

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0464254	<b>(X3) Date Survey Completed</b>  10/26/2018
<b>Name of Provider or Supplier</b>  Arthritis & Diabetes Clinic, Inc, The	<b>Street Address, City, State</b>  3402 Magnolia Cove, Monroe, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Certification Survey was performed on October 25, 2018 through October 26, 2018 at Arthritis & Diabetes Clinic, Inc. - CLIA ID # 19D0464254. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: I. Based on observation, record review and interview with personnel, the laboratory failed to have complete performance specification studies for the Bioscience TOSOH AIA-360 analyzer. Findings: 1. Observation by surveyor during the laboratory tour on October 25, 2018 revealed the laboratory utilizes the Bioscience TOSOH AIA-360 analyzer for Parathyroid (PTH) testing. 2. Review of the performance study records for the TOSOH AIA-360 revealed the laboratory performed accuracy, precision to include day to day and operator variance, and reference range; However, the laboratory did not include the following studies performed: a) Simple precision: run to run and within run b) Reportable Range 3. In interview on October 25, 2018 at 1:42 pm, the Technical Consultant/General Supervisor stated the field service representative performed the simple precision and linearity studies but the testing personnel did not participate in that testing. The Technical Consultant/General Supervisor confirmed the above findings. 4. Review of the Task 1 &amp; 3 form provided</p>

to surveyor revealed the laboratory performs one thousand two hundred eighty seven (1287) PTH tests annually. II. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance studies for the Sysmex XN-L 550 Hematology analyzer. Findings: 1. Observation by surveyor during the laboratory tour on October 25, 2018 revealed the laboratory utilizes the Sysmex XN-L 550 analyzer for Complete Blood Count (CBC) testing for the following analytes: \*White Blood Cell (WBC), Red Blood Cell (RBC), Hemoglobin (HGB), Hematocrit (HCT), Platelet (PLT), and Automated Differential 2. Review of the performance study records for the Sysmex XN-L 550 revealed the laboratory performed accuracy, precision, and reference range; However, the laboratory did not include the following: a) Reportable Range studies b) In-house data to support complete precision (day to day, run to run, within run, and operator variance) 3. In interview on October 25, 2018 at 2:46 pm, the Technical Consultant/General Supervisor stated she was unaware the laboratory did not retain all the in-house data to support the precision studies. The Technical Consultant/General Supervisor further stated the laboratory did not perform the studies for Reportable Range. 4. In further interview on October 25, 2018, the Technical Consultant/General Supervisor confirmed the above findings. 5. Review of the Task 1 & 3 form provided to surveyor revealed the laboratory performs 12,479 CBC tests annually. III. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance studies for the Siemens Dimension EXL 200 Chemistry analyzer. Findings: 1. Observation by surveyor during the laboratory tour on October 25, 2018 revealed the laboratory utilizes the Siemens Dimension EXL 200 analyzer for Chemistry testing for the following analytes: \* Albumin (ALB), Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Total Bilirubin (TBIL), Calcium (CA), Chloride (CL), High Density Lipoprotein (HDL), Cholesterol (CHOL), Creatine Kinase (CK), Carbon Dioxide (CO<sub>2</sub>), Creatinine (CREA), Glucose (GLUC), Iron (FE), Magnesium (MG), Phosphorus (PHOS), Potassium (K), Total Protein (TP), Sodium (NA), Total Iron Binding Capacity (TIBC), Triglyceride (TRIG), Blood Urea Nitrogen (BUN), Uric Acid (UA), Complement (C3/C4), C-Reactive Protein (CRP), Rheumatoid Factor (RF), Vitamin B12 (B12), Folate (FOL), Free Triiodothyronine (FT3), Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Vitamin D 25 OH 2. Review of the performance study records for the Siemens Dimension EXL 200 revealed the laboratory performed accuracy, reportable range and reference range. 3. Further review of the Dimension EXL 200 studies revealed the laboratory retained all in-house documentation for the precision studies; However, the laboratory did not document how complete precision was obtained from the in-house data. 4. In interview on October 25, 2018 at 3:06 pm, the Technical Consultant/General Supervisor stated the laboratory testing personnel performed the studies along with the field service representative. The Technical Consultant/General Supervisor further stated she was unaware complete precision was not documented. 5. In further interview on October 25, 2018, the Technical Consultant/General Supervisor confirmed the above findings. 6. Review of the Task 1 & 3 forms provided to surveyor revealed the laboratory performs the following tests annually: Albumin (ALB) -- 13213 Alkaline Phosphatase (ALP) -- 13213 Alanine Aminotransferase (ALT) -- 13213 Aspartate Aminotransferase (AST) -- 13213 Total Bilirubin (TBIL) -- 13213 Calcium (CA) -- 13213 Chloride (CL) -- 13213 High Density Lipoprotein (HDL) -- 1508 Cholesterol (CHOL) -- 1508 Creatine Kinase (CK) -- 8898 Carbon Dioxide (CO<sub>2</sub>) -- 13213 Creatinine (CREA) -- 13216 Glucose (GLUC) -- 13364 Iron (FE) -- 286 Magnesium (MG) -- 193 Phosphorus (PHOS) -- 13213 Potassium (K) -- 13213 Total Protein (TP) -- 13213 Sodium (NA) -- 13213 Total Iron Binding Capacity (TIBC) -- 292 Triglyceride (TRIG) -- 1508 Blood Urea Nitrogen (BUN) --

