

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0958035	(X3) Date Survey Completed 05/24/2018
Name of Provider or Supplier Community Physicians/Sager Pediatric	Street Address, City, State 1101-2 North Progress Ave, Siloam Springs, AR	
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: Through observations made during a tour of the laboratory and interviews with laboratory staff, it was determined the laboratory failed to follow manufacturer's instructions for performing the Osom Mono Test. Survey findings include: A. During a tour of the laboratory at 8:35 a.m. on 5/24/2018 the surveyor observed one kit of Osom Mono Test (lot #171225) on the laboratory counter. The manufacturer's expiration date of the test kit was 4/30/2018 (24 days prior to the survey). B. In an interview at 8:35 a.m. on 5/24/2018, the technical consultant (as listed on the form CMS-209) confirmed the Osom Mono Test was available for use when it had exceeded the manufacturer's expiration date.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Through a review of the Diatron Abacus manufacturer's instructions, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document daily maintenance for Diatron Abacus as specified by the</p>

manufacturer. Survey findings include: A. The Diatron Abacus manufacturer's instructions include the following daily maintenance: Check reagent condition; Check the contents of the waste tank; run blank measurement; run required daily cleaning at the end of the day. B. Through a review of the January 2018 through May 2018 Problem Log (used by the laboratory to document start up and maintenance) it was determined the laboratory had no documentation of checking the reagent condition, or running the daily cleaning at the end of the day. C. In an interview, at 9:52 a.m. on 5/24/2018, the technical consultant confirmed the lack of documented daily maintenance for the Diatron Abacus.