. Review of the Sysmex XP-300 CBC instrument Quick Guide instructions for use revealed the following statement related to daily operating procedures: "Record the background check on a daily checklist or keep a copy of the printout for documentation. Compare the results to the acceptable background limits." 2. Review of the laboratory's instrument maintenance records for the Sysmex XP-300 for 2016, 2017, and 2018 revealed there was no record of the results of the background count or documentation that the results were acceptable. 3. Interview with testing personnel number one on May 18, 2018 at 10:00 am confirmed that testing personnel number one is responsible for daily operation of the Sysmex XP-300, she did not know what the background was, had never seen the screen that displays the results of the background count, does not record or retain the background count, or check for acceptability. Testing personnel number one confirmed the laboratory failed to follow manufacturer's instructions for recording, retaining, and determining background count acceptability for the Sysmex XP-300 in 2016, 2017, and 2018.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR

	CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: The laboratory director failed to ensure proficiency testing reports are reviewed to evaluate laboratory performance (Refer to D6018); failed to ensure that the quality control program is maintained (Refer to D6020) and failed to ensure the quality assessment program is maintained (Refer to D6021), resulting in immediate jeopardy.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that 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 review of the laboratory's American Academy of Family Physicians (AAFP) proficiency testing documents for 2017 event 3 and 2018 event 1, the Centers for Medicare and Medicaid Services (CMS) Casper report 155, and interview with testing personnel number one, the laboratory director failed to ensure that proficiency testing reports were reviewed to identify problems that require corrective action in 2017 and 2018, resulting in immediate jeopardy. The findings include: 1. Review of the laboratory's AAFP proficiency testing documents for 2017 event 3 and 2018 event 1 revealed that performance evaluation documents were not present for either event. 2. Review of the CMS report 155 revealed the following: 2017 event 3-Overall score of 74% with 60% score for red blood cell count, hematocrit and hemoglobin, 80% score for white blood cell count; 2018 event 1-Overall score of 86% with 80% score for red blood cell count and hematocrit, 60% score for hemoglobin. 3. Interview with testing personnel number one on May 18, 2018 at 11:45 am confirmed that no performance evaluation reports were available for proficiency testing 2017 event 3 and 2018 event 1, the reports had not been reviewed, she did not know how the laboratory receives their reports and the laboratory director failed to ensure the proficiency testing reports were evaluated to identify problems that require corrective action in 2017 and 2018.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the Sysmex XP-300 Complete blood count (CBC) instrument quality control (QC) records beginning October 26, 2016 to current date (May 18, 2018), the Centers for Medicare and Medicaid Services (CMS) form 2567 from the previous survey, and interview with testing personnel number one and the laboratory director, the laboratory director failed to ensure the quality control program was established and maintained in 2016, 2017, and 2018, resulting in immediate jeopardy. The findings include: 1. Review of the laboratory's quality control records for the Sysmex XP-300 CBC instrument revealed the following: Lot #s 62860710, expiration date 01.18.2017 In use dates 10.26.2016 to 01.13.2017 Limit entry for lot # 62860710-correct QC limits for mean corpuscular hemoglogin concentration (MCHC) =30.4 g /dL to 41.4 g/dL, incorrect entered limit = 0.0 g/dL to 0.0 g/dL. No signature indicating 2nd person verification of QC limit entry as specified in plan of correction from survey on 05.25.2016. No signature of lab director indicating review of cumulative quality control data and graphs. Lot #s 70040710, 70040711, 70040712, expiration date 04.12.2017 In use dates 01.13.2017 to 04.05.2017 No signature indicating 2nd person verification of QC limit entry as specified in plan of correction from survey on 05.25.2016. No signature of lab director indicating review of cumulative quality control data and graphs. Lot #s 70880710, 70880711, 70880712, expiration date 07.05.2017 No signature indicating 2nd person verification of QC limit entry as specified in plan of correction from survey on 05.25.2016. Lot #s 71720710, 71720711, 71720712, expiration date 09.27.2017 Lot # 71720710-correct QC limits for hemoglobin = 5.4 g/dL to 6.3 g/dL, incorrect entered limit = 0.0 g/dL to 0.0 g/dL. Lot # 71720712-correct QC limit entry for red blood cell analyte = 5.04 x10^6/uL to 5.58 x 10^6/uL incorrect entered limit = 0.0 x 10^6/uL to 0.0 x 10^6/uL. No signature of 2nd person verification of QC limit entry as specified in plan of correction from survey on 05.25.2016. Lot #s 72560710, 72560711, 71720712, expiration date 12.20.2017, in use date of 10.2.2017 No QC limits entered for lot #72560710, 72560711, or 71720712. No signature of 2nd person to verify QC limit entry as specified in plan of correction from survey on 05.25.2016. No documented review of quality control by laboratory director. Lot #s 73400710, 73400711, 73400712, expiration date 03.14.2018 No QC limits entered for lot # 73400710, 73400711, 73400712. No signature of 2nd person to verifiy QC limit entry as specified in plan of correction from survey on 05.25.2016. No documented review of quality control by laboratory director. Lot #s 80580710, 80580711, 80580712, expiration date 06.06.2018 (current lot) No QC limits entered for lot #80580710, 80580711, 80580712. No signature of 2nd person to verifiy QC limit entry as specified in plan of correction from survey on 05.25.2016. 2. Review of the laboratory's Centers for Medicare and Medicaid Services (CMS) form 2567 (Statement of Deficienies and Plan of Correction) from the prior survey performed on 05.25.2016 and signed by the laboratory director revealed the following statement: "Our quality assurance did not find the clerical error upon entering control values. We will establish a new procedure guideline to ensure value are entered correctly by requiring 2 personnel-one to enter values-initial-and check and one to check against control print out and package insert-initial check. This will be done with each new lot number by the testing personnel and lab director." "Lab director will review monthly with quality assurance review." 3. Review of the document titled "Monthly Quality Assurance Checklist" revealed signatures of testing personnel indicating who performed the monthly quality assessment for the dates of June 2016, July 2016, August 2016, September 2016, October 2016, November 2016, December 2016, January 2017, February 2017, March 2017, April 2017, May 2017, June 2017, July

