Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0707377	04/27/2022
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all testing personnel who performed patient testing during 2020. This was noted for three out of three Chemistry and Hematology PT events. During 2020, nine out of fifteen Testing Personnel listed on the CMS - 209 Laboratory Personnel Report were performing patient testing in the laboratory. The findings include: 1. A review of the API PT records determined Testing Personnel #3 performed 2020 Chemistry and Hematology 1st, 2nd, and 3rd Events. 2. During an interview on April 27, 2022 at 1: 30 PM, Testing Personnel #1 confirmed the above findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a lack of documentation for Quality Assessment, a review of the Laboratory

	Quality Control and Quality Assurance Guidelines for Quality Assurance procedure, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to implement and follow the written policy and procedure for quality assessment activities. This was noted from previous survey (08/29/2019) to current survey (04/27/2022). The findings include. 1. The laboratory lacked documentation for Quality Assessment monitors. 2. A review of Laboratory Quality Control and Quality Assurance Guidelines for Quality Assurance procedure revealed under Quality Assessment Process "...B. Frequency of review: 1. Establish a schedule or plan of monitoring...C. Corrective action process: 1. Identification of the problem...7. Document! Document! Document!" 3. During an interview on April 27, 2022, at 2:00 PM, Testing Personnel #1 confirmed quality assessment monitors were not being documented.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control records for Hematology and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure at least two levels of quality control were acceptable on June 19, 2020, prior to testing patient specimens and reporting the results. The laboratory tested five patient CBC (Complete Blood Count) specimens on this day when all three levels of quality control were found unacceptable. This affected one day out of ten months of quality control and patient testing reviewed by the surveyor. This is a repeat deficiency. The findings include. 1. A review of the Hematology control for June 19, 2020 revealed the low, normal, and high level quality controls were outside of the acceptable ranges. 2. During an interview on April 27, 2022, at 2:30 PM, Testing Personnel #1 confirmed all three levels of QC were unacceptable on June 19, 2020, and five patient CBCs were performed that day.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the temperature records, the Quidel Triage Total 5 Control Product Insert, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to document corrective actions when the freezer temperatures

	were outside of acceptable limits (colder than -20 degrees Celsius) . This was noted for 26 out of 26 months reviewed by the surveyor for 2020 - 2022. The findings include. 1. A review of the temperature records revealed freezer temperatures were warmer than -20 degrees Celsius and no corrective action documented as follows: a) January through December 2020 - 224 days b) January through December 2021 - 162 days c) January and February 2022 - 31 days. 2. A review of Quidel Triage Total 5 Control Product Insert stated "Store frozen at -20 degree C or colder in a non-defrosting freezer." 3. During an interview on April 27, 2022 at 1:40 PM, Testing Personnel #1 confirmed the above findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of personnel records, Laboratory Quality Control and Quality Assurance Guidelines procedure, and an interview with Testing Personnel #1, the laboratory director failed to assign (in writing) the duties/responsibilities for each position (Laboratory Director, Clinical Consultant, Technical Consultant, and Testing Personnel). This was noted from the previous survey (08/29/2019) to the current survey (04/27/2022). The findings include: 1. A review of personnel records revealed the lack of documentation for duties/responsibilities (Job Descriptions) for the following positions: a) Laboratory Director b) Clinical Consultant c) Technical Consultant d) Testing Personnel 2. A review of the Laboratory Quality Control and Quality Assurance Guidelines procedure revealed under E. Personnel Competency "1. Create and maintain written job responsibilities/ job description...". 3. During an interview on April 27, 2022 at 2:15 PM, Testing Personnel #1 confirmed the duties /responsibilities (Job Description) had not been created in writing for all positions.