Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D1096988	02/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Newsouth Neurospine Llc	2470 Flowood Dr Ste 2300, Flowood, 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
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 the Boule Medonic M-Series hematology maintenance from the day of the last survey, 3/16/16 to 2/1/18, the laboratory failed to document as performed the monthly and quarterly maintenance on the Medonic M-Series hematology analyzer as required by the manufacturer. Findings include: Maintenance not documented as performed: Monthly Maintenance: Bleach cleaning - April 2016 through January 2018 Quarterly Maintenance: Enzymatic probe cleaning of both reagent probes - April 2016 through January 2018
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on the Boule Medonic M-Series calibration documentation and interview with staff at 10:30 am on the day of survey, 2/27/18, the laboratory failed to perform the required calibration on the Medonic M-Series hematology analyzer at least once every 6 months according to the frequency required by the manufacturer. Findings include: On the day of the last survey (3/16/16), calibration of the Boule Medonic M-series was due on 3/28/16. Calibration was documented as performed on 10/3/16. No other calibrations were documented from 10/3/16 through 2/27/18. This time frame exceeds the 6 month manufacturer's calibration requirement.