Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0707377	08/29/2019
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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing records and an interview with the General Laboratory Manager (GLM), the surveyor determined the laboratory failed to implement and document corrective actions for proficiency testing scores less than one hundred percent (%). This affected Hematology Event #2, 2017 and Event #2, 2019, two of seven testing events reviewed by the surveyor. The findings include: 1. A review of the API proficiency testing records revealed the laboratory scored 80 % for Hematocrit (HCT), Hemoglobin (HgB) and Red Blood Cell Count (RBC) for Event #2 of 2017; and 80 % for HCT, HgB and RBC for Event #2, 2019. The laboratory did not implement and document corrective actions for these scores of less than one hundred percent. 2. During an interview at 1:00 PM on August 29, 2019, the GLM confirmed the laboratory did not document corrective actions, because the scores were eighty percent and considered passing scores. 3. The surveyor's review of other eighty percent scores (i.e. Event #1, 2018) revealed the laboratory documented the likely cause of the errors.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (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, a review of patient test records by the General Laboratory Manager (GLM), and an interview with the GLM, the surveyor determined the laboratory failed to analyze quality control for CBC (Complete Blood Count) testing on August 3, 2019. The laboratory tested two patient CBC specimens on this day when no quality control material was run and documented. This affected one day of thirteen months of quality control and patient testing reviewed by the surveyor. The findings include. 1. A review of the Hematology control for 2019 (January - July) revealed no quality control for CBC testing was documented. 2. During an interview on August 29, 2019 at 1:00 PM, the surveyor inquired if the laboratory performed any testing on this day, as there was no quality control documented. The GLM reviewed the electronic system, and stated the laboratory was open, ran two patient CBCs, and confirmed no quality control was tested.
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, a review of patient test records by the General Laboratory Manager (GLM), and an interview with the GLM, the surveyor determined the laboratory failed to ensure at least two levels of quality control were acceptable on April 24, 2019, prior to testing patient specimens and reporting the results. The laboratory tested five patient CBC (Complete Blood Count) specimens on this day when only one of three levels of quality control was found acceptable. This affected one day of thirteen months of quality control and patient testing reviewed by the surveyor. The findings include. 1. A review of the Hematology control for 2019 (January - July) revealed the high level of quality control (QC) for CBC testing was the only acceptable level. The low and normal levels of QC were outside of the acceptable ranges. 2. During an interview on August 29, 2019 at 1:00 PM, the surveyor inquired if the laboratory performed any CBC testing on this day, as the laboratory failed to ensure at least two levels of QC were acceptable. The GLM reviewed the electronic system and stated the staff ran five patient CBCs. The GLM also confirmed two of three levels of quality control were unacceptable for Hemoglobin.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

	This STANDARD is not met as evidenced by: . Based on a review of API (American Proficiency Institute) proficiency testing records and an interview with the General Laboratory Manager (GLM), the surveyor determined the Laboratory Director failed to ensure the laboratory's proficiency testing results were submitted to API within the established timeframes for grading. This affected one of seven testing events reviewed by the surveyor. The findings include: 1. A review of the API proficiency testing records for Chemistry Event #2, 2019 revealed the laboratory was given zero scores for serum-Hcg, CK-MB, Troponin I, D-dimer and Myoglobin, due to a "Failure to Participate." The laboratory self-evaluated the results to determine the accuracy of its testing. The laboratory also documented the results were not transmitted within the established timeframe. 2. During an interview on August 29, 2019 at 1:40 PM, the GLM confirmed the laboratory did not submit the results to API within the timeframe to ensure grading by the provider. The GLM further stated she attempted to electronically transmit the results, but failed to ensure the results were transmitted/submitted.