Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 25D2162868	**(X3) Date Survey Completed** 06/11/2021
Name of Provider or Supplier Hattiesburg West Tc Llc	**Street Address, City, State** 6176 Us Hwy 98, Hattiesburg, MS	
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**
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory's Quality Systems Manual, and personnel records since the last survey on 9/4/19, the laboratory failed to establish and follow written policies and procedures to assess consultant competency. Findings include: Review of the laboratory's Quality Systems Manual revealed no written policies and procedures to assess consultant competency. Review of the personnel records since the last survey on 9/4/19 revealed no documentation of assessment of technical consultant competency since the last survey on 9/4/19. Refer to D6053 (Technical consultant failure to perform semiannual evaluations of testing personnel). Refer to D6054 (Technical consultant failure to perform annual evaluations of testing personnel).
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 the laboratory's Hematology Procedure Manual, Quality Systems Manual, and the Coulter AcT diff Analyzer Operator's Guide, the laboratory failed to establish written procedures for the verification of complete blood count (CBC) results when patient results are flagged by the AcT diff hematology analyzer for white blood cell (WBC) differential abnormalities. Findings include: The Coulter AcT diff Analyzer Operator's Guide states for WBC differential flags - 1, 2, 3, 4, M - to verify results according to your laboratory's protocol. Review of the laboratory's Hematology Procedure Manual and Quality Systems Manual revealed no written procedure for verifying patient WBC differential results flagged by 1, 2, 3, 4, M.
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 CMS 209 personnel form and personnel records since the last survey on 9/4/19, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year these individuals tested patient specimens. Findings include: Review of the CMS 209 personnel form and personnel records since the last survey on 9/4/19 revealed the technical consultant failed to evaluate and document the performance of the following testing personnel, listed on the CMS 209 personnel form, at least semiannually during the first year these individuals tested patient specimens: Testing Personnel #1, date of hire 6/10/19. Testing Personnel #2, date of hire 7/6/20. Testing Personnel #3, date of hire 9/9/20. Testing Personnel #8, date of hire 6/6/19.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form and personnel records since the last

	survey on 9/4/19, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually, after the first year. Findings include: Review of the CMS 209 personnel form and personnel records since the last survey on 9/4/19 revealed the technical consultant failed to evaluate and document the performance of the following testing personnel, listed on the CMS 209 personnel form, at least annually after the first year these individuals began testing patient specimens: Testing Personnel #1, date of hire 6 /10/19. Testing Personnel #8, date of hire 6/6/19.