

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D0993828	<b>(X3) Date Survey Completed</b> 01/07/2020
<b>Name of Provider or Supplier</b> Carolina Arthritis Center	<b>Street Address, City, State</b> 2355 Hemby Lane, Greenville, NC	
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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) Levey-Jennings (LJ) records and interview with general supervisor (GS) 1/7/20, the laboratory failed to retain all daily QC records for the hematology and chemistry testing performed. Findings: The laboratory performs hematology testing on the Medonic M-series analyzer and chemistry testing on the Medica Easy RA analyzer. The laboratory prints LJ reports as documentation of daily QC for the hematology and chemistry analyzers. 1. Review of LJ reports for the Medonic M-series hematology analyzer revealed the following dates in which LJ reports were not printed and retained: a. June 18 through June 24, 2019. b. July 26, through August 2, 2019. August 2, 2019. 2. Review of LJ reports for the Medica Easy RA chemistry analyzer revealed the following dates in which LJ reports were not printed and retained: a. October 30 through December 10, 2018. b. January 18 through January 21, 2019. c. May 10 through May 18, 2019. d. June 19 through June 24, 2019. e. July 26 through August 4, 2019. Interview with GS at approximately 3:00 p.m. confirmed the LJ reports were not printed and retained, she stated that some of the dates in question may have been on the weekend in which daily QC would not have been run as the laboratory was closed on weekends.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, review of personnel records, and interview with clinical consultant (CC) 1/7/20, the laboratory failed to establish written policies and procedures for evaluating the competency of providers who perform microscopy and the GS. Findings: 1. Review of the laboratory's procedure manual revealed it did not include a written policy or procedure for evaluating the competency of providers who perform microscopic examinations of synovial fluid for the presence of crystals. During interview at approximately 12:40 p. m., the CC confirmed the laboratory did not have a written competency evaluation policy for providers. 2. Review of personnel records revealed the GS had a performance review in February 2019 which included items such as communication, dependability, job knowledge, and teamwork. The GS also had a competency evaluation of her technical skills in April 2019. There was no written policy or procedure for evaluation of the GS delegated responsibilities, and there was no documentation the laboratory director evaluated her competency as a general supervisor in 2019.

**D5211**

EVALUATION OF PROFICIENCY TESTING PERFORMANCE  
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, review of 2017, 2018, and 2019 American Proficiency Institute (API) proficiency testing records and interview with GS 1/7/20, the laboratory failed to evaluate ungraded proficiency testing results. The laboratory's "Proficiency Testing" procedure states "... 12. ... d. All ungraded challenges must be reviewed against the Participant Summary to evaluate the lab's performance, with comments made on the result form indicating acceptability of results. ..." Review of 2017, 2018, and 2019 API proficiency testing results revealed the laboratory failed to document evaluation of ungraded samples on the following test events: 1. 2017 Immunology 3rd event; 2. 2018 Immunology 1st and 3rd events; 3. 2019 Immunology 1st, 2nd, 3rd events. During interview at approximately 3:00 p.m. the GS stated they review all proficiency testing results, but she was unaware they needed to document evaluation of ungraded results.

**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 review of a random patient test report (#8945), review of 2018 and 2019 American Proficiency Institute (API) and College of American Pathologists (CAP) proficiency testing records, the absence of verification records, and interview with the GS 1/7/20, the laboratory failed to enroll in proficiency testing or establish a system to

verify the accuracy of the microscopic synovial fluid examinations at least twice a year. Review of a random patient test report (ID #8945) revealed the test report included a synovial fluid examination. The test report stated "Assessment and Plan ... s /p inj right knee 1/7/20 - no crystals seen ...". Review of 2018 and 2019 API and CAP proficiency testing records revealed the laboratory was not enrolled in proficiency testing for the microscopic synovial fluid examinations for the presence of crystals performed by providers. There were no records available to demonstrate that the laboratory had a system in place to verify the accuracy of the microscopic synovial fluid examinations for the presence of crystals at least twice a year. During interview at approximately 3:30 p.m., the GS confirmed that the providers perform microscopic synovial fluid examinations for the presence of crystals.

**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 laboratory's policies and procedures, review of a random patient test report (ID #8945), and interview with the GS 1/7/20, the laboratory's procedure manual was not complete and current for the testing performed. Review of the laboratory's procedure manual revealed it did not include a procedure for the microscopic examination of synovial fluid for the presence of crystals. Review of a random patient test report (ID #8945) revealed the test report included a synovial fluid examination. The test report stated "Assessment and Plan ... s/p inj right knee 1/7/20 - no crystals seen ...". During interview at approximately 3:30 p.m., the GS confirmed that the providers perform microscopic synovial fluid examinations for the presence of crystals. She stated the laboratory performed 29 microscopic synovial fluid examinations for the presence of crystals in 2019.

