

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2010825	(X3) Date Survey Completed 05/09/2019
Name of Provider or Supplier Byron Center Family Medicine	Street Address, City, State 7740 Byron Center Ave, Ste 202, Byron Center, MI	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: . Based on record review, observation, and interview with the office manager, the laboratory failed to (1) identify the type of container used in urinalysis with microscopic evaluation and culture and sensitivity testing and (2) provide a current procedure from the reference laboratory for culture and sensitivity testing collection for 2 (May 2017 to May 2019) of 2 years. Findings include: (1) A. A record review of the "Complete Urinalysis with Microscopic Examination" procedure failed to identify the type of container used for routine urinalysis and microscopic evaluation collection. B. An observation by the surveyor at approximately 1:30 pm on 5/9/19 revealed nonsterile Styrofoam cups were used in urine collection. C. An interview with the office manager at approximately 1:30 pm on 5/9/19 confirmed nonsterile Styrofoam cups were used for routine urine collection, then poured into sterile containers if a culture was indicated and sent to the reference laboratory. (2) A. A record review revealed the lack of a current manual for the reference laboratory specimen requirements regarding test referral. When requested by the surveyor, the office manager failed to provide a current manual for test referral. B. An interview with the office manager at approximately 1:30 pm on 5/9/19 confirmed a current manual for the reference laboratory specimen requirements regarding test referral was not available.</p>

D5313

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

CFR(s): 493.1242(b)

The laboratory must document the date and time it receives a specimen.

This STANDARD is not met as evidenced by:

. Based on record review, observation, and interview with the office manager, the laboratory failed to document the date and time it receives specimens into the laboratory for 2 (May 2017 to May 2019) of 2 years. Findings include: 1. A record review of the "Complete Urinalysis with Microscopic Examination" procedure failed to include a section about documenting date and time of specimen receipt into the laboratory. 2. An observation by the surveyor at approximately 1:30 pm on 5/9/19 revealed specimen cups labeled with patients' first name and doctor's initials. 3. An interview with the office manager at approximately 1:30 pm on 5/9/19 confirmed the above findings.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Based on record review, observation, and an interview with the office manager, the laboratory failed to perform, and document (1) centrifuge electrical safety inspection for 1 of 2 years and (2) thermometer calibration for 2 (May 2017 to May 2019) of 2 years. Findings include: (1) A. A record review of the "Centrifuge Maintenance" procedure showed, "top speed, ground continuity, and line breakage is to be tested every year." B. On 5/9/19 at 12:14 pm, the surveyor observed a sticker fixed on the centrifuge stating, "electrical safety inspection due 3/19." C. An interview with the office manager on 5/9/19 at 12:14 pm confirmed the centrifuge maintenance was not performed and documented. (2) 1. On 5/9/19 at 12:14 pm, the surveyor observed stickers on the back of the refrigerator and freezer thermometers had a calibration expiration date of August 2010. 2. A review of the "QuantScopics Urinalysis Microscopics Control" package insert indicated the temperature range for storage was between 2 and 8 degrees C. 3. An interview with the office manager on 5/9/19 at 12:14 pm confirmed the above findings.