Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2331331	06/30/2026
Name of Provider or Supplier	**Street Address, City, State**	
Medhelp Clinic For Chronic Illness	790 Montclair Rd Ste 150, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Quidel Triage install validation process for the Cardiac and D-Dimer testing and an interview with the Technical Consultant (TC), the laboratory failed to provide documentation of the validation/verification studies. Surveyor noted there was no evidence of validation study documentation from the effective testing date of October 13, 2025, through the date of the current survey, June 30, 2026. Findings included: 1. A review of the Quidel Triage analyzer install validation process revealed no documentation of the following required verification studies for the past six and a half months. A) Accuracy B) Precision C) Reportable Range 2. TC confirmed the above findings during the exit conference on 06-30-2026 at 1:45 PM.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 reviews of the Quidel Triage analyzer calibration records, the Quidel Triage Quality Assurance Plan (QAP) procedure and an interview with the Technical Consultant (TC), the laboratory failed to document the Calibration-Verification (C-V) at least every six months. The surveyor noted a lack of C-V documentation for the first six months in 2026. The findings include: 1. A review of the calibration records for the Quidel Triage calibration records revealed the C-V for the Cardiac and D-Dimer testing was performed when the analyzer was installed on October 13, 2025. 2. A review of the Quidel Triage QAP procedure revealed instructions to perform C-V at least every six months. However, the next C-V due around March 2026 did not have any documentation of performance. 3. TC confirmed the above findings during the exit conference on 06-30-2026 at 1:45 PM.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on reviews of the validation records for the Quidel Triage analyzer and an interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure the Cardiac and D-Dimer testing on the Quidel Triage analyzer was verified for pertinent performance characteristics of this method. The surveyor noted a lack of validation studies when testing went live, 10-13-2025, through the date of the current survey, 06-30-2026. The findings include: 1. A lack of validation records for the Quidel Triage analyzer revealed the LD failed to ensure the following validation studies were performed and approved prior to patient testing on 10-13-2025. A) Precision B) Accuracy C) Linearity or Reportable Range 2. TC confirmed the above findings during exit conference on 06-30-2026 at 1:45 PM.