Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0915829	11/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Medhelp 280	4600 Highway 280 E, Birmingham, AL	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of Policies and Procedures and an interview with Testing Personnel #1, the Laboratory Director failed to approve the procedure for Emerald Cell Dyn Hematology analyzer prior to patient testing. This was noted from the time patient testing began in March 2023 to the date of the current survey, November 15, 2023. The findings include: 1. A review of the Policies and Procedures revealed no evidence of a written procedure for the newly implemented Emerald Cell Dyn Hematology analyzer. 2. During an interview on 11/14/2023 at 1:00 PM, Testing Personnel #1 confirmed the procedure was available online, however, it was not reviewed or approved by the Laboratory Director before patient testing began.
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 a review of Policies and Procedures, the calibration verification records for the Vitros 5600, and an interview with Testing Personnel #1, the laboratory failed to perform calibration verifications at least every six months for the Chemistry analytes with less than three routine calibrators. This was noted for one out of three calibration verifications performed from April 2022 to July 2023. The findings include: 1. A review of Policies and Procedure revealed the following text listed under "Calibration Verification, Linearity, and Instrument Validations": "...Calibration Verification is to be made every 6 months on all instruments of Moderate to High Complexity..." 2. A review of the calibration verification records for Vitros 5600 revealed the following: a) Total Iron Binding Capacity (TIBC), Total Cholesterol, and Low-density Lipoprotein (LDL) had a calibration verification performed on 4/14/2022. The next calibration verification was not recorded until 1/23/2023. b) Vitamin D had a calibration verification performed on 4/15/2022. The next calibration verification was not recorded until 1/30/2023. 3. During an interview on 11/15/2023 at 12:15 PM, Testing Personnel #1 confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Emerald Cell Dyn Hematology Quality Control (QC) records and an interview with Testing Personnel #1, the laboratory failed to have a procedure in place that monitors the accuracy and precision of test performance over time. The findings include: 1. A review of Emerald Cell Dyn QC records revealed only raw data from the instrument. No evidence of Levy Jennings charts or peer group data was available for review at the time of survey. 2. During an interview on 11/14/2023 at 2: 00 PM, the Surveyor inquired about the review of Levy Jennings charts for the Hematology analyzer. Testing Personnel #1 confirmed that the laboratory was not monitoring Levy Jennings charts for shifts or trends for that testing system.

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 a review of Personnel records and an interview with Testing Personnel #1, the Technical Consultant failed to assess competency for the Emerald Cell Dyn Hematology analyzer at least semi annually during the first year of patient testing. This was noted for two out of eleven Testing Personnel documented on the Laboratory Personnel Report (CMS-116). The findings include: 1. A review of Personal records revealed the following: a) Testing Personnel #5 had an initial training for the Cell Dyn Hematology analyzer documented on 3/2/2023. No evidence of a six month competency assessment was available for review. b) Testing Personnel #6 had an initial training for the Cell Dyn Hematology analyzer documented on 3/1 /2023. No evidence of a six month competency assessment was available for review. 2. During an interview on 11/15/2023 at 12:00 PM, Testing Personnel #1 confirmed the above findings.