

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2052831	(X3) Date Survey Completed 08/26/2021
Name of Provider or Supplier Spectrum Health Medical Clinic Llc	Street Address, City, State 2500 North Mayfair Rd Suite 630, Wauwatosa, WI	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures and interview with testing personnel, the laboratory started amphetamine testing on March 5, 2021 and did not have an approved procedure for the test. Findings include: 1. Review of laboratory testing records showed the laboratory started testing specimens for amphetamine on March 5, 2021. 2. Review of the laboratory procedure manual showed no evidence of an approved procedure for amphetamine testing. 3. Interview with the testing person on August 26, 2021 at 11:00 AM confirmed the laboratory added amphetamine testing to the test menu on March 5, 2021 and confirmed the laboratory did not have an approved procedure for amphetamine testing available to laboratory personnel.</p>
D5409	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures and interview with testing personnel, the laboratory procedure for methadone was not maintained with</p>

the May 7, 2021 date of discontinuance. Findings include: 1. Review of laboratory testing records showed the laboratory discontinued testing specimens for methadone on May 7, 2021. 2. Review of the laboratory procedure manual showed no evidence the laboratory discontinued testing for methadone. 3. Interview with the testing person on August 26, 2021 at 11:00 AM confirmed the laboratory discontinued methadone testing on May 7, 2021 and confirmed the procedure was not maintained with the date of discontinuance.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory records and interview with testing personnel, the technical consultant did not evaluate and document the performance of one of one testing personnel in 2019 or 2020. Findings include: 1. Review of competence evaluation records for the only testing person showed no evidence of evaluation in 2019 or 2020. 2. Interview with the testing person on August 26, 2021 at 10:08 AM confirmed the records did not show evaluation in 2019 or 2020.