Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0707377	03/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Medhelp Lakeshore Pc	1 W Lakeshore Drive Suite 100, 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
D0000	The following deficiencies are a result of proficiency testing scores obtained from the national database and verified with the testing personnel on-site. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of proficiency testing records obtained from the Certification and

	Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and verified with the testing personnel on-site, the laboratory failed to successfully participate in a Proficiency Testing program for the Hematology analyte Platelet (PLT). This was noted for two out of three events reviewed in 2023. The fingings include: 1. Refer to D2130
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing (PT) records on 3/12/2024, the laboratory failed to achieve satisfactory performance for Platelet in two of three 2023 testing events. The findings include: 1. A review of the API PT results revealed unsuccessful performance for Platelet for two out of three consecutive PT events, as follows: A) Year 2023 - 1st Event: 0% B) Year 2023 - 3rd Event: 60% 2. During an interview on 3/12/24 at 10:15 AM, Testing Personnel #1 confirmed the above findings.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, a review of corrective action documents, and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure PT results were submitted before the postmark due date. This was noted for one of six Hematology events reviewed in 2023. The findings include: 1. A review of the API PT records revealed a score of 0% and "Failure to participate" on 2023 Complete Blood Count Hematology Event 1 with a deadline date of 3/29/2023. 2. A further review of the corrective action document revealed TP #1 submitted PT results on 4/5/2023. 3. At 10:15 AM on 3/12/2024, TP #1 confirmed the PT results were submitted after the deadline due to Testing Personnel being on medical leave.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by:

	Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute evaluation reports, the Laboratory Director failed to ensure successful participation for the analyte Platelet (PLT) for two of three Hematology testing events in 2023. The findings include: 1. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute evaluation reports, the laboratory director failed to ensure successful performance for the analyte Platelet for two of three Hematology testing events in 2023. The findings include: 1. Refer to D2130