

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0067411	(X3) Date Survey Completed 07/21/2026
Name of Provider or Supplier Arthritis Treatment Center	Street Address, City, State 3377 Main St, Springfield, MA	
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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(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. (b)(2)(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 and interview with the general Supervisor (GS) the laboratory failed to have have a written procedure for performing function checks on three of three centrifuges used to prepare platelet poor plasma (PPP) for lupus anticoagulant testing and failed to perform the required function checks to verify the centrifuges produced PPP containing fewer than 10,000 platelets as required by the reference laboratory. Findings include: 1. Record review on 7/14/2026 of the reference laboratory's specimen requirements for lupus anticoagulant testing revealed: "Platelet poor plasma: Centrifuge light blue tube for 15 minutes at approximately 1500 g within 60 minutes of collection. Using a plastic pipette remove plasma taking care to avoid the WBC platelet buffy layer and place it into a plastic vial. Centrifuge a second time and transfer platelet poor plasma into a new plastic vial. Plasma must be free of platelets (less than 10,000/mcL). Freeze immediately and ship on dry ice." 2. Record review on 7/14/2026 of the laboratory's centrifuge calibration and maintenance records for three of three centrifuges used to process patient specimens for PPP revealed no documentation that the laboratory had verified the centrifuges produced PPP containing fewer than 10,000 platelets/mcL, as required for lupus anticoagulant testing. 3. Staff interview with the GS on 7/14/2026 at 1:00 PM confirmed the

	laboratory had not verified that processed plasma met the reference laboratory's requirement of fewer than 10,000/L (mcL) platelets prior to freezing and shipping specimens for lupus anticoagulant testing.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on record review and confirmed by staff interview with the General Supervisor (GS) the laboratory director (LD) failed to ensure new testing personnel (TP) received training prior to performing patient testing. Findings include: 1. Record review on 7/14 /2026 of the laboratory's TP records revealed one of one newly hired TP did have documented training prior to performing patient testing on the Beckman Olympus AU400e in the specialty of chemistry, subspecialty of routine chemistry, or prior to performing urine sediment examinations in the specialty of chemistry, subspecialty of urinalysis. 2. During an interview with the GS on 7/14/2026 at 10:15 AM, the GS confirmed the laboratory did not have documented training for 1 of 1 new testing personnel in the subspecialties of routine chemistry and urinalysis. 3. The laboratory performs 25,094 tests annually in the specialty of chemistry.