Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0707201	06/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis Clinic Of Central Utah	3650 N University Ave Ste 150, Provo, UT	

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
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on proficiency test (PT) review and interview with staff, the laboratory failed to achieve satisfactory performance in 1 of 6 chemistry PT events reviewed (3rd event of 2017) by failing to submit test results, resulting in a score of 0%. Findings include: 1. Federal CASPER report and American Proficiency Institute (API) report review document scores of 0% for 15 of 15 chemistry analytes. 2. Staff stated on 06/28/2018 at approximately 11:00 a.m., they were busy working with a vendor on a new instrument installation and missed the result submission date. They had not suspended patient testing.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on lack of documentation, and interview with staff, the laboratory failed to verify the accuracy of 1 of 17 tests performed (ESR) twice annually for 2 years of records reviewed (2016 and 2017). The laboratory performs approximately 40 ESR tests daily. Finding include: 1. The laboratory lacked documentation of they had verified ESR test accuracy in 2016 and 2017. 2. Staff stated on 06/28/2018 at approximately 2:00 p.m. they did not have a procedure for verifying ESR accuracy.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on Micros 60 user's manual review, laboratory procedure manual review, and interview with staff, the procedure manual failed to include instructions for interpreting test results with instrument generated flags or alarms for 1 of 3 tests methods in use (complete blood cell counts {CBC} performed on the Micros 60). Finding include: 1. The Micros 60 user's manual identifies instrument flags that can be caused by instrument malfunction and/or blood sample abnormalities. The manuals states, "Important: All Anomalies and/or Abnormal distribution flags given by the ABX MICROS 60 should be Manually verified by the examination of a stained peripheral blood smear for the presence of pathological elements." 2. The laboratory procedure manual failed to include the course of action to take when CBC results contained flagged results. 3. In an interview on 06/29/2018 at approximately 1:00 p. m., staff stated there was no written protocol to follow with flagged results. Testing was usually repeated and results were sent to the electronic medical record (EMR) even if the flags remained on repeat analysis. Staff stated instrument flags did not cross over into the EMR and no comments were added to the result to alert the provider of potentially erroneous results. 4. Since the laboratory did not print results from the Micros 60 and flags did not cross over into the EMR, the surveyor could not determine how many patient results could have been affected.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)

	Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on procedure manual and method verification record review, and interview with staff, the laboratory director failed to sign and date as approved 2 of 2 new chemistry procedures put in use from 04/2016 to 06/2018. Finding include: 1. The laboratory began chemistry testing on the ACE Alera on 11/03/2016 and the Envoy 500+ on 09/14/2017. 2. The procedure manual lacked the director's signature and date of approval for both analyzers. 3. Staff stated on 06/28/2018 at approximately 12:00 p. m. the director had not signed the procedures indicating his approval for testing on the Alera or Envoy.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on manufacturer's instructions review, direct observation, and interview with staff, the laboratory failed to label 15 of 15 chemistry reagents loaded on the Envoy 500+ with the on-board stability date. The laboratory performs approximatley 40 chemistry test panels daily. Findings include: 1. The manufacturer's instructions state, once opened and loaded on the Envoy 500+ analyzer, reagents were only stable from 2-28 days (depending on the reagent). 2. The surveyor observed no open dates or revised expiration dates on reagents loaded on the analyzer to ensure they were not used past their on-board stability date. 3. Staff stated on 06/28/2018 at approximately 11:00 a.m., they did not always write the new expiration date on the reagent bottles when loaded on the analyzer and the instrument did not track and alert the operator when the on-board stability was exceeded.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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 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 calibration verification record review, and interview with staff, the laboratory failed to verify calibration at least every 6 months using a minimal, mid-point, and maximum value in their reportable range for 15 of 15 chemistry analytes tested for 2 years of records reviewed (02/2016-06/2018). The laboratory performs approximately 40 chemistry panels consisting of 15 analytes daily. Findings include: 1. Chemistry method verification documentation included documentation of calibration verification for 15 analytes included in the laboratory's chemistry panel as part of installation for the Alera on 11/03/2016 and the Envoy 500+ on 09/14/2017. 2. The laboratory failed to document calibration verification from 02/18/2016 until their original Envoy analyzer was replaced on 11/03/2016, failed to document calibration on the Alera analyzer from the install date of 11/03/2016 until it was replaced on 09/14 /2017, and failed to document calibration verification on the new Envoy 500+ analyzer from installation on 09/14/2017 until the survey date on 06/28/2018. 3. Staff stated on 06/28/2018 at approximately 12:00 p.m. they failed to perform calibration verification/linearity studies every 6 months on their chemistry analyzers.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on patient test record review, quality control (QC) record review, and interview with staff, the laboratory failed to test 2 levels of quality control each day of testing for erythrocyte sedimentation rate (ESR) testing on the Excyte analyzer for 1 of 6 days of testing reviewed. Finding include: 1. Patient test records document ESR patient testing performed on 01/10/2017. 2. ESR QC records failed to include documentation QC was performed on 01/10/2017. 3. Staff confirmed on 06/28/2018 at approximately 2:00 p.m. the laboratory had no record of ESR QC on 01/10/2018 This is a repeat deficiency.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The

	laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on quality control record review, lack of documentation, and interview with staff, the laboratory failed to document corrective actions taken for 2 of 6 days of patient testing reviewed when quality control results failed to meet the laboratory's establish criteria for acceptability. Finding include: 1. Quality control records on 01/10 /2017 document the red blood cell count (RBC) on 1 of 3 complete blood count (CBC) controls was outside the acceptable range (normal control). 2. Quality control records on 10/12/2017 document RBC, white blood cell count (WBC), hemoglobin (HGB), Hematocrit (HCT) and granulocyte number on 1 of 3 CBC controls were outside the acceptable range (high control). 3. Chemistry quality control records on 10 /12/2017 document results of level 1 albumin control was outside the acceptable range when repeated. 4. The laboratory lacked documentation of acceptable results on repeat testing or corrective action taken when quality control results failed to meet their acceptance criteria. 5. Staff stated on 06/28/2018 at approximately 2:00 p.m. laboratory policy required all 3 levels of CBC controls to be within the acceptable range.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on procedure manual review, Envoy maintenance chart review, lack of documentation, and interview with staff, the director failed to ensure quality assessment programs were maintained for 2 of 2 years of records reviewed (06/2016-06/2018). Finding include: 1. The laboratory procedure manual contained a quality assessment plan that included a quarterly report that was to be done one quarter/year with the data to be monitored and summarized on a monthly basis by administrator, lab director, or other specifically assigned personnel, and analyzed quarterly. 2. The laboratory lacked documentation of quarterly reports or other quality assessment activities for 2 of 2 years reviewed. 3. The chemistry Envoy maintenance chart includes weekly documentation of Levy Jennings (LJ) analyte graph review by the operator and monthly LJ print out for the director to review. 4. The laboratory lacked documentation of weekly operator LJ chart review for 22 of 36 weeks reviewed from 10/2017-06/2018. The laboratory lacked documentation of director monthly LJ review for 8 of 9 months of testing reviewed from 10/2017-06/2018. 5. Staff confirmed on 06 /28/2018 at approximately 1:00 p.m. the laboratory did not consistently document corrective actions taken when problems occur in the laboratory.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the technical consultant failed to document the performance of 1 of 1 testing personnel annually for 2 of 2 years reviewed (2016 and 2017). Findings include: 1. The laboratory lacked documentation competency had been assessed for hematology and chemistry testing personnel from 01/01/2016 to 06/28/2018. 2. In an interview with staff on 06/28/2018 at approximately 1:00 pm, staff stated the director/technical consultant usually wrote a letter attesting to the competency of testing staff. The laboratory failed to produce any documentation of competency assessment from 01/01/2016 to 06/28/2018.