

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0440645	(X3) Date Survey Completed 12/12/2018
Name of Provider or Supplier Arthritis Consultants, Inc	Street Address, City, State 522 N New Ballas, Suite 240, Saint Louis, MO	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2017, 2018 proficiency testing(PT) results for complete blood cell counts(CBC) performed on the ACT T diff 2 hematology analyzer, procedure manual and interview with the technical consultant, the laboratory failed to test the PT samples the same number of times as patient samples. Findings: 1. Review of 2017 first and second PT events for CBC results performed on the ACT T diff 2 analyzer showed the laboratory repeated the specimens three times. 2. Review of the 2018 second and third PT events for CBC results performed on the ACT T diff 2 analyzer showed the laboratory repeated the specimens three times. 3. Review of the procedure manual revealed "ensure PT is performed in the same manner as patient testing". 4. Interview with the technical consultant on December 12, 2018 at 10:30 AM confirmed the laboratory does not routinely repeat patient samples three times and failed to test PT samples the same number of times as patient samples.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit</p>

of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of hematology calibration records for the Beckman Coulter ACT T diff 2 analyzer, review of the procedure manual and interview with the technical consultant, the laboratory failed to perform calibration verification procedures on the hematology analyzer for complete cell counts at least once every six months for 2017. Findings: 1. Review of calibration records for the ACT T diff 2 for 2017 revealed the laboratory failed to perform 1 of 2 calibrations for the required 6 month interval. 2. Review of the procedure manual revealed an approved policy to "verify calibrations are performed at frequency indicated by the manufacturer or at least every six months". 3. Interview with the technical consultant on December 12, 2018 at 10:30 AM confirmed the laboratory failed to perform calibration of the hematology analyzer every six months for 2017.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of the procedure manual, personnel documentation and interview with the technical consultant, the laboratory director failed to ensure the technical consultant maintained competency for 2017 and to date December 4, 2018. Findings: 1. Review of 2017, 2018 employee competencies revealed "documentation of an evaluation every six months for the first year and annually thereafter". 2. Review of personnel documentation revealed the laboratory director failed to ensure the technical consultant had an evaluation annually for 2017 and to date December 12, 2018. 3. Interview with the technical consultant on December 12, 2018 at 10:30AM confirmed the laboratory director failed to ensure competencies for 2017 and to date December 12, 2018 for the technical consultant were completed.