

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2275735	(X3) Date Survey Completed 01/31/2024
Name of Provider or Supplier Seark Children's Clinic	Street Address, City, State 702 HI Ross Dr, Monticello, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Through a review of the laboratory test menu, a review of CASPER 155 reports for 2023, lack of documentation, and interviews with laboratory personnel, it was observed the laboratory failed to enroll in proficiency testing for CBC (complete blood count). Survey findings include: A. A review of the laboratory's test menu revealed the laboratory performed CBCs on the Sysmex XN-330. B. No proficiency test results for the facility were shown for 2023 in the CASPER 155 reports. C. In an interview, at 8:58 a.m. on 1/3/24, laboratory personell #1 (as listed on the form CMS-209) confirmed the laboratory was not enrolled in proficiency testing for CBC.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p>

This STANDARD is not met as evidenced by:
Through observation and interview with laboratory staff it was determined that the laboratory had supplies available for use after their expiration date. Findings follow:
A) During a tour of the laboratory on 01/31/24 at 11:20 a.m. one (of one) BRT Liquid Assayed Chemistry + Liquid Control (Lot: 2207030, ref: 100-9010, 2Lx 6Vx1.0mL, expiration date 12/31/2023) was observed in the laboratory. B) In an interview on 01/31/24 at 11:20 a.m. laboratory staff member (listed as #1 on the CMS 209 form) confirmed that the item, identified above, had exceeded its expiration date and was available for use.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory test menu, a lack of CASPER 155 reports for 2023, lack of documentation, and interviews with laboratory personnel, it was determined the laboratory director failed to ensure the laboratory was enrolled in proficiency testing for the CBCs as cited at D2000.