

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0915829	(X3) Date Survey Completed 10/07/2025
Name of Provider or Supplier Medhelp 280	Street Address, City, State 4600 Highway 280 E, 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:</p> <p>This STANDARD is not met as evidenced by: Based on a review of the serum Human Chorionic Gonadotropin (hCG) QC (Quality Control) records, the serum hCG IQCP (Individualized Quality Control Plan), and an interview with Testing Personnel #1, the Laboratory failed to document the serum hCG QC every month as per the IQCP. The surveyor noted 1 out of 22 months of QC not documented reviewed from 2023 through 2025. The findings include: 1. A review of the serum hCG records revealed the laboratory exceeded the monthly requirements for external serum hCG QC for the period between 1/11/2024 to 3/27/2024; 44 days overdue. 2. A review of the serum hCG IQCP revealed, "Three levels of control must be ran each month..." 3. During an interview on October 7, 2025, at 3:47 PM, Testing Personnel #1 confirmed the above findings.</p>