

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0267193	(X3) Date Survey Completed 03/17/2021
Name of Provider or Supplier Arthritis & Osteoporosis Treatment Center Pa	Street Address, City, State 2100 Kingsley Ave, Orange Park, FL	
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	At the time of the on-site recertification survey, Arthritis and Osteoporosis Treatment Center was found to NOT be in compliance with the CLIA laboratory requirements of 42 CFR 493. .
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory did not have documentation of signed attestations for two of three events reviewed in 2020. The findings include: Review of the WSLH proficiency records for 2020 showed the Laboratory Director or Designee had not signed the attestations for Hematology events "HemeReg1" and "HemeReg2". During an interview with Laboratory Manager on 3/17/21 at 3:00 PM, it was confirmed the Laboratory Director had not signed the attestations for the two events. .</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two</p>

years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to retain the Cell-Dyn 1800 instrument reports for their proficiency testing results for 1 of 5 events reviewed in 2019 and 2020. The findings include: A record review of the WSLH proficiency test events for 2019 and 2020 showed that no records from the instrument (Cell-Dyn 1800) used to perform the Complete Blood Count (CBC) was maintained for the 3rd event in 2020. An interview with the Laboratory Manager on 3/17/21 at 3:00 PM confirmed that the records from the Cell-Dyn 1800 were missing. .

D5200

GENERAL LABORATORY SYSTEMS
CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on record review and interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory system and correct identified problems in 2019 - 2020. The findings include: 1. The laboratory failed to document evaluation of proficiency testing results that were ungraded for 5 of 5 testing events reviewed (2019-2020). Cross Reference D5215 2. The laboratory's quality assessment (QA) program failed to assess and correct problems with proficiency testing (PT) of white blood cells, red blood cells, and hematocrit during events in 2019 and 2020. Cross Reference D5291 .

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:
Based on review of WSLH (Wisconsin State Laboratory of Hygiene) proficiency testing results and staff interview, the laboratory failed to document evaluation of proficiency testing results that were ungraded for 5 of 5 testing events reviewed (2019-2020). The findings include: 1. Review of WSLH proficiency testing (PT) results in the 2nd testing event of 2019 showed a comment of "Not scored - Insufficient peer group" for Leukocytes (WBC), Erythrocytes (RBC), and Hematocrit (HCT). 2. Review of WSLH proficiency testing results in the 3rd testing event of 2019 showed a

comment of "Not scored - Insufficient peer group" for RBC and HCT. 3. Review of WSLH proficiency testing results in the 1st testing event of 2020 showed a comment of "Not scored - Insufficient peer group" for HCT. 4. Review of WSLH proficiency testing results in the 2nd testing event of 2020 showed a comment of "Not scored - Insufficient peer group" for RBC and HCT. 5. Review of WSLH proficiency testing results in the 3rd testing event of 2020 showed a comment of "Not scored - Insufficient peer group" for RBC and HCT. The PT program assigned an artificial score of 100% due to the insufficient peer group. The instructions provided by WSLH indicated a self-evaluation must be performed. There was no documentation showing the laboratory performed the required self-evaluation of the analytes. During an interview on 3/17/21 at 3:30 PM, the Laboratory Manager confirmed that the laboratory did not evaluate the ungraded scores. .

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory's quality assessment (QA) program failed to assess and correct problems with proficiency testing (PT) of white blood cells, red blood cells, and hematocrit during events in 2019 and 2020. The findings include: The review of the laboratory's QA records showed the laboratory did not monitor the review of proficiency test results. The review of PT results indicated 5 events with scores of "Not scored - Insufficient peer group". The interview with the Laboratory Manager on 3/17/21 at 3:00 PM confirmed the QA program did not identify the PT error. .

D5400

ANALYTIC SYSTEMS

CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on record review, and interview with laboratory staff, the laboratory did not meet the condition of analytic systems. Findings include: 1. The laboratory failed to identify that the room temperature range established to run the Cell- Dyn 1800 was outside the required operating temperature range for two of two years reviewed. (2019-2020). Cross Reference to D5413 2. The laboratory failed to ensure that the Cell-Dyn 1800 analyzer was calibrated at a minimum of every 6 months. Cross Reference D5439 3. The laboratory failed to have an effective QA program that identified or corrected problems with calibration records of the Cell-Dyn 1800 and room temperature documentation. Cross Reference D5791 .

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:

Based on record review and interview, the laboratory failed to identify that the room temperature range established to run the Cell- Dyn 1800 was outside the required operating temperature range for two of two years reviewed. (2019-2020) The findings include: The Cell-Dyn 1800 Operators Manual states in Section 2-4 "To ensure the instrument and reagents function properly, it is important to maintain the temperature between 68F and 86F (20C and 30C). The review of the laboratory room temperature logs indicated a "Normal Temperature Range" of 59F and 86F. Between the months of April 2019 and March 2021, the laboratory recorded a range below 68F 236 times. The interview with the Laboratory Manager on 3/17/21 at 3:00 PM, it was confirmed the laboratory was not monitoring room temperature based on manufacturers instructions. .

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure that the Cell-Dyn 1800 analyzer was calibrated at a minimum of every 6 months. The findings include: Review of calibration verification records for the hematology analyzer

	<p>showed that calibration verifications were performed on 6/13/2019, 2/11/20, 6/8/20, and 2/22/21. The interview with the Laboratory Manager on 3/17/21 at 3:00 PM confirmed the calibrations were not performed every 6 months. .</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review of Quality Assessment (QA) documents and interview with laboratory staff, the laboratory failed to have an effective QA program that identified or corrected problems with calibration records of the Cell-Dyn 1800 and room temperature documentation. The findings include: The review of the laboratory's QA records showed the laboratory did not monitor the timeliness of calibrations performed on the Cell-Dyn 1800. The QA program failed to identify the wrong temperature range was used to monitor the operating room temperature of the Cell-Dyn 1800. The interview with the Laboratory Manager on 3/17/21 at 3:00 PM confirmed the QA program did not identify the errors. .</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview the Laboratory Director failed to ensure the proficiency testing reports of "not graded" were evaluated (See D6018), and failed to ensure the Cell-Dyn was operated at the correct room temperature and calibrations were performed every 6 months (See D6023). .</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Directory failed to identify problems in proficiency testing (PT) that required corrective action. The findings</p>

include: The PT results were signed by the Laboratory Director indicating the results were reviewed. The laboratory failed to perform a self-evaluation on the required "Not Graded" analytes. During an interview on 3/17/21 at 3:30 PM, the Laboratory Manager confirmed that the laboratory did not evaluate the ungraded scores. .

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, the Laboratory Director failed to ensure the Cell-Dyn was operated at the correct room temperature and calibrations were performed every 6 months. The findings include: The Laboratory Director failed to identify an incorrect room temperature range was being used as "Normal Temperature Range" for the operation of the Cell-Dy 1800 hematology analyzer. The Laboratory failed to identify that calibrations of the Cell-Dyn 1800 were performed every 8 months instead of the required 6 months. The 3/17/21 interview with the Laboratory Manager at 3:30 PM confirmed the errors were not identified by the Lab Director.