

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0931266	(X3) Date Survey Completed 03/02/2021
Name of Provider or Supplier Arthritis Centers Of Texas	Street Address, City, State 3600 Gaston Ave Suite 100, Dallas, TX	
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
D0000	<p>An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records, laboratory records, and interview with staff, the</p>

laboratory failed to test chemistry PT samples in the same manner as it tested patient specimens for 4 of 5 specimens in the 1st Chemistry PT event of 2021. Findings included: 1. Review of the laboratory policy titled "Proficiency Testing"(Effective date June 15th, 2003) stated the following: "Procedure to Assure Satisfactory PT Performance PT samples should be tested just like patient samples." 2. Review of the laboratory policy titled "Critical Values"(Effective 4/6/04) stated the following: "...If a critical value is reached, follow these guidelines: 1. Repeat the test to confirm result ..." The policy failed to include critical values for Vitamin B12, Ferritin, and Folate analytes. 3. Review of the API 2021 Chemistry 1st Event revealed the following samples were part of the event: IA-01, IA-02, IA-03, IA-04 and IA-05. Of these samples, 4 of 5 had repeated tests results from the instrument and were not designated as critical values. The following PT sample/analytes were repeated: IA-01 1st run 11:20 a.m. Jan 21st 2021 Results: Vitamin B12- 1517 pg/mL Ferritin- 265 ng/mL Folate- 6.5 ng/mL 2nd run 13:31 a.m. Jan 21st 2021 Results: Vitamin B12- 1548 pg/mL Ferritin- 270 ng/mL Folate- 6.6 ng/mL The results reported, for sample IA-01, to the American Proficiency Institute for the 1st Chemistry PT event of 2021 were: Vitamin B12- 1517 pg/mL Ferritin- 265 ng/mL Folate- 6.6 ng/mL IA-02 1st run 11:20 a.m. Jan 21st 2021 Results: Vitamin B12- 184 pg/mL Ferritin- 27 ng/mL Folate- 0.8 ng/mL 2nd run 13:32 a.m. Jan 21st 2021 Results: Vitamin B12- 187 pg/mL Ferritin- Not repeated Folate- 0.7 ng/mL The results reported, for sample IA-02, to the American Proficiency Institute for the 1st Chemistry PT event of 2021 were: Vitamin B12- 187.0 pg/mL Folate- 0.8 ng/mL Ferritin- 27.0 ng/mL IA-03 1st run 11:20 a.m. Jan 21st 2021 Results: Vitamin B12- 1230 pg/mL Ferritin- 210 ng/mL Folate- 4.9 ng/mL 2nd run 13:33 a.m. Jan 21st 2021 Results: Vitamin B12- 1301 pg/mL Ferritin- Not Repeated Folate- 5.2 ng/mL The results reported, for sample IA-03, to the American Proficiency Institute for the 1st Chemistry PT event of 2021 were: Vitamin B12- 1230 pg/mL Ferritin- 210 ng/mL Folate- 4.9 ng/mL IA-04 1st run 11:20 a.m. Jan 21st 2021 Results: Vitamin B12- 851 pg/mL Ferritin- 148 ng/mL Folate- 3.3 ng/mL 2nd run 13:39 a.m. Jan 21st 2021 Results: Vitamin B12- Not repeated Ferritin-Not repeated Folate- 3.4 The results reported, for sample IA-04, to the American Proficiency Institute for the 1st Chemistry PT event of 2021 were: Vitamin B12- 851 pg/mL Ferritin- 148 ng/mL Folate- 3.4 ng/mL 4. In an interview with staff on 03/01/2021 at 12:34pm in an office area, the Laboratory Manager confirmed the PT samples were tested in duplicate. The Laboratory Manager stated their policy requires only critical patient results are repeated. However, these analytes, Vitamin B12, Ferritin, Folate, do not have defined critical ranges at their facility. The laboratory failed to follow its own policy for testing PT samples in the same manner as it tested patient specimens