13213 Uric Acid (UA) -- 8873 Complement (C3/C4) -- 1661 C-Reactive Protein (CRP) -- 9137 Rheumatoid Factor (RF) -- 1038 Vitamin B12 (B12) -- 1771 Folate (FOL) -- 1692 Free Triiodothyronine (FT3) -- 2743 Free Thyroxine (FT4) -- 3268 Thyroid Stimulating Hormone (TSH) -- 3260 Vitamin D 25 OH -- 1260

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

**\*\*REPEAT DEFICIENCY\*\*** Based on record review and interview with personnel, the laboratory failed to ensure daily maintenance for the Inova Bio-Flash Immunology Analyzer was performed and documented for three (3) of four hundred fourteen (414) days reviewed. Findings: 1. Review of the Inova Bio-Flash Immunology analyzer's maintenance records indicated the laboratory was to perform and document daily maintenance to include the following: a) Load Cuvettes b) Add Fluids c) Initialize and Prime End of Day: d) Dispose of Cuvette Waste e) Dispose of Waste Fluid f) Clean Reagent and Sample Probes 2. Further review of the Inova Bio-Flash Immunology analyzer's maintenance records from September 1, 2017 through October 19, 2018 revealed the laboratory did not document the following daily maintenance: a) November 24, 2017 b) February 16, 2018 c) October 2, 2018 3. In interview on October 26, 2018 at 11:08 am, the Technical Consultant/General Supervisor stated she was not sure why the daily maintenance was not documented as performed for those days. The Technical Consultant/General Supervisor confirmed the daily maintenance was not documented for the three (3) days cited above.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues. Findings: 1. The laboratory failed to have complete performance specification studies for the Bioscience TOSOH AIA-360 analyzer. Refer to D5421 I. 2. The laboratory failed to have complete performance studies for the Sysmex XN-L 550 Hematology analyzer. Refer to D5421 II. 3. The laboratory failed to have complete performance studies for the Siemens Dimension EXL 200 Chemistry analyzer. Refer to D5421 III. 4. The laboratory failed to ensure daily maintenance for the Inova Bio-Flash Immunology Analyzer was performed and documented for three (3) of four hundred fourteen (414) days reviewed. Refer to D5429.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Findings: 1. The laboratory failed to have complete performance specification studies for the Bioscience TOSOH AIA-360 analyzer. Refer to D5421 I. 2. The laboratory failed to have complete performance studies for the Sysmex XN-L 550 Hematology analyzer. Refer to D5421 II. 3. The laboratory failed to have complete performance studies for the Siemens Dimension EXL 200 Chemistry analyzer. Refer to D5421 III.

**D6021**

**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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5793.

**D6023**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5429.

**D6036**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5429.

**D6040**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Findings: 1. The laboratory failed to have complete performance specification studies for the Bioscience TOSOH AIA-360 analyzer. Refer to D5421 I. 2. The laboratory failed to have complete performance studies for the Sysmex XN-L 550 Hematology analyzer. Refer to D5421 II. 3. The laboratory failed to have complete performance studies for the Siemens Dimension EXL 200 Chemistry analyzer. Refer to D5421 III.