| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>03D0966441 | (X3) Date Survey Completed<br>01/10/2018 |
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| Name of Provider or Supplier<br>Acp - Arthritis Associates | Street Address, City, State<br>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 |
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| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's procedure manual and interview with the facility personnel, the laboratory failed to have the current laboratory director approve and sign test procedures before use. Findings include: 1. The laboratory performs synovial fluid testing in the sub-specialty of Routine Chemistry, with an approximate annual test volume of 80. 2. The procedure manual presented for review was not approved, signed and dated by the current laboratory director. 3. Review of the audit records for CLIA# 03D0996441 in the CMS database indicated the current laboratory director has been listed as director since 08/30/2016. 4. The facility personnel confirmed that the procedure manual indicated above was not approved, signed and dated by the current laboratory director before use. |
| **D6102** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(12)<br><br>The laboratory director must 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of training documentation for one out of one testing personnel and |

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| | interview with the facility personnel, the laboratory director failed to ensure that all testing personnel receive the appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: 1. No initial training documentation was presented for review for one testing personnel who performed one patient test (EMRN# 210542) on 01/06/17. 2. The facility personnel confirmed that the laboratory failed to have documentation of initial training for the testing personnel indicated above, demonstrating that they can perform all testing operations reliably and accurately prior to testing patients' specimens. |
| **D6103** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(13)<br><br>The laboratory director must 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of policies and procedures for review and interview with the facility personnel, the laboratory director failed to ensure that policies and procedures are established for monitoring individuals who perform patient testing to assure that they are competent and maintain their competency to perform test procedures and report test results promptly and proficiently. Findings include: 1. No policies and procedures as indicated above were presented for review during the survey. 2. The facility personnel confirmed that the labortatory did not have established policies and procedures in place at the time of the survey for monitoring individuals who perform patient testing. |