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on review of the Sysmex XN-330 hematology analyzer laboratory policies, random review of patient records (02/02/2021 - 03/01/2021), and staff interview, it was revealed the laboratory failed to follow their own policy for 3 of 6 flagged Complete Blood Count (CBC) results. Findings included: 1. The laboratory policy

titled, "Sysmex XN-330 Flags" (signed by the laboratory director 01/30/2020) stated the following: "WBC flagsNeutropenia, Neutrophilia, Lymphopenia, Lymphocytosis, Monocytosis, Eosinophilia, and Basophilia: If the numerical (*) results are given then verify by repeat analysis and record flags under notes. If (--) are in place of numerical results after repeat then reflex to manual diff and record flags under notes ... PLT flags: PLT ABN Distribution, PLT clumps, PLT ABN Scattergram: Remix and repeat. If flag does not clear, then reflex to Plt scan. Record flags under notesRef: Sysmex XN-L Series Flagging Guide." Further review of laboratory policies revealed the policy titled, "Platelet Clumping Procedure" (signed by the laboratory director 10/24/2019). This policy stated, " ...If platelet clumps are flagged by the analyzer and/or identified on the blood smear, steps should be taken to eliminate the clumps because they can artificially decrease the platelet count. In addition, platelet clumps may count as leucocytes. The measured mean platelet volume (MPV) may also be affected. The first step to resolve platelet clumping is to recollect the sample in a non-EDTA tube, such as a blue-top sodium citrate tube. The platelet count is obtained from the sodium citrate tube and must be multiplied by 1.1 to account for the different blood-to-anticoagulant ratio in the citrate tube." 2. A random review of patient complete blood count reports from 02/02/2021 through 03/01/2021 revealed the laboratory failed to follow their own policy for the following 3 of 6 flagged CBC results: a. Patient 00323238 Results from Instrument: Test Date 02/02/2021; Test Time 13:14:54; PLT=225 Sysmex XN-330 Flag: PLT Abn Distribution Result on Patient Final Report: PLT=225 The laboratory failed provide documentation of repeat platelet testing per laboratory policy. b. Patient 00323411 Results from Instrument: Test Date 02/05/2021; Test Time 11:27:21; PLT=17 Sysmex XN-330 Flag: PLT Abn Distribution, Thromocytopenia Repeated Results from Instrument: Test Date 02/05/2021; Test Time 11:45:57; PLT=48 Sysmex XN-330 Flag: PLT Abn Distribution, Thromocytopenia Result on Patient Final Report: PLT=48.0, Verified by repeat analysis PLT Estimate=Normal PLT Morphology= Too many clumped platelets to get accurate count. Estimate in normal range. Few large plts. The laboratory failed to resolve platelet clumping by recollecting the sample in a blue-top sodium citrate tube, obtaining the platelet count from the sodium citrate tube and multiplying by 1.1 to account for the different blood-to-anticoagulant ratio in the citrate tube per laboratory policy. c. Patient 00324051 Results from Instrument: Test Date 03/01/2021; Test Time 10:12:14 Sysmex XN-330 Flag: Monocytosis Repeated Results from Instrument: Test Date 03/01/2021; Test Time 10:15:08 Sysmex XN-330 Flag: Monocytosis Result on Patient Final Report: Mono% 20.7; Verified by repeat analysis No manual differential blood smear testing was documented. The laboratory failed to record flags under notes or perform a manual differential per laboratory policy. 5. In an interview with the Technical Consultant on 03/02/2021 at 11:00am in the breakroom, after review of the records, confirmed the above findings. WORD KEY: ABN=Abnormal Mono=Monocyte PLT=Platelet

