

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0966441	(X3) Date Survey Completed 08/11/2022
Name of Provider or Supplier Acp - Arthritis Associates	Street Address, City, State 2102 N Country Club, Ste 3, Tucson, AZ	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on record review of patient testing logs and interview with the laboratory director (LD) on August 11, 2022 , the laboratory failed to have a policy and procedure for conducting quality control (QC) on synovial body fluid microscopic evaluations, and microscopic examination procedures for detection of inadequately prepared slides. The findings include: 1. The laboratory conducts microscopic review of synovial body fluids for crystals, white blood cells and red blood cell presence. 2. The laboratory had no policy or procedure as to how the laboratory would perform and document QC on each day of patient testing. 3. The laboratory director confirmed</p>

by email on August 16, 2022 at 09:00 a.m. the lack of policy and procedures for microscopic quality control and detection of adequately prepared specimens. 4. The laboratory reports performing 24 patient synovial body fluids annually.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on record review of the laboratory systems daily maintenance, and interview with the laboratory director (LD) on August 11, 2022, the laboratory failed to perform function checks on (2) of (2) microscopes utilized for body fluid analysis. The findings include: 1. The laboratory microscope tags on 2 of 2 microscopes utilized to identify synovial body fluids elements, were dated 2019. 2. The laboratory did not have documentation of the function check tests being performed for 2020, 2021 or 2022. 3. The laboratory director confirmed by email on Augusts 16, 2022 09:00 a.m. that the function checks where not performed for 2020, 2021 and 2022. 4. The laboratory reports performing 24 synovial body fluid evaluations annually.

D5485

CONTROL PROCEDURES
CFR(s): 493.1256(h)

If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.

This STANDARD is not met as evidenced by:
Based on record review of the laboratory policy and procedures, and interview with the laboratory director (LD) on August 11, 2022, the laboratory failed to identify and perform a mechanism for performing quality control for synovial fluid microscopic analysis. The findings include: 1. The laboratory performs synovial fluid analysis on two microscopes for identification of crystals, red blood cells and white blood cells. The laboratory failed to have documentation of performing quality control (QC) for determining acceptability of slide preparations for (6) of (6) patients reviewed for synovial body fluid testing performed. Date Patient 03/30/2021 85102 01/06/2021 449678 05/26/2021 483841 02/05/2022 754709 06/20/2022 221223 07/11/2022 346686 2. The laboratory failed to perform the microscope maintenance/function checks for the testing dates listed above, potentially affecting the slide reviews. See D 5431. 3. The laboratory director confirmed by email on 08/16/2022 09:00 a.m., the laboratory did not perform or document quality control assessments for slide reviews of synovial body fluids. 4. The laboratory reports performing 24 microscopic body fluid review annually.