Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1013212	08/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Longleaf Wellness, Pllc	1090 East Central Ave, Raeford, NC	

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 testing personnel (TP) records, review of review of 2018 and 2019 American Proficiency Institute (API) hematology proficiency testing (PT) records and interview with testing personnel (TP) 8/28/19, the laboratory failed to ensure all testing personnel who routinely perform patient testing participated in the hematology proficiency testing events. Review of laboratory TP records revealed the laboratory employs 2 TP. TP #1 began employment prior to 2017 and TP #2 began employment in April of 2018. Review of 2018 and 2019 API PT records revealed that TP #2 did not sign attestation statements for any of the API PT testing events. All attestation statements were signed by TP #1. Interview with TP #1 at approximately 12:00 p.m. confirmed TP #2 did not participate in any API PT testing events for 2018 and 2019. She stated she was planning to have her participate in the next upcoming PT event.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory quality control records, review of laboratory calibration

	records and interview with testing personnel (TP) 8/28/19, the laboratory failed to retain manufacturer's quality control and calibration assay sheets for the Medonic M-series hematology analyzer for at least 2 years. Review of laboratory quality control records revealed no quality control assay sheets were retained for the hematology testing performed. Review of laboratory calibration records revealed only the calibration assay sheet from the 8/10/17 initial set-up of the hematology analyzer was retained. Interview with TP#1 at approximately 11:00 a.m. confirmed the laboratory had not retained the manufacturer's quality control assay sheets and had only retained the manufacturer's calibration assay sheet from the initial calibration of the hematology analyzer.
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 laboratory procedure manual and interview with laboratory director (LD) 8/28/19, the laboratory procedure manual failed to include the laboratory's system for entering results in the patient record and failed to include the course of action to take if the Medonic M-Series hematology analyzer becomes inoperable. Findings: Review of laboratory procedure manual revealed no procedure for entering results in the patient record. Review of laboratory procedure manual revealed no procedure for the course of action to take if the hematology analyzer becomes inoperable. Interview with LD at approximately 1:00 p.m. confirmed the laboratory procedure manual did not include a procedure for entering results in the patient record or for the course of action to take if the hematology analyzer becomes inoperable.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper

	use. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, surveyor observation, and testing personal (TP) interview 8/28/19, the laboratory failed to label quality control (QC) reagents with an expiration date after they were put in use. Review of laboratory procedure for the Medonic M-Series hematology analyzer revealed "QC material must not be tested beyond the expiration date on the package. Opened vials must not be tested beyond the opened expiration date of 14 days. During tour of laboratory, the surveyor observed three vials of Boule Con-Diff QC reagents, which were in use and not labeled with expiration dates. Interview with TP#1 at approximately 12:00 p.m. confirmed the three vials of Boule Con-Diff QC reagents were not labeled with expiration dates after they were put in use. She stated she takes turns each week with TP#2 running the QC and knows when it is her week to open new vials of QC.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, review of manufacturer's instructions, review of Medonic M-Series hematology analyzer maintenance records and interview with testing personnel (TP) 8/28/19, the laboratory failed to perform and /or document required maintenance for the Medonic M-series hematology analyzer. Findings: Review of laboratory procedure manual for the hematology analyzer revealed "MAINTENANCE: Daily cleaning should be performed according to the Medonic M-Series User's Manual. Instrument maintenance is performed monthly and semi-annually according to the manufacturer's instructions, utilizing the Boule Cleaning Kit...All maintenance should be documented (a maintenance log is recommended), and the documentation saved for a minimum of 2 years." Review of manufacturer's instructions for the hematology analyzer revealed the following maintenance should be performed and documented: Daily cleaning, monthly cleaning and a six-month cleaning. Review of maintenance records for the hematology analyzer revealed one monthly maintenance log dated August 2018. Maintenance was documented on August 24, 2018 for the daily, monthly and six-month cleaning. There was no additional documentation that maintenance had been performed from time of last survey 8/31/17 until time of current survey 8/28/19. A period of approximately 24 months in which only one day of maintenance was documented and/or performed. Interview with TP #1 at approximately 11:00 a.m. confirmed the laboratory did not document the required maintenance for the Medonic M-series analyzer as required. She stated they do print out a daily background check and she was pretty sure the required maintenance had been performed.
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 review of laboratory procedures, review of calibration records and testing personnel (TP) interview 8/28/19, the laboratory failed to perform calibration every 6 months as required for the Medonic M-Series hematology analyzer. Findings: Review of laboratory procedure for the hematology analyzer revealed "CALIBRATION: Calibration must be performed upon setup of the instrument and then at a minimum of every 6 months." Review of calibration records for the hematology analyzer revealed calibration was completed on 8/10/17 and 10/5/18, a period of approximately 14 months between calibrations. At time of survey, 8/28/19, calibration had not been completed since 10/5/18, a period of approximately 10 months in which calibration was not completed. Interview with TP #1 at approximately 11:00 a.m. confirmed the laboratory did not perform calibrations every 6 months as required. She stated the service representative for the Medonic M-Series hematology analyzer told them the analyzer required calibration once a year. This deficiency was previously cited 8/10 /11 and 4/24/13.
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: Based on review of laboratory records 8/28/19 the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure all testing personnel whom routinely perform patient testing participated in the hematology proficiency testing events. See D6016. 2. The laboratory director failed to ensure manufacturer's calibration and quality control assay sheets were retained. See D6020. 3. The laboratory director failed to ensure reagents were properly labeled. See D6020. 4. The laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided. See D6021. 5. The laboratory director failed to ensure

