

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2115357	(X3) Date Survey Completed 06/10/2021
Name of Provider or Supplier Froedtert Community Hospital - New Berlin	Street Address, City, State 4805 S Moorland Rd - Garden Level, New Berlin, 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
D3029	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2)</p> <p>Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the technical consultant, the laboratory did not have a copy of the procedure for the Abbott I-Stat analyzer after discontinuation of the basic metabolic panel (BMP) testing in December 2019. Findings include: 1. Review of laboratory procedures showed no evidence of the Abbott I-Stat BMP procedure. 2. Interview with the technical consultant on June 10, 2021 at 11:20 AM confirmed the laboratory did not have a copy of the Abbott I-Stat BMP procedure after discontinuation of the testing.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory did not have analytical system records for the Abbott I-Stat analyzer for testing performed in 2019. Findings include: 1. Review of laboratory records for the Abbott I-Stat analyzer revealed no quality control, maintenance and</p>

calibration records for 2019. 2. Interview with the technical consultant on June 10, 2021 at 11:20 AM confirmed the laboratory did not have analytical system records for the Abbott I-Stat analyzer for testing performed in 2019.

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the technical consultant, the laboratory did not retain the PT records for PT testing performed in 2019. Findings include: 1. Review of API PT records showed no evidence of testing records, signed attestation statements, PT result scores from the provider, and documentation of result review for 2019. 2. Interview with the technical consultant on June 10, 2021 at 10:35 AM confirmed the laboratory did not have PT testing records and documented review of results for PT testing performed in 2019.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory director did not assure compliance with the applicable regulations pertaining to retention requirement at CFR 493.1105. Findings include: 1. Review of laboratory procedures showed no evidence of the Abbott I-Stat BMP procedure. 2. Review of analytical records showed no evidence of quality control, maintenance and calibration records for 2019. 3. Review of proficiency testing (PT) records showed no evidence of testing records, signed attestation statements, PT results and scores from the provider and documentation of result review for PT testing performed in 2019. 4. Interview with the technical consultant on June 10, 2021 at 11:20 AM confirmed the laboratory director did not assure compliance with the applicable regulations pertaining to retention requirements at CFR 493.1105.