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

I. Based on direct observation, review of laboratory policies, operator's manual for the Sysmex XN-330 hematology analyzer (Revised June 2017), random review of laboratory environmental records (03/2020, 04/2020, 05/2020, 11/2020 and 12/2020), and staff interview, the laboratory failed to ensure room temperature ranges for the Hematology room were within manufacturer's specifications for 5 of 5 months. Findings included: 1. During a tour of the laboratory on 03/01/2021 at 10:05am the following laboratory instruments were observed in the Hematology room: Sysmex XN-330 hematology analyzer Excyte 40 Automated ESR (Erythrocyte Sedimentation Rate) analyzer. 2. The laboratory policy titled, "Reagent Management" (signed by the laboratory director 04/04/2019) stated, "Storage: Always follow manufacturer's instructions for storage conditions on each individual item. Establish acceptable temperature ranges, The laboratory must establish acceptable temperature ranges for applicable requirements: room temperature, refrigerator, and freezer. These ranges must accommodate the highest "low" and the lowest "high" in order to satisfy storage requirements for all reagents and analyzers to do this, make a list of temperature ranges for all test systems, and then choose the narrowest range to satisfy all acceptable storage temperatures. Document all temperatures on days that the lab is in operation. Perform corrective actions as needed." Further review of laboratory policies revealed the laboratory policy titled, "Excyte 40 Automated ESR Analyzer" (signed by the laboratory director 04/01/2019) stated, "Reagent Storage: Tubes should be stored at 4 - 25 CQuality Control Policy ESR: ...Controls are stored between 18 - 30 C ..." 3. The operator's manual for the Sysmex XN-330 hematology analyzer (Revised June 2017) Chapter 7 Reagents stated the following storage and usage temperatures for Sysmex XN-330 reagents: a. Cellpack DCL; storage temperature 2 to 35C; Usage temperature 15 to 35C b. Cellpack DST; storage temperature 2 to 35C; Usage temperature 15 to 30C c. Cellpack DFL; storage temperature 2 to 35C; Usage temperature 15 to 35C d. Sulfolyser; storage temperature 1 to 30C; Usage temperature 15 to 35C e. Lysercell WDF; storage temperature 2 to 35C; Usage temperature 15 to 35C f. Fluorocell WDF; storage temperature 2 to 35C; Usage temperature 15 to 35C g. Fluorocell RET; storage temperature 2 to 35C; Usage temperature 15 to 35C h. CellClean Auto; storage temperature 1 to 30C; Usage temperature 15 to 35C 4. A random review of laboratory environmental records (03/2020, 04/2020, 05/2020, 11/2020 and 12/2020) revealed the laboratory defined the room temperature acceptable range for the Hematology room as 2 - 30C. The laboratory failed to ensure room temperature ranges for the Hematology room were within manufacturer's specifications. 5. In an interview with the Technical Consultant on 03/01/2021 at 2:10pm in the breakroom, after review of the records, he agreed that the laboratory failed to ensure hematology room temperature ranges were within manufacturer's specifications. This confirmed the above findings. II. Based on direct observation, review of laboratory policies, manufacturer's instructions, random review of laboratory environmental records (03/2020, 04/2020, 05/2020, 11/2020 and 12/2020), and staff interview, the laboratory failed to ensure freezer ranges were within manufacturer's specifications for 5 of 5 months. Findings included: 1. During a tour of the laboratory on 03/01/2021 at 10:05am, a freezer was observed in the Chemistry area. The freezer contained the following control and calibration material: BioRad Liquichek Immunoassay Plus Controls BioRad Liquichek Immunoassay Controls Calibration material for Vitamin D and Creatinine Kinase 2. The laboratory policy titled, "Reagent Management" (signed by the laboratory director 04/04/2019) stated, "Storage: Always follow manufacturer's instructions for storage conditions on each individual item. Establish acceptable temperature ranges, The laboratory must establish acceptable temperature ranges for applicable requirements: room

