

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0969376	(X3) Date Survey Completed 07/13/2023
Name of Provider or Supplier Arizona Arthritis & Rheumatology Associates	Street Address, City, State 5681 W Beverly Lane Ste 101, Glendale, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of 2021 and 2022 chemistry proficiency testing (PT) results and interview with the technical consultant, the laboratory failed to successfully participate in PT. See D-tag 2096; unsatisfactory performance in two out of three Total Bilirubin PT challenges.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of chemistry proficiency testing (PT) results for 2021 and 2022 and interview with the technical consultant, the laboratory failed to achieve satisfactory performance for Total Bilirubin (TBIL) in two out of three PT events. Findings: 1. Review of chemistry PT results for the third event of 2021 revealed the laboratory obtained an unacceptable score of 60 percent for TBIL. 2. Review of chemistry PT results for the second event of 2022 revealed the laboratory obtained an unacceptable score of 20 percent for TBIL. 3. Interview with the technical consultant on July 13, 2023 at 11:30 AM confirmed the laboratory failed to achieve satisfactory performance for TBIL in two out of three testing events.

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 review of the procedure manual and interview with the technical consultant (TC), the laboratory failed to have a step by step procedure for instrument comparisons. Findings: 1. Review of the procedure manual showed no procedure for instrument comparisons. 2. Interview with the TC on July 13, 2023 at 11:30 AM confirmed the laboratory failed to have a step by step procedure for performing instrument comparisons.

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 observation of the reagent refrigerator located in the laboratory and interview with the technical consultant (TC), the laboratory failed to label one of one bottle of Hepatitis C virus (HCV) quality control (QC) with the preparation and expiration dates. Findings: 1. Observation of the reagent refrigerator located in the laboratory showed one bottle of HCV control lot #42480BE00 opened and in use with no preparation (open date) and expiration date. 2. Interview with the TC on July 13, 2023 at 11:00 AM confirmed the laboratory failed to label the HCV control with a preparation and expiration date. 3. The laboratory reports approximately 8,760 HCV patient results annually.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Review of 2021, 2022 instrument comparisons for immunology testing and interview with the technical consultant (TC), the laboratory failed to perform comparisons for two of three Gold Standard Thunderbolt analyzers. Findings: 1. Review of 2021, 2022 instrument comparisons revealed no documentation for Gold Standard Thunderbolt #TB018 and #TB019. 2. Interview with the TC on July 13, 2023 at 11:30 AM confirmed the laboratory failed to perform instrument comparisons for two of three Gold Standard Thunderbolt analyzers. 3. The laboratory results approximately 89,360 immunology patient results annually.

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on review of approved reference ranges in the laboratory procedure manual, five of five patient reports, and interview with the technical consultant, the laboratory failed to ensure the test report included pertinent normal ranges as determined by the laboratory. 11 of the 21 routine chemistry parameters and 18 of 20 complete blood cell (CBC) parameters listed on the laboratory information system (LIS) report differed from those in the approved procedure manual. Findings: 1. Review of five of five patient reports from the LIS system revealed 11 of the 21 routine chemistry parameters and 18 of 20 complete blood cell (CBC) parameters failed to correctly match those reference ranges in the procedure manual. LIS report Procedure WBC 4.1-10.9 3.70-10.1 RBC 4.2-6.3 4.06-4.69 Hemoglobin 11.5-16.0 12.9-14.2 Hematocrit 37.0-51.0 37.7-53.7 MCV 80.0-97.0 81.1-96.0 MCH 26.0-32.0 27.0-31.2 MCHC 31.0-

36.0 31.8-35.4 Platelets 140-440 155-366 Neutrophil absolute 2.0-6.9 1.63-6.96
Lymphocyte absolute 0.6-3.4 1.09-2.99 Monocyte absolute 0.0-0.9 0.240-0.790
Eosinophil absolute 0.0-0.7 0.030-0.440 Basophil absolute 0.0-0.2 0.00-0.080
Neutrophil % 37.0-80.0 39.3-73.7 Lymphocyte % 10.0-50.0 18.0-48.3 Monocyte %
0.0-12.0 4.40-12.7 Eosinophil % 0.0-7.0 0.600-7.30 Basophil % 0.0-2.5 0.00-1.70
BUN 7-17 males-8.4-25.7 females-7.0-20.0 Creatinine 0.5-1.0 males-0.72-1.25
females-0.57-1.11 Glucose 74-106 75-105 Sodium 137-145 136-145 Total Bilirubin
0.2-1.3 0.2-1.2 Total Protein 6.3-8.2 6.4-8.3 Globulin 1.5-4.5 no value Anion Gap 7.0-
34.0 no value A/G Ratio 0.6-2.2 no value Bun/Creat 8.0-36.0 no value TSH 0.4-4.9
0.35-4.94 2. Interview with the TC on July 13, 2023 at 11:00 AM confirmed the
laboratory failed to ensure correct reference ranges approved in the procedure manual
were included on the LIS patient report. 3. The laboratory reports out approximately
762,000 chemistry and 29,000 hematology tests annually.