

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0927498	(X3) Date Survey Completed 02/26/2019
Name of Provider or Supplier Buttermilk Falls Pediatrics Pllc	Street Address, City, State 22 Arrowwood Drive, Suite A, Ithaca, NY	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the ESA Lead Care II Quality control (QC) records and an interview with the License Practical Nurse (LPN)/testing person, the laboratory failed to follow the Magellan Diagnostic Lead Care manufacturer's QC requirements. FINDINGS: The LPN/testing confirmed on February 26, 2019 at approximately 11:00 AM, the laboratory did not record the QC results for Lead Care II Controls I & II Lot # 1804M expiration date 01-09-2019. a. The lab did retain the control assay sheets (Level I Range 5.1-11.1 and Level II Range 20.8-28.8). b. The lab did not record the date the controls were opened (90 days for stability). Therefore, the surveyor could not determine when this lot of cassettes 1804M expiration date 01-09-2019 was used for patient testing. c. The last date that the laboratory documented the open date for both the controls & test cassettes (lot # 1814M expiration date 2-8-20) was 1-25-19.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's competency assessment policies,</p>

the testing personnel's competency records, and an interview with the LPN/testing person, the laboratory failed to follow the laboratory's written competency assessment policies and failed to perform an annual competency evaluation for the ten testing personnel and general supervisor in the 2018 calendar year. FINDINGS: The LPN /testing person confirmed on February 26, 2019 at approximately 11:30 AM, the laboratory to follow the laboratory's written competency assessment policies, that requires an annual evaluation for the testing personnel. a. the laboratory director failed to perform annual competency evaluations for the ten testing personnel and general supervisor in the 2018 calendar year.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on surveyor's review of the laboratory's Quality Assessment (QA) policies and procedures and confirmed in an interview with the LPN/testing person, at the time of this survey, the laboratory failed to follow their established QA policy and perform a QA review for the 2018 calendar year.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on surveyor's review of the laboratory QA policy and interview with the LPN /testing person, the laboratory director failed to follow their QA procedure for having an ongoing mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system for bacteriology in the calendar year 2018. Refer to D1001, D5209 and D5291.