temperature, refrigerator, and freezer. These ranges must accommodate the highest "low" and the lowest "high" in order to satisfy storage requirements for all reagents and analyzers to do this, make a list of temperature ranges for all test systems, and then choose the narrowest range to satisfy all acceptable storage temperatures. Document all temperatures on days that the lab is in operation. Perform corrective actions as needed." Further review of the laboratory policy revealed the following products and storage temperatures: Controls: BioRad Liquichek Immunoassay Plus Controls (Liquichek Immuno); storage temperature -20 to -70C BioRad Liquichek Immunoassay Controls (Liquichek Immuno+); storage temperature -20 to -70C Calibrators: Vitamin D (Vit D); storage temperature -25 to -15C Creatinine Kinase (CKI); storage temperature -25 to -15C 3. The manufacturer's instructions for BioRad Liquichek Immunoassay Plus Controls (2020-04, 4203-00) and BioRad Liquichek Immunoassay Controls (2018-02, 3200-00) stated, "Storage and Stability: This product will be stable until the expiration date when stored unopened at -20 to -70C." 4. A random review of laboratory environmental records (03/2020, 04/2020, 05/2020, 11/2020 and 12/2020) revealed the laboratory defined the freezer temperature acceptable range as -18 to -70C. The laboratory failed to ensure the freezer range was within manufacturer's specifications for reagents stored in the freezer. 5. In an interview with the Technical Consultant on 03/02/2021 at 11:00am in the breakroom, after review of the records, he agreed that the laboratory failed to ensure freezer ranges were within manufacturer's specifications. This confirmed the above findings.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:
Based on review of laboratory's verification studies for the Siemens Dimension EXL (Serial Number DR272524), the laboratory's reportable ranges, and staff interview, it was revealed the laboratory failed to ensure the reportable ranges for 10 of 31 analytes in use were verified by the laboratory's verification studies. Findings included: 1. Review of the verification studies for the Siemens Dimension EXL chemistry analyzer (Serial Number DR272524) performed on 06/01/2020 - 06/05/2020 revealed the following proven reportable ranges: a. Aspartate Aminotransferase 8.333 - 914.00 b. Calcium 1.967 - 13.333 c. Chloride 54.00 - 166.00 d. Complement C3 18.333 - 392.333 e. Complement C4 5.40 - 99.200 f. C-Reactive Protein 0.3333 - 11.4333 g. Sodium 50.33 - 164.33 h. Thyroxine 0.633 - 18.433 i. Thyroid Uptake 17.00 - 61.67 j. Triglycerides 21.00 - 482.00 2. A review of the laboratory's reportable ranges for analytes tested on the Siemens Dimension EXL chemistry analyzer revealed the following reportable ranges in use were not proven by the laboratory's verification studies. a. Aspartate Aminotransferase Reportable range in use: 0.00 - 1000.00 Verification Study results: 8.333 - 914.00 b. Calcium Reportable range in use: 5.00 - 15.00 Verification Study results: 1.967 - 13.333 c. Chloride Reportable range in use: 50.0 - 200.0 Verification Study results: 54.00 - 166.00 d. Complement C3 Reportable range in use: 10.00 - 350.00 Verification Study results: 18.333 - 392.333 e.

Complement C4 Reportable range in use: 5.00 - 140.00 Verification Study results: 5.40 - 99.200 f. C-Reactive Protein Reportable range in use: 0.200 - 12.000 Verification Study results: 0.3333 - 11.4333 g. Sodium Reportable range in use: 50.0 - 200.0 Verification Study results: 50.33 - 164.33 h. Thyroxine Reportable range in use: 0.50 - 24.00 Verification Study results: 0.633 - 18.433 i. Thyroid Uptake Reportable range in use: 15.0 - 68.0 Verification Study results: 17.00 - 61.67 j. Triglycerides Reportable range in use: 15.0 - 1000.0 Verification Study results: 21.00 - 482.00 3. In an interview with the Technical Consultant on 03/02/2021 at 10:30am in the breakroom, after review of the records, he agreed that the studies performed did not support the reportable ranges in use by the laboratory. This confirmed the above findings.