

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0894546	(X3) Date Survey Completed 10/20/2020
Name of Provider or Supplier Medical Group Of Corry Rhc	Street Address, City, State 315 York Street, Corry, PA	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant (TC), the laboratory failed to monitor and document the temperature of 1 of 1 Frigidaire refrigerator used for the storage of 2 of 2 bottles of 5 ml MedTox toxicology urine quality control materials from 2018 to the date of survey. Findings include: 1. On the date of survey 10/20/2020, review of the laboratory's temperature records revealed, the laboratory did not document the temperature of 1 of 1 Frigidaire refrigerator. 2. The refrigerator housed: - 1 of 1 bottle of 5 ml MedTox Toxicology Negative control lot# N00168-2 expiration date: 10/31/2022 - 1 of 1 bottle of 5 ml MedTox Toxicology Positive control lot# CC01024 expiration date: 10/31/2022. 3. In 2018 (11/15/2018 to 12/31/2018), 379 urine toxicology screening tests were performed. 4. In 2019, 195 urine toxicology screening tests were performed. 5. In 2020 (01/01/2020 to 10/20/2020) 66 urine toxicology screening tests were performed. 6. The TC confirmed the findings above on 10/20/2020 at 11:00 a.m.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the Technical Consultant (TC), the laboratory failed to replaced or calibrate the thermometer for 1 of 1 Frigidaire refrigerator in 2019. Findings Include: 1. On the day of survey, 10/20/2020, while the surveyors were touring the laboratory, 1 of 1 Frigidaire refrigerator thermometer observed, was due for calibration on 8/8/2019. 2. The refrigerator housed: - 1 of 1 bottle of 5 ml MedTox Toxicology Negative control lot# N00168-2 expiration date: 10/31/2022 - 1 of 1 bottle of 5 ml MedTox Toxicology Positive control lot# CC01024 expiration date: 10/31/2022. 4. In 2019, 195 urine toxicology screening tests were performed. 5. The TC confirmed the findings above on 10/20/20 at 11:15 a.m.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) record and interview with the Technical Consultant (TC), the laboratory failed to include a positive and negative control each day of patient testing for the MedTox Diagnostic 10-panel drug of abuse test kits from 2018 to the date of survey. Findings include: 1. On the day of survey, 10/20/2020, review of MedTox QC records revealed, the laboratory did not include a negative and positive control material at least each day of patient testing from 11/15/2018 to 10/20/2020. 2. In 2018 (11/15/2018 to 12/31/2018) 379 urine toxicology screening tests were performed. 3. In 2019, 195 urine toxicology screening tests were performed. 4. In 2020 (01/01/2020 to 10/20/2020) 66 urine toxicology screening tests were performed. 5. The TC confirmed the findings above on 10/20/2020 at 10:00 a.m.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Technical Consultant (TC), the laboratory failed to provide a corrective action for out of range room temperatures where the MedTox toxicology kits are store for 8 of 20 days in August 2020 and 9 of 13 days in October 2020. 1. The laboratory defined room temperature ranges were 18 to 25 degrees Celsius. 2. On the date of survey, 10/20/2020, review of the room temperature records revealed, room temperatures were out of range on 8 of 20 days in

August of 2020 and 9 of 13 days in October of 2020. 3. The TC could not provide documentation for days room temperature were found out on range in August and October of 2020. 3. There were 2 of 2 boxes of Profile IIA Medtox (lot #P00447D21 expiration date 2021-04-30) store in the room. 4. In 2020 (01/01/2020 to 10/20/2020) 66 urine toxicology screening tests were performed. 5. The TC confirm the findings above on 10/20/2020 at 11:30 a.m.