Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2056419	05/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Medhelp Trussville	5915 Chalkville Mountain Rd 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. This was noted on seven out of seven chemistry PT events and six out of seven hematology PT events performed by Testing Personnel #16 from 2020 to 2021 (a total of 18 Testing Personnel were listed on the CMS - 209 Laboratory Personnel Report who performed patient testing in the laboratory). The findings include: 1. A review of the API PT records determined the following events were performed by Testing Personnel #16: a) 2020 Chemistry and Hematology 1st Event, 2nd Event, and 3rd Event b) 2021 Chemistry and Hematology 1st Event, 2nd Event, and 3rd Event c) 2022 Chemistry 1st Event 2. During an interview on May 5, 2022 at 12:45 PM, Testing Personnel #1 confirmed the above findings.
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 the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to document the evaluation and verification activities for PT scores less than hundred percent (100%). This was noted for two out three Microbiology (Molecular Virology-Respiratory) events from 2021 - 2022. The findings include: 1. A review of the API PT records revealed the following events did not have documented corrective action for scores less than 100%: a) Microbiology 3rd Event 2021 - Respiratory Syncytial Virus (RSV) B scored 80% (99% for overall Molecular Virology - Respiratory) b) Microbiology 1st Event 2022 - Respiratory Syncytial Virus (RSV) scored 80% (99% for overall Molecular Virology - Respiratory) 2. During an interview on May 5, 2022 at 12:45 PM, Testing Personnel #1 confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 a review of the validation documentation for the QIAstat - Dx Respiratory analyzer and an interview with Testing Personnel #1, the laboratory failed to provide interpreted data for the accuracy and precision of the QIAstat - DX Respiratory analyzer. This affected one of one new non-waived test implemented since previous survey. The findings include: 1. A review of the QIAstat - Dx Respiratory analyzer validation documentation revealed 16 test reports with no indication of results being interpreted for accuracy or precision. 2. An interview on May 3, 2022 at 11:10 AM, Testing Personnel #1 stated "validation was run by using a kit provided by the manufacturer." The surveyor asked about interpretation of data, and Testing Personnel #1 stated "they only had the test reports provided and they were acceptable because Testing Personnel #16 stated they were acceptable." Testing Personnel #1 was unsure how or if the data was interpreted to determine the accuracy or precision of the analyzer.
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 freezer temperatures were outside of acceptable limits (acceptable limit: colder than -20 degrees Celsius). This was noted for 19 months out of 27 months from 2020 to 2022. The findings include: 1. A review of the temperature records for the freezer revealed the following months had temperatures documented warmer than -20 degrees Celsius and no corrective action documented: a) 2020 - January, April, June, August, September, October, November, and December b) 2021 - January, February, March, April, May, July, August, September, and October c) 2022 - February and March 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 May 3, 2022 at 12:45 PM, Testing Personnel #1 confirmed the above findings.