

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 36D0340535	<b>(X3) Date Survey Completed</b> 02/14/2024
<b>Name of Provider or Supplier</b> Crystal Arthritis Center, Inc	<b>Street Address, City, State</b> 471 North Cleveland-Massillon Road, Akron, OH	
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>D2087</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Technical Supervisor (TS), the laboratory failed to achieve a proficiency testing (PT) score of 80% (percent) for the analyte sodium (Na) for the third PT event in 2023 in the specialty of Chemistry. This deficient practice had the potential to affect 53 out of 53 patient Na test results from the second PT event in 2023 to the first PT event in 2024. Findings Include: 1. Review of the laboratory's "Crystal Clinic, Inc. Laboratory Standard Operating Procedures" manual, approved by the Laboratory Director via signature and date on 12/05/2021 and provided on the date of the inspection, found a policy titled "Survey Policy" and did not find any mention of review and evaluation of the College of American Pathologists (CAP) PT Evaluation report of results and scoring. 2. Review of the laboratory's CAP Chemistry PT documentation from the third testing event of 2023, provided on the date of the inspection, revealed the following unsatisfactory analyte testing score: Third PT Event 2023 Na; 20% CHM-12 (by TP#1); unacceptable CHM-13 (by TP#3); unacceptable CHM-14 (by TP#3); unacceptable CHM-15 (by TP#3); unacceptable 3. The TS confirmed the unsatisfactory Na PT score in the third testing event of 2023. The interview occurred on 02/14/2024 at 9:45 AM. TP; Testing Personnel</p>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and</p>

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 record review, direct observation and an interview with the Technical Supervisor (TS), the laboratory failed to label the secondary containers of reagents, solutions and stains in the manual differential (mdiff) slide stain station with their contents, lot numbers and expiration dates, which were utilized for high complexity white blood cell (WBC) mdiff testing procedures performed in the specialty of Hematology. This deficient practice had the potential to affect two out of two manual WBC performed from the last CLIA inspection on 02/09/2022 through 02/14/2024. Findings Include: 1. Review of the laboratory's "Crystal Clinic, Inc. Laboratory Standard Operating Procedures" manual, approved by the Laboratory Director via signature and date on 12/05/2021 and provided on the date of the inspection, did not find any mention of labeling instructions for reagents, solutions and stains. 2. Direct observation of the secondary containers in the mdiff slide stain station on 02/14/2024 at 11:35 AM, did not find each container labeled with their contents, lot numbers and expiration dates. 3. Direct observation of the stock bottles of Methanol and HemaQuik stain found them to be labeled by the manufacturer, however found the following: Methanol; lot# 1172, expired on 06/21/2023 HemaQuik; lot#124562, expired on 11/20/2023 4. The Inspector requested the laboratory's labeling policy and procedure, reagent log documentation of reagents, solutions and stains utilized, to include the products, lot numbers and the expiration dates along with the laboratory's indated Methanol and HemaQuik stain from the TS. The TS stated the laboratory did not have a labeling policy and procedure, did not have a reagent log established and confirmed the secondary containers were not labeled as required. The TS further confirmed the Methanol and HemaQuik stain were utilized for mdiff testing procedures performed and the Methanol and HemaQuik stain were expired. The interview occurred on 02/14/2024 at 11:35 AM.

**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 record review, direct observation and an interview with the Technical Supervisor (TS), the laboratory failed to ensure the Methanol and HemaQuik stain, utilized for high complexity white blood cell (WBC) manual differential (mdiff) testing procedures performed in the specialty of Hematology, were not used when they had exceeded their expiration date. This deficient practice had the potential to affect two out of two manual WBC performed from the last CLIA inspection on 02/09/2022 through 02/14/2024. Findings Include: 1. Review of the laboratory's "Crystal Clinic, Inc. Laboratory Standard Operating Procedures" manual, approved by the Laboratory Director via signature and date on 12/05/2021 and provided on the date of the inspection, did not find any mention of labeling instructions for reagents, solutions and stains. 2. Direct observation of the laboratory, on 02/14/2024 at 11:35 AM, found the Methanol and HemaQuik stain in secondary coplin jars in the WBC mdiff stain

station, unlabeled with contents, lot numbers and expiration dates. 3. Direct observation of the stock bottles of Methanol and HemaQuik stain found them to be labeled by the manufacturer, however found the following: Methanol; lot# 1172, expired on 06/21/2023 HemaQuik; lot#124562, expired on 11/20/2023 4. The Inspector requested the laboratory's labeling policy