

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0915829	(X3) Date Survey Completed 10/27/2021
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Vitros 5600 Procedure Manual and an interview with Testing Personnel #1, the Laboratory Director failed to approve the Vitros 5600 Procedures, before patient testing began in November 2019. This was noted on one of three new instruments installed since the previous survey. The findings include: 1. A review of the Vitros 5600 Procedure Manual revealed it was online and there was no evidence that the Laboratory Director reviewed the procedures, prior to patient testing starting in November 2019. 2. During an interview on 10/27/2021 at 11:22 AM, Testing Personnel #1 confirmed the procedures online were not reviewed by the Laboratory Director.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless</p>

the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of calibration verification records for the Vitros 5600 and Tosoh G8, and an interview with Testing Personnel (TP) #1, the laboratory failed to perform calibration verifications at least every six months for the Chemistry analytes with less than three routine calibrators. This affected two opportunities in 2020 and one opportunity in 2021 for the Vitros 5600 and Tosoh G8. This is a repeat deficiency. The findings include: 1. A review of the calibration verification records for the Vitros 5600 revealed calibration verification had not been performed since patient testing started in November 2019. The following analytes have less than three calibrations: a) Direct Low-Density Lipoprotein Cholesterol (dLDL) b) Estradiol c) Total Iron-Binding Capacity (TIBC) d) Follicle-Stimulating Hormone (FSH) e) Luteinizing Hormone (LH) f) Prolactin g) Vitamin B12 h) Vitamin D 2. A review of the calibration verification records for Tosoh G8 revealed the last calibration verification for Hemoglobin A1c was performed on 12/03/2019. 3. During an interview on 10/27 /2021 at 12:10 PM, Testing Personnel #1 confirmed calibration verifications had not been performed every 6 months for the tests listed above.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(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-- (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.

This STANDARD is not met as evidenced by:

Based on a review of the IQCP (Individualized Quality Control Plan), the Quality Control (QC) records for the Luminex Verigene - Respiratory Panel and Luminex Aries - Clostridium difficile (C. Difficile) and an interview with Testing Personnel #1, the laboratory failed to ensure two levels of quality control (QC) were performed and documented every 31 days of patient testing as per the IQCP. This was noted one time since patient testing started in November 2020 for Respiratory Panel and March 2021 for C. Difficile. The findings include: 1. A review of the IQCP for the Luminex Verigene - Respiratory Panel and Luminex Aries - Clostridium difficile (C. Difficile) revealed a QC Plan which specified two levels of QC should be performed and documented every 31 days of patient testing. 2. A review of the November 2020 to September 2021 Luminex Verigene - Respiratory Panel QC revealed QC was

performed on 07/08/2021 and not performed again till 08/23/2021 (more than 31 days). From 08/09/2021 to 08/22/2021, 128 patient tests were performed. 3. A review of the March 2021 to October 2021 Luminex Aries - Clostridium difficile (C. Difficile) QC revealed QC was performed on 07/08/2021 and not performed again till 08/23/2021. From 08/09/2021 to 08/22/2021, 2 patient tests were performed. 4. During an interview on 10/27/2021 at 3:00 PM, Testing Personnel #1 confirmed the laboratory failed to follow their IQCP and perform QC every 31 days.

