Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0683989	09/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hollandale Family Care Pc	1257b Hwy 61 South, Hollandale, 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 a review of documented annual evaluations/competencies for laboratory personnel and interview with the Technical Consultant (TC) at 4:30 pm on 9/4/19, the laboratory failed to follow written policies to assess competency of the TC at least annually since employment began in December 2017. On the day of survey there was no annual competency available for review for the TC for 2018 performed by the laboratory director. Findings include: 1. Based on review of the personnel records on 9 /4/19, there was no annual competency of the TC for the year 2018 performed by the laboratory director. 2. Interview with the TC listed on the Centers for Medical & Medicaid Services (CMS) 209 form indicated that no evaluation/competency had been performed by the laboratory director on the TC since initial employment in December 2017.
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 procedure manual and confirmation with the technical consultant (TC) at 2:00 pm on 9/4/19 (day of survey), the laboratory did not have available written approved procedures that included protocols on how to report panic values or steps to take when the Hematology analyzer becomes inoperable. Findings include: 1. The laboratory procedure manual was reviewed on 9/4/19 (day of survey). 2. The approved procedures did not include the following: a. The laboratory's system for reporting imminently life threatening results, or panic, or alert values. b. Written procedures to follow when the Boule Medonic M series hematology analyzer becomes inoperable. 3. Interview with the TC on the day of survey at 2:00 pm confirmed that the written approved procedure did not include a protocol to report panic or alert values or steps to take when the Hematology analyzer becomes inoperable.