Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2273154	07/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Williamson Memorial, Inc	859 Alderson St, Williamson, WV	

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
D0000	An initial certification survey was conducted at Williamson Memorial, Inc., on July 17, 2024, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on chemistry analyzer record review and interview the laboratory failed to ensure systems were in place to identify and take corrective action on patient results from the Carolina Liquid Chemistries CLC 800 analyzer falling outside the verified reportable ranges for 30 of 30 chemistry analytes. Findings: 1. Review of the CLC 800 chemistry analyzer validation records (put into use February 2024) revealed established reportable ranges with upper and lower limits verified for 30 of 30 analytes tested. 2. During an interview with the technical supervisor (TS), 7/17/24 at 1:00 PM, the state surveyor asked what system was in place to prevent the release of patient results outside the established reportable ranges. TS stated that no upper and lower limits for the reportable ranges of the 30 analytes had been programmed onto

	the CLC 800 chemistry analyzer or in the Skylab LIS to identify or prevent the release of patient results. 3. During an exit interview with the TS and administration, 7/17/24 at 5:00 PM, the TS confirmed the findings, stating the instrument installer/service representative did not program limits for the reportable ranges into the CLC 800 chemistry analyzer and the facility information technology (IT) staff did not program limits for the reportable ranges into the LIS before the chemistry analyzer was put into use.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of test reports, DxH 900 analyzer printouts, and interview the laboratory failed to ensure that all 21 parameters analyzed in a complete blood cell count (CBC) were (c)(4) identified and (c)(6) resulted on a patient test report. Findings: 1. Review of CBC test reports from the DxH 900 analyzer and Skylab LIS identified 21 parameters listed on the analyzer test report. The Skylab LIS test reports listed 20 parameters. Examination determined that the absolute basophil (basophil #) parameter was not included on the final patient report from the Skylab LIS. 2. An interview with the technical supervisor (TS), 7/17/24 at 2:30 PM, confirmed the final CBC patient test report did not include a result for the absolute basophils (basophil #) parameter analyzed in the DxH 900 CBC testing. 3. An exit interview with the TS, 7 /17/24 at 5:00 PM, confirmed the findings.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of analyzer verification records, policies and procedures (P&P), patient test reports, lack of documentation, and interview the laboratory failed to provide the reference intervals for 6 of 20 complete blood cell count (CBC) parameters and for 8 of 30 chemistry analytes on the patient test reports from the laboratory. Findings: 1. Review of verification records for the DxH 900 Hematology analyzer (put into use April 2024) identified reference intervals for 20 CBC parameters established during the verification of performance specifications. Hematology P&P stated reference intervals for 20 of 20 parameters. 2. Review of a CBC patient test report identified no stated reference intervals for 6 of the 20 parameters (lymphocyte %, monocyte %, eosinophil %, basophil %, neutrophil %,

	corrected WBC) listed on the final report. One parameter (basophil #) analyzed on the DxH 900 was not reported on the CBC patient test report (refer to D5805). 3. An interview with the technical supervisor (TS), 7/17/24 at 2:30 PM, confirmed the lack of reference intervals for the 6 parameters and the lack of absolute basophil (basophil #) on the patient test reports. 4. Review of verification records for CLC 800 Chemistry analyzer (put into use February 2024) identified reference intervals for 30 chemistry analytes established during the verification of performance specifications. Chemistry P&P stated reference intervals for the 30 analytes tested on the CLC 800. 5. Review of a patient test report from the CLC 800 chemistry analyzer identified 8 analytes (ALT, CK, CREAT, CRP, GLU, HA1C, LDH, PHOS) with listed reference intervals that differ from the stated reference intervals in the P&P. No documentation for the discrepancy in patient test report reference intervals and P&P stated reference intervals could be located. 6. An interview with the technical supervisor (TS), 7/17/24 at 2:30 PM, confirmed the 8 analytes (ALT, CK, CREAT, CRP, GLU, HA1C, LDH, PHOS) had a reference interval that were different from the stated reference interval in the P&P. 7. An exit interview with the TS and administration staff, 7/17/2024 at 5: 00 PM, confirmed the lack of reference intervals on the final test report for the 6 CBC parameters and the discrepancy between reference intervals for the 8 chemistry analytes.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of verification records, policies and procedures (P&P), patient test reports, Skylab LIS reports, lack of documentation, and interview the laboratory failed to establish a quality assurance (QA) process or system to ensure accurate reference intervals and patient results on the final test reports in chemistry and hematology testing. Findings: 1. Review of CLC 800 validation records and interviews revealed no limits programmed for 30 of 30 chemistry analytes to identify and prevent test results released outside the verified reportable ranges for the analytes. Refer to D5781. 2. Review of patient test reports and DxH hematology analyzer reports revealed 20 of 21 CBC parameters tested were reported on a final patient test report. Refer to D5805. 3. Comparison of verification records, P&P, and Skylab LIS reports for the CLC 800 chemistry analyzer and the DxH 900 hematology analyzer identified missing and inaccurate reference intervals for 8 of 30 chemistry analytes and 6 of 20 CBC parameters. Refer to D5807. 4. Review of general laboratory, hematology, and chemistry P&P revealed no documented processes or systems to ensure results were not released when outside the reportable range and that accurate reference intervals and complete patient results were included on the final test reports. 5. An exit interview with the technical supervisor (TS), 7/17/24 at 5:00 PM, confirmed the findings.