

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0892372	(X3) Date Survey Completed 11/01/2022
Name of Provider or Supplier Rheumatic Disease Center Physicians Sc	Street Address, City, State 150 N River Rd, Des Plaines, IL	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical consultant (TC); the laboratory failed to outline all components of the testing procedures for two of two analytical systems; the Ace Axcel analyzer (clinical chemistry), and the CDS / Medonic M-series analyzer (hematology) in 2020, 2021, and 2022. Findings Include: 1. Review of laboratory records (2020, 2021, and 2022) revealed the laboratory's "Ace Axcel Operating Procedure" failed to outline the following required components of the testing procedures for albumin, alkaline phosphatase, alanine transaminase (ALT), aspartate aminotransferase (AST), blood urea nitrogen (BUN), calcium, carbon</p>

dioxide (CO₂), chloride, creatinine, globulin, glucose, magnesium, potassium, sodium, total bilirubin, total protein and C-Reactive Protein: a. Requirements for specimen transportation and referral; and criteria for specimen acceptability and rejection. b. Step-by-step performance of the procedure and interpretation of results. c. Preparation of slides, solutions, calibrators, reagents, stains, and other materials used in testing. d. Calibration and calibration verification procedures. e. The reportable range for test results for the test system as established or verified. f. Control procedures. g. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. h. Limitations in the test methodology, including interfering substances. i. Reference intervals (normal values). j. Imminently life-threatening test results, or panic or alert values. k. Pertinent literature references. l. 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. 2. Review of laboratory records (2021 and 2022) revealed the laboratory's "Laboratory Procedures Monday through Thursday (CDS / Medonic M-series Hematology Analyzer)" failed to outline the following required components of the testing procedures for red blood cells, white blood cells, platelets, hemoglobin, hematocrit, and automated differentials: a. Requirements for specimen transportation and referral; and criteria for specimen acceptability and rejection. b. Interpretation of results. c. Preparation of slides, solutions, calibrators, reagents, stains, and other materials used in testing. d. The reportable range for test results for the test system as established or verified. e. Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. f. Limitations in the test methodology, including interfering substances. g. Reference intervals (normal values). h. Imminently life-threatening test results, or panic or alert values. i. Pertinent literature references. j. 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. 3. On 11/01/2022 at 9:57 a.m., the TC confirmed the above findings.

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 review of laboratory records, patient testing reports (PTR), and interview with the technical consultant (TC), the laboratory failed to ensure two of two procedures manuals were approved and signed by the laboratory director before use in hematology, and general chemistry testing from 2020 to date of survey in 2022. Findings Include: 1. Review of laboratory records revealed the laboratory director failed to approve, sign, and date two of two laboratory procedures in use for testing Complete Metabolic Profile (CMP) C-Reactive Protein (CRP), and Complete Blood Count (CBC). a. "Ace Axcel Operating Procedure"- Approved Date: November 1, 2016. Effective Date: September 26, 2016. Prepared by: TC. Approved by: TC. b. "Laboratory Procedures Monday through Thursday (CDS / Medonic M-series Hematology Analyzer)" 2. Review of eight patient reports revealed the following: a. CMP - Total volume of 116 analytes tested b. CRP - Total volume of five antibodies tested c. CBC - Total volume of 40 hematological tests 3. On 11/01/2022, at 11:30 a.m., the TC confirmed the above findings. TEST KEY: CMP = albumin, alkaline phosphatase, alanine transaminase (ALT), aspartate aminotransferase (AST), blood

urea nitrogen (BUN), calcium, carbon dioxide (CO₂), chloride, creatinine, globulin, glucose, magnesium, potassium, sodium, total bilirubin, and total protein CBC = red blood cells, white blood cells, platelets, hemoglobin, hematocrit, and automated differential CRP = C-Reactive Protein

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 records, patient testing reports (PTR), and interview with the technical consultant (TC), the laboratory failed to verify the manufacturer's accuracy, precision, and reportable range for the Medonic Hematology Analyzer (2021 and 2022). Findings Include: 1. Review of laboratory records revealed a Medonic M Series Method Validation Evaluation, Instrument Serial #: 48527, Installation Date: 01/14/2021. a. "NOTE: Linearity Material: CDS Reportable Range Verification Kit, Lot #: 2009 - 101, Exp. Date: 4 - Feb - 21. NOTE: Linearity Material is used for Accuracy, Precision and Reportable Range validation." b. "Instructions: #3 - Reference Range Validation: The Laboratory Medical Director must examine all reference ranges provided by the manufacturer and determine if they are appropriate for the lab's patient population." c. "Instructions: #4 - The Lab Director must sign and date below to indicate all documents have been reviewed and accepted." d. "I have evaluated the validation data for this analyzer and find the accuracy, precision, and linearity/reportable range __ are __ are not within the limits stated by the manufacturer." e. "I __ do __ do not approve this instrument for use in this lab." 2. Surveyor review revealed the laboratory director failed to sign and date the Medonic M Series Method Validation Evaluation listed in Finding one. 3. Review of patient testing reports (PTR) revealed five patients tested for complete blood counts (CBC) in 2021 and 2022 using the analyzer listed in Finding one. a. Date Reported: 01/19/2021 - PTR: #31370 - Test: CBC b. Date Reported: 02/24/2021 - PTR: #41287 - Test: CBC c. Date Reported: 02/24/2021 - PTR: #30967 - Test: CBC d. Date Reported: 07/06/2021 - PTR: #21257 - Test: CBC e. Date Reported: 05/19/2022 - PTR: #20126 - Test: CBC 4. On 11/01/2022 at 9:57 a.m., interview with the TC revealed the Medonic Hematology Analyzer Serial #: 48527 in use on 01/18/2021. The TC also confirmed the above findings.

D5479

CONTROL PROCEDURES

CFR(s): 493.1256(e)(5)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on review of laboratory records, patient testing reports (PTR), and interview with the technical consultant (TC), the laboratory failed to follow the manufacturer's specifications for documenting control reagents for one of ten testing dates reviewed for C-Reactive Protein (CRP) in 2020, 2021, and 2022. Findings Include: 1. Review of the "CRP For the Quantitative Determination of C-Reactive Protein (CRP) in Serum (Cat. No. KAI-026) K-ASSAY" package insert revealed the following: a. "QUALITY CONTROL - It is recommended that commercially available control serum with known concentration of CRP be included in all assay runs." 2. Review of the CRP quality control records on dates 11/02/2020, 11/05/2020, 11/09/2020 thru 11/12/2020, 11/24/2020, 01/18/2021, 07/06/2021, and 05/19/2022 revealed the laboratory failed to document the assay quality control results for one of ten CRP run dates. a. No CRP assay quality control documented for patient test date 11/24/2020. 3. Review of the dates listed in finding two revealed the laboratory failed to document quality control values for CRP testing on 11/24/2020 affecting one of one patients tested. a. Date Reported: 11/24/2020 - PTR: #40685 - Test: CRP 4. Interview with the TC on 11/01/2022 at 1:30 p.m., confirmed the above findings.

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 review of laboratory records, patient testing reports (PTR), and interview with the technical consultant (TC), the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for the Medonic Hematology Analyzer (2021 and 2022). Refer to D5421.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
 Based on review of laboratory records, lack of documentation, patient testing reports (PTR), and interview with the technical consultant (TC); the laboratory director failed ensure that approved procedures manuals were available to all testing personnel for the analytical systems utilized for testing hematology and general chemistry patient samples from 2020 to the date of survey in 2022. Refer to D5403 and D5407.