

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1009754	(X3) Date Survey Completed 05/12/2022
Name of Provider or Supplier Medhelp Pelham	Street Address, City, State 3170 Pelham Parkway, Pelham, 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>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. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Quidel Triage Meter (Cardiac Panel and D-Dimer) Quality Control (QC) documentation, the IQCP (Individualized Quality Control Plan) for the Biosite Triage Meter, patient test logs, and an interview with Testing Personnel #1, the laboratory failed to ensure two levels of quality control (QC) were within two standard deviations (2 SD) and documented monthly, as per the IQCP. This was noted for seven out of twenty-seven months reviewed by the surveyor. The findings include: 1. A review of the Quidel Triage Meter QC documentation revealed: a) On 05/19 /2020 Level 2 D-Dimer control was greater than 2 SD. The next acceptable QC run was 06/17/2020. b) On 06/17/2020 Level 2 Troponin (Cardiac Panel) was greater than 2 SD. The next acceptable QC run was 06/24/2020. c) On 07/17/2020 Level 1 Myoglobin (Cardiac Panel) was greater than 2 SD. The next acceptable QC run was 07 /27/2020 d) On 9/15/2020 and 10/14/2020 Level 1 Myoglobin (Cardiac Panel) was greater than 2 SD. The next acceptable QC run was 11/02/2020. e) On 12/03/2020 Cardiac Panel QC was performed, however the next run was not until 02/15/2021. This exceeded the monthly requirement for QC per the IQCP. f) On 05/04/2021 Creatine Kinase - MB and Troponin (Cardiac Panel) were greater than 2 SD. The next acceptable QC run was 05/11/2021. 2. A review of the IQCP for the Biosite Triage</p>

Meter revealed, under External Control "Two levels of control must be ran and in range in order to test patients. Results must be compared to the QC range chart.... you should compare results to the 2 SD column. If it falls out of range, QC must be repeated." 3. A review of patient test logs revealed the following: a) for D-Dimer from 05/19/2020 to 06/17/2020 16 patient tests were performed. b) for Cardiac Panel from 06/17/2020 to 06/24/2020 3 patient tests were performed. c) for Cardiac Panel from 07/17/2020 to 07/27/2020 1 patient test was performed. d) for Cardiac Panel from 09/15/2020 to 11/02/2020 17 patient tests were performed. e) for Cardiac Panel from 01/03/2021 to 02/15/2021 18 patient tests were performed. f) for Cardiac Panel from 05/04/2021 to 05/11/2021 2 patient tests were performed. 4. During an interview on May 12, 2022 at 12:50 PM, Testing Personnel #1 confirmed the above findings.

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 the Quality Control (QC) documentation for the Horiba Micros 60 Hematology analyzer and an interview with Testing Personnel #1, the laboratory failed to ensure at least two levels of QC were acceptable on April 1, 2020, prior to testing patient specimens and reporting the results. The laboratory tested three patient CBC (Complete Blood Count) specimens on this day when two out of three levels of QC were found unacceptable. This was noted for one day out fifteen months reviewed by the surveyor. The findings include: 1. A review of the Horiba Micros 60 QC for April 1, 2020 revealed the normal and high level QC were outside of the acceptable ranges. 2. During an interview on May 12, 2022 at 1:15 PM, Testing Personnel #1 confirmed two out of three levels of QC were unacceptable on April 1, 2020, and three 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", the Horiba Micros 60 User Manual, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to document corrective actions when freezer temperatures and room temperatures were outside of acceptable limits. This was noted for the freezer temperatures for 26 out of 28 months and the

room temperatures for 16 months out of 28 months from 2020 to 2022. The findings include: 1. A review of the temperature records revealed the following : a) Freezer temperatures had temperatures documented warmer than -20 degrees Celsius with no corrective action documented for the months listed below: i) 2020 - January, February, March, April, May, July, August, October, November, and December ii) 2021 - January through December iii) 2022 - January through April b) Room temperatures had temperatures documented colder than 18 degrees Celsius with no corrective action documented for the months listed below: i) 2020- April, May, July, August, November, and December ii) 2021- January, February, April, June, November, and December iii) 2022- January through April 2. A review of the "Quidel Triage Total 5 Control Product Insert" revealed "Store frozen at -20 degree C or colder in a non-defrosting freezer." 3. A review of the Horiba Micros 60 User Manual revealed "The ABX Micros 60 must operate between temperatures of 18 to 32 degrees Celsius...". 4. During an interview on May 12, 2022 at 1:15 PM, Testing Personnel #1 confirmed the above findings.