	2017, August 2017, September 2017, October 2017, November 2017, December 2017, 1/5/18, 2/26/18, 3/30/18,4/11/18, 5/11/18. There were no problems documented on any of the quality assessment documents. Correct quality control limits entry was not included as part of the Monthly Quality Assurance Checklist. The lab director's signature was not on any of the documents reviewed. 4. Interview with testing personnel number one on May 18, 2018 at 3 pm confirmed that QC limit entry was incorrect for multiple lot numbers, QC limit entry was not being verified by 2 people, there have been no QC limits assigned for any lot used since 10.02.2017 and patient testing has been performed with approximately 150 patients tested since 10.02.2017. Testing personnel number one stated the only parameters she knew she was suppose to enter were the lot number and expiration date and she did not know how to enter the quality control acceptable limits for each lot number. 5. Interview with the laboratory director on May 18, 2018 at 4:00 pm confirmed that the laboratory has not been using correct quality control limits for multiple lot numbers in 2016, 2017, and 2018. The laboratory's quality assessment process failed to identify problems with control limit entry. The laboratory director stated he had never heard of two people verifying QC limits as outlined in the previous plan of correction.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy titled "Quality Assurance Plan", the laboratory's quality control records, proficiency testing records, and the laboratory's form documenting quality assessment activities, interview with testing personnel number one and the laboratory director, the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided in 2016, 2017, and 2018, resulting in immediate jeopardy. The findings include: 1. Review of the laboratory's policy titled "Quality Assurance Plan" revealed the following: "2. Identify problems in our laboratory and apply corrective action." "III. Proficiency testing-We will evaluate the results of our proficiency testing with the laboratory director within one week of their return from the PT program. We will carefully evaluate any unacceptable, unsatisfactory, or unsuccessful PT result in an effort to identify the cause of failure. If a cause is found, we will take necessary corrective action and reevaluate the PT results after the next PT challenge. This information will be recorded and kept with our Quality Assurance records." "X. Quality Assurance Records-The record of our quality assurance review are filled with this plan and are available for review by the director, consultant, staff, and laboratory surveyors. All records are dated and initialed by the staff performing the review, and by the laboratory director." 2. Review of quality control records revealed multiple problems with quality control limit entry that were not identified by the laboratory's quality assurance processes for lot numbers 62860710 (in use 10.26.2016 to 01.13.2017), 71720710 and 71720712 (expiration date of 09.27.17), 72560710, 72560711, 72560712 (in use beginning 10.02.2017), 73400710, 73400711, 73400712 (expiration date of 03.14.18), 80580710, 80580711, 80580712 (current lot).

	3. Review of the laboratory's proficiency testing records revealed that failures in proficiency testing were not evaluated to investigate the cause of failures for 2017 event three and 2018 event one. 4. Review of the form used to document quality assessment activities from June 2016 to May 2018 revealed that no errors were detected and the forms were not signed by the laboratory director. 5. Interview with testing personnel number one and the laboratory director on May 18, 2018 confirmed the laboratory director failed to ensure the quality assessment program was maintained in 2016, 2017, and 2018.