**D5411**

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

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as

determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on review of operator's manual, review of 2018 and 2019 analyzer maintenance records, review of manufacture's instructions, surveyor observation and interview with GS 01/07/20, the laboratory failed to document required maintenance for the Dynex DSX immunology analyzer and failed to follow specimen centrifuge requirements for testing performed on the Dynex DSX immunology analyzer. Findings: 1. Review of operator's manual for the Dynex DSX analyzer revealed the following, "Chapter 10 Service and Maintenance...Routine Maintenance Procedures...Daily Maintenance... verify that the self-test passes...verify the washer does not have clogs...Dynex recommends creating an assay to test the washer...this assay should be run at beginning of each shift...Shutdown the system...Dynex recommends creating an assay flush the wash head with distilled/deionized water as part of the daily shutdown procedure...Empty and clean the tip waste container...Clean all plate drawers and external surfaces, using ...Clean the pipette tip, using...Purge the washer with 50 milliliters (mL) of deionized water...Weekly maintenance...Empty the wash buffer containers and clean them with disinfectant or ...Six-month maintenance...Replace the dispense tubing...Replace the aspiration tubing..". Review of Dynex DSX analyzer 2018 and 2019 maintenance records revealed no documentation of daily and weekly maintenance. Interview with GS at approximately 3:00 p.m. confirmed daily and weekly maintenance had not been documented for 2018 and 2019. She stated that they do the maintenance, and the analyzer would not run if the daily self-test did not pass, but they had not documented it. 2. Review of manufacturer's instructions for Rheumatoid Factor (RF), and Anti-Nuclear Antibody (ANA) Screen revealed the following under Section II, "Specimen Collection and Handling...For separation of the serum, the sample is centrifuged for 10 minutes at approximately 2000 revolutions per minute (rpm)...". The laboratory utilizes a reference laboratory centrifuge to also process specimens for in-house testing. The reference laboratory maintains and sets the centrifuge specifications. Surveyor observed that the specification label on the centrifuge states 15 minutes at 3352 rpm. Interview with GS at approximately 3:30 p. m. confirmed the laboratory utilizes the reference laboratory's centrifuge to process specimens for in-house testing. She stated she was unaware the centrifuge settings were different than the manufacturer's recommendations.

**D5417**

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation 1/7/20, the laboratory failed to discard supplies that exceeded their expiration dates. During a tour of the laboratory at approximately 2:30 p.m., the surveyor observed the following supplies in the laboratory's refrigerator, available for use: 1. 1 box of GC1 Calibration Verification Test Set (lot #11AG26218), expiration date 9/24/19; 2. 1 box Boule Cal (lot #21909-44) expiration date 11/29/19.

**D5781**

CORRECTIVE ACTIONS  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, review of 2018 and 2019 temperature and humidity logs, and interview with the GS 1/7/20, the laboratory failed to perform and document corrective action for the incubator temperatures outside acceptable limits. The laboratory's "Quality Assessment" policy states on page 3 "TEMPERATURE, HUMIDITY MONITORING, and EYEWASH MAINTENANCE The lab must ensure that temperature requirements for instruments and testing are met, that storage temperatures for reagents and controls and calibrators are maintained within range, and that humidity levels are within acceptable limits for operation of any instrumentation. ... any corrective actions needed for out-of-range results will be documented on a log. ..." Review of 2018 and 2019 temperature and humidity logs revealed the laboratory failed to document corrective action for incubator temperatures outside the acceptable range of 37 degrees Celsius +/- 1. Examples: 1. March 1 and 4, 2019 when the incubator temperature was 35.5 degrees Celsius; March 26, 2019 when the incubator temperature was 35.7 degrees Celsius; March 13 and 27, 2019 when the incubator temperature was 35.8 degrees Celsius; and March 8, 21, and 29, 2019 when the incubator temperature was 35.9 degrees Celsius; 2. April 23, 2019 when the incubator temperature was 35.7 degrees Celsius, and April 3, 9, 10, 11, 16, 17, 18, 24, and 30, 2019 when the incubator temperature was 35.9 degrees Celsius; 3. May 15, 2019 when the incubator temperature was 35.8 degrees Celsius, and May 1, 2, 3, 6, 7, 9, 10, and 16, 2019 when the incubator temperature was 35.9 degrees Celsius; 4. July 23, 2019 when the incubator temperature was 35.7 degrees Celsius; 5. September 17, 18, 19, 25, and 27, 2019 when the incubator temperature was 35.9 degrees Celsius. During interview at approximately 3:40 p.m., the GS stated that they don't usually have problems with the incubator temperature. She stated that the temperature was probably adjusted but the adjustment was just not documented on the log.