Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0307305	12/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Willard M West Md	1425 W Baddour Pkwy, Lebanon, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance (QA) procedure and interview with the lead testing person, the laboratory failed to perform monthly QA monitors as indicated in the QA procedure for 2018 and 2019. The findings include: 1. Lack of monthly QA documents available for review for 2018 and 2019. 2. Interview with the lead testing person at 1:45 p.m. on December 16, 2019 confirmed the laboratory did not assess monthly QA as indicated in the QA procedure for 2018 and 2019.
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 patient chart audit review and interview with the lead testing person the laboratory failed to perform calibration every 6 months per manufacturers instructions for the Beckman Coulter ACT-5 Complete Blood Count (CBC) analyzer in 2018. The findings include: 1. Review of patient chart audit to include calibration review determined there was only one calibration performed for the Beckman Coulter ACT-5 Complete Blood Count (CBC) analyzer in 2018. 2. Interview with the lead testing person at 1:45 p.m. on December 16, 2019 confirmed there was only one calibration performed for the Beckman Coulter ACT-5 Complete Blood Count (CBC) analyzer in 2018.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient Complete Blood Count (CBC) results, laboratory's CBC quality control (QC) procedure and interview with the lead testing person determined the laboratory failed to ensure CBC QC was performed prior to testing patient in 2018 and 2019. The findings include: 1. Review of 24 patients CBC results revealed QC was not performed on 5 out of 24 patients prior to resulting the CBC result on the following days 06/08/18, 05/07/19, 05/24/19, 06/26/19, 07/23/19. 2. Review of the laboratory's CBC QC procedure revealed 3 levels of QC must be run prior to patient testing. 3. Interview with the lead testing person on December 16, 2019 at 1:30 p.m. confirmed the laboratory failed to ensure CBC QC was performed prior to testing patient in 2018 and 2019
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 review of the laboratory's Quality Control (QC) procedure, Quality Assessment (QA) procedure and interview with the lead testing person the Technical Consultant failed to ensure quality control are maintained throughout the entire testing process (D6042), evaluate competency of all testing personnel (D6046) and evaluate performance of testing persons semiannually for the Complete Blood Count (CBC) test (D6053) in 2018 and 2019.
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 review of patient Complete Blood Count (CBC) results, laboratory's CBC quality control (QC) procedure and interview with the lead testing person determined the Technical Consultant failed to ensure CBC QC was performed prior to testing patient in 2018 and 2019. The findings include: 1. Review of patient CBC results found 5 of 24 did not have QC performed prior to reporting the CBC results on 06/08 /18, 05/07/19, 05/24/19, 06/26/19, 07/23/19. 2. Review of the laboratory's CBC QC procedure revealed 3 levels of QC must be run prior to patient testing. 3. Interview with the lead testing person on December 16, 2019 at 1:30 p.m. confirmed the Technical Consultant failed to ensure CBC QC were performed prior to testing patient on 06/08/18, 05/07/19, 05/24/19, 06/26/19, 07/23/19.
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 testing personnel record review and interview with the lead testing person the Technical Consultant (TC) failed to evaluate competency assessment for the Complete Blood Count (CBC) for 2 of 2 testing persons in 2018 and 2019. The findings include: 1. Review of the testing personnel competency assessment record revealed 2 of 2 testing persons did not have documentation of the six required criteria of competency that include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills in 2018 and 2019. 2. Interview with the lead testing person at 1:30 p.m. on December 16, 2019 confirmed the TC did

	not evaluate competency assessment for the CBC test for 2 of 2 testing persons in 2018 and 2019.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the testing personnel records and interview with the lead testing person the Technical Consultant (TC) failed to evaluate 2 of 2 testing persons semiannually for the new Beckman Coulter ACT- 5 Complete Blood Count (CBC) analyzer in 2019. The findings include: 1. Testing person 1 and 2 did not have semiannual competency assessment by the TC for the new Beckman Coulter ACT- 5 CBC analyzer in 2019. 2. Interview with the lead testing person at 1:35 p.m. on December 16, 2019 confirmed the TC failed to asses testing persons 1 and 2 semiannual competency assessment for the new Beckman Coulter ACT- 5 CBC analyzer in 2019.