Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0685153	01/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ron Fulkerson Md Psc	1300 West Lexington Avenue, Winchester, KY	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing results from the American Proficiency Institute proficiency testing agency and staff interview on 01/07/19, the laboratory failed to ensure Hematology proficiency testing samples were tested by all testing personnel who routinely perform Complete Blood Cell (CBC) patient testing. Findings include: Review of attestation statements, revealed only one (1) of two (2) testing personnel listed on the Centers for Medicare and Medicaid Services (CMS) Form 209 tested proficiency samples for three (3) testing events in 2017 and three (3) testing events in 2018. Testing personnel acknowledged in an interview, on 01/07/19 at 11:42 AM, the laboratory failed to establish a policy to ensure proficiency testing samples were rotated among all testing personnel responsible for CBC testing.
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 staff interview and record review of proficiency testing records from the American Proficiency Institute on 01/07/19, the testing personnel failed to sign

	attestation statements for six (6) of six (6) hematology testing events from January 1, 2017 through December 31, 2018. Findings include: Attestation statements were not signed for six (6) of six (6) events from January 1, 2017 through December 31, 2018. The staff acknowledged in an interview on 01/07/19 at 11:42 AM, they did not have a mechanism to ensure the laboratory testing staff signed and retained all attestation statements.
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 desk review of Hematology proficiency testing results from the American Proficiency Institute on 01/07/19, the laboratory failed to successfully participate in the platelet certified analyte in two (2) of three (3) consecutive testing events. See D2121 and D2130
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on staff interview and record review, on 01/07/19, the laboratory failed to attain an overall satisfactory score of at least eighty (80) percent in two (2) Hematology testing events. Findings include: The facility scored sixty (60) percent in the first testing event of 2018 and scored sixty (60) percent in the third testing event of 2018.
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 desk review of Hematology proficiency test results from the American Proficiency Institute on 01/07/19, the laboratory failed to successfully achieve satisfactory performance for the platelet Cell Count in two (2) of three (3) consecutive testing events. Findings include: The facility scored sixty (60) percent in the first testing event of 2018 and scored sixty (60) percent in the third testing event of 2018 resulting in an unsuccessful performance.
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 staff interview, and review of the Laboratory Procedure Manual on 1/07/19, the laboratory failed to ensure the policies and procedures used in the Laboratory Procedure Manual were signed and dated by the Laboratory Director prior to patient testing. Findings include: Review of the Laboratory Procedure Manual, revealed the Laboratory Director failed to sign four (4) out of four (4) procedures prior to placing the procedures in place. They include: 1. Quality Assurance Program 2. QBC Capillary Blood Tubes 3. QBC Centrifugal Hematology System Calibration Procedure 4. Ames Reagent Strips Interview with staff at on on 1/07/19 at 12:05 PM, revealed the Laboratory Director did not have a system in place to ensure all policies and procedures were signed and dated, prior to patient testing and reporting.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on staff interview and record review, on 01/07/19 at 11:55 AM, the laboratory failed to monitor and document the humidity in the laboratory where the testing was performed. Humidity was not recorded from 12/14/16 through 01/06/19. Findings include: The Manufacturer's Operations Manual for the QBC Autoread analyzer lists an operating range for humidity for the analyzer between ten percent (10%) and ninety-five percent (95%) Review of the Maintenance Log, revealed no documented evidence the humidity had been monitored and recorded from 12/14/16 through 01/06 /19. Testing personnel acknowledged in an interview on 01/07/19 at 11:55 AM, the Laboratory Director failed to have a system in place to ensure the humidity was monitored and documented daily.

D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on staff interview and record review on January 7, 2019, the Technical Consultant failed to perform and document annual competency using the six (6) mandated competency assessment requirements for testing personal. Competency assessment were performed using zero (0) of six (6) methods of assessment for two (2) out of two (2) employees from December 16, 2016 through January 03, 2019. Findings include: Record review on January 7, 2019, revealed there was no documented competency assessments between December 16, 2016 and January 03, 2019, for two (2) employees that included the following: competency assessments failed to include direct observation of routine patient test performance, direct observation of performance of instrument maintenance function checks and calibration, monitoring the recording and reporting of test results, review of worksheets, review of quality control records, review of proficiency test results, review of maintenance records, and assessment of testing external proficiency testing samples and problem solving skills. Interview with the staff on January 7, 2019 at 11: 10 AM, revealed the facility failed to have a system in place between December 16, 2016 and January 03, 2019 to ensure competency was performed using all six (6) mandated competency assessment requirements from December 16, 2016 through January 3, 2019.