	maintenance for the Medonic M-Series hematology analyzer was performed and documented. See D6023. 6. The laboratory director failed to ensure calibrations for the Medonic M-Series hematology analyzer were performed every 6 months. See D6023. 7. The laboratory director failed to ensure ensure that policies and procedures were established for evaluating the competency of testing personnel for all phases of the testing and reporting process. See D6030. 8. The laboratory director (technical consultant) failed to ensure testing personnel maintained competency in the performance of instrument maintenance for the Medonic M-Series hematology analyzer. See D6050. 9. The laboratory director (technical consultant) failed to assure testing personnel maintained competency in the testing of external proficiency testing samples. See D6051.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) records, review of review of 2018 and 2019 American Proficiency Institute (API) hematology proficiency testing (PT) records and interview with testing personnel (TP) 8/28/19, the laboratory director failed to ensure all proficiency testing samples are tested as required. Findings: Review of TP records and review of 2018 and 2019 API hematology PT records revealed 1 of 2 TP participated in PT testing. See D2007.
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 laboratory procedures, review of laboratory quality control and calibration records, surveyor observation and interview with testing personnel (TP) 8 /28/19, the laboratory director failed to ensure the quality control program was maintained to assure the quality of laboratory services provided. Findings: 1. The laboratory director failed to ensure quality control and calibration assay sheets were retained for at least two years. See D3031. 2. The laboratory director failed to ensure in use quality control reagents were labeled with expiration dates. See D5415.
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 laboratory procedure manual, review of laboratory records and interview with laboratory director (LD) and testing personnel (TP) 8/28/19, the laboratory director failed to ensure quality assessment programs were maintained to assure the quality of laboratory services offered. Findings: Review of laboratory procedure manual revealed no policies or procedures for the quality assessment of the laboratory. Review of laboratory records; calibration, quality control, and maintenance records for Medonic M-Series analyzer revealed no documentation of the laboratory director's periodic review for quality assessments. Interview with LD and TP #1 at approximately 1:00 p.m. confirmed the laboratory was not performing quality assessments. TP #1 stated that quality control was reviewed daily, but no monthly or quarterly assessments were done. The LD stated they had done quality assessments in the past, but she did not know what happened to the procedure or the quality assessment checklists used previously. The LD confirmed that no quality assessments were completed from time of last survey 8/31/17 through time of current survey, a period of approximately 24 months.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of manufacturer's instructions, review of Medonic M-Series hematology analyzer maintenance records and calibration records and interview with testing personnel (TP) 8/28/19, the laboratory director failed to ensure the calibration and maintenance of the Medonic M-Series hematology analyzer to assure acceptable levels of analytical performance. Findings: 1. The laboratory director failed to ensure maintenance was performed and documented as required on the Medonic M-Series hematology analyzer. See D5429. 2. The laboratory director failed to ensure calibration was performed as required on the Medonic M-Series hematology analyzer. See D5439.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency records, review of laboratory procedure manual, and interview with laboratory director (LD) 8/28/19, the laboratory director failed to ensure that policies and procedures were established for evaluating the competency of testing personnel for all phases of the testing and reporting process. Findings: Review of laboratory procedure manual and review of TP competency records revealed a "Lab Personnel Evaluation Checklist", used to document TP competency assessments. The checklist is a list of evaluations that are answered yes, no or not applicable. The checklist fails to indicate it is a competency assessment. The checklist fails to indicate how the evaluations are conducted and documented. And the checklist fails to indicate the criteria used to determine if TP would require remedial training to improve skills. For example: The checklist states "Observation of all phases of testing show that all written steps of the procedure are followed without deviation." There is no documentation to support what was observed and no indication of what the phases of testing consist of. The checklist states "When problems arise, the testing analyst knows how to assess the situation and does what is required to resolve the problem." There was no indication of what problems were assessed. There is no documentation to support what problems were assessed or how it was determined that the TP was able to correctly resolve the problem. Interview with LD at approximately 1:00 p.m. confirmed the laboratory did not have a current procedure for competency assessment, she stated she was not sure what became of it. She also stated she was unaware that they needed documentation of what was assessed for competency and the checklist is what they have always used.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency records and review of maintenance records for the Medonic M-series hematology analyzer 8/28/19, the technical consultant (laboratory director) failed to assure TP maintained competency in the performance of instrument maintenance for the Medonic M-Series hematology analyzer. Findings: Review of TP competency records revealed the "Lab Personnel Evaluation Checklist", used to document annual TP competency, states "Instrument maintenance and function checks are performed and documented according to written procedures." TP #1 checklist dated 4/18/19 and TP #2 checklist dated 8/19/19 are marked "Yes" and signed by the technical consultant (laboratory director). Review of maintenance records for the Medonic M-series hematology analyzer revealed

	maintenance was not performed and/or documented according to laboratory procedures. See D5429.
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 review of testing personnel (TP) competency records and review of 2018 and 2019 American Proficiency Institute (API) hematology proficiency testing (PT) records 8/28/19, the technical consultant (laboratory director) failed to assure TP #2 maintained competency in the testing of external proficiency testing samples. Findings: Review of TP competency records revealed the "Lab Personnel Evaluation Checklist", used to document annual TP competency, states "Accurate test performance has been proven by successful proficiency testing." The checklist for TP #2, dated 8/19/19 is marked "Yes", and signed by the technical consultant (laboratory director). Review of 2018 and 2019 API hematology PT records revealed TP #2 did not participate in the testing of PT samples. See D2007.