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 review of quality control records for Chemistry testing and an interview with Testing Personnel #1 (TP #1), the laboratory failed to provide documentation of at least two acceptable levels of Quality Control (QC) for TIBC (Total Iron-Binding Capacity), Total Bilirubin, Phosphorus, Estradiol, Folate, and Free triiodothyronine (FT3) for days in May of 2021. This was noted for one month out the following three months reviewed by the surveyor, December 2019, July 2020, and May 2021. This is a repeat deficiency. The findings include: 1. A review of the quality control records for Chemistry and Endocrinology testing, performed on the Vitros 5600, revealed several days in May 2021 when documentation indicated that not at least two levels of QC were within acceptable ranges. The following was revealed: a) TIBC acceptable range in the Laboratory Information System (LIS) was 8.21 to 757.56 for Level 1, according to the 10 data runs when the ranges were established by the laboratory the acceptable range should have been 239.47 to 255.895. For the month of May 2021 the observation range was 215.56 to 225.74, meaning Level 1 for TIBC was unacceptable for each day of patient testing. b) Total Bilirubin Level 1 was unacceptable 05/04/2021, 05/05/2021, and 05/06/2021 according to the acceptable range in the LIS. c) Phosphorus Level 1 was unacceptable 05/20/2021, 05/21/2021, and 05/24/2021 according to the acceptable range in the LIS. d) Estradiol Level 1 was unacceptable 05/11/2021 according to the acceptable range in the LIS. e) Folate Level 1 was unacceptable 05/25/2021 according to the acceptable range in the LIS. f) FT3 Level 1 was unacceptable 05/03/2021 according to the acceptable range in the LIS. 2. During an interview on 10/27/2021 at 1:20 PM, the surveyor and Testing Personnel #1 reviewed the Chemistry QC reports from May 2021. TP #1 explained the QC values must have shifted when the ranges were changed, but could not provide documentation of the QC being within range. TP #1 explained they were using unassayed controls and would change the baseline every 30 days, but could not provide documentation of changes in baselines, only the original 10 day control evaluation where the means and standard deviations were determined.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on a review of quality control records, a review of personnel records, a review of the procedure manual, and interviews with Testing Personnel #1, the Technical Consultant failed to fulfil her responsibilities. The findings include: 1. Refer to D6042. 2. Refer to D6046. 3. Refer to D5481.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
Based on review of quality control records for Chemistry testing, Chemistry Quality Control Procedure, and an interview with Testing Personnel #1 (TP #1), the Technical Consultant failed to establish a quality control program for Chemistry testing. This was noted for one month out the following three months reviewed by the surveyor, December 2019, July 2020 , and May 2021. The findings include: 1. Refer to D5481. A review of the Chemistry Quality Control revealed the Technical Consultant reviewed the QC, but failed to document the outliers. 2. A review of the Chemistry Quality Control Procedure revealed no information on using unassayed controls for the Vitros 5600 and how ranges would be determined or changed when needed. 3. During an interview on 10/27/2021 at 2:20 PM, TP #1 confirmed the laboratory was using unassayed controls and did not have a procedure for this process. QC reviewed in May 2021 revealed QC being out of range according to the Laboratory Information System (LIS) printouts and Instrument printouts reviewed by the surveyor. No documentation could be provided to show the controls being within range on dates listed in D5481.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on a review of personnel records, proficiency testing records, and an interview with Testing Personnel #1, the Technical Consultant failed to assure Testing Personnel (TP) #1 maintain competency to perform Complete Blood Count (CBC), serum human Chorionic Gonadotropin (hCG), and Cardiac Panel (Triage Meter). This was noted on one of twelve testing personnel. The findings include: 1. A review of personnel records revealed Testing Personnel #1 had competency evaluated for Vitros 5600, Tosoh G8, Luminex Verigene, and Luminex Aries annually. TP #1 did not have records of competency evaluation on Horiba ABX Micros 60 (CBC), Triage Meter (Cardiac and D-Dimer Panel), and Serum hCG. 2. A review of proficiency testing records revealed Testing Personnel #1 performed the following testing events: a) 2020

Chemistry - Core 1st Event Triage Meter (Cardiac and D-Dimer Panel) and Serum hCG b) 2021 Chemistry - Core 2nd Event Triage Meter (Cardiac and D-Dimer Panel) and Serum hCG c) 2021 Chemistry - Core 3rd Event Triage Meter (Cardiac and D-Dimer Panel) and Serum hCG e) 2019 Hematology 2nd Event Horiba ABX Micros 60 (CBC) f) 2020 Hematology 3rd Event Horiba ABX Micros 60 (CBC) g) 2021 Hematology 2nd Event Horiba ABX Micros 60 (CBC) 3. During an interview on 10/26/2021 at 3:00 PM, Testing Personnel #1 confirmed competency evaluations for Horiba ABX Micros 60 (CBC), Triage Meter (Cardiac and D-Dimer Panel), and Serum hCG had not been performed. TP #1 also confirmed she periodically would run patient testing on these tests and performed training/competency evaluations on urgent care staff, who also performed these tests.