Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2275735	10/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Seark Children's Clinic	702 Hl 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Through review of package inserts, observation, and interview it was determined that the laboratory did not change expiration dates on control materials after opening as required by manufacturer. Finding follow: A) Review of the package insert for XN-L Check Hematology controls revealed that the product expires in 15 days after vial is opened and put into use and the expiration dates should be changed as required after opening. B) During a tour of the laboratory on 10/22/25 at 3:35 p.m.the surveyor observed a plastic container with three vials of XN-L Check hematology controls , lot #' 523514 expiration date 2025-12-02. The vials did not have new expiration dates or dates put into use indicated on the testing materials or the container and were identified as the controls currently in use. C) In an interview on 10/22/25 at 03:35 p.. m. laboratory staff member (number 1 on form CMS 209) confirmed that no amended expiration date or date when put into use were written on the vials or container.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based upon review of Sysmex XN-300 Hematology Analyzer Checklist, lack of documentation and interviews with laboratory staff, the laboratory failed to perform required maintenance on the Sysmex XN-300 Hematology Analyzer in 2025 Survey findings include: A) The Sysmex XN-300 Maintenance Checklist includes a required weekly "Clean SRV Tray" and monthly maintenance "monthly clean RBC and WBC Transducer "and "Clean Waste Chamber". B) Review of the Sysmex XN-300 maintenance log for 2025 revealed weekly maintenance was not documented for any weeks in July 2025, August 2025, and September 2025 and monthly maintenance was not documented for any month in 2025. C) In an interview, at 03:30 p.m. on 10/22/25, laboratory staff member #1 (as listed on the form CMS-209) confirmed that weekly and monthly required maintenance for the Sysmex XN-300 was not documented in 2025.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based upon review of patient reports and interview with laboratory staff the laboratory did not make a reference range for complete blood cell (CBC) assays available to the individual responsible for using the test results. Findings follow: A) Review of the final report for a CBC assay on a patient identified as number 2579 revealed that, under the heading "Reference Range", the report was blank and no reference range was given. B) In an interview on 10/22/25 at 03:40 p.m., laboratory staff member (1 on form CMS 209) confirmed that the reference range was not included on the report identified above, and that investigation of other CBC reports showed that the reference range was not included.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Based upon review of personnel files for testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, the laboratory director failed to authorize five of five testing personnel to perform testing without direct supervision. Survey findings include: A) Review of personnel files for five testing personnel listed on form CMS-209 (Personnel #'s 2, 3, 4, 5, 6) revealed written authorization from the laboratory director to perform moderately complex testing without direct supervision was not present. B) In an interview, at 12:50 p.m. on 10/22/25 laboratory staff member #1 (as listed on the form CMS-209) confirmed the

	lack of written authorizations to test for employees (#'s 2 , 3, 4, 5, 6) on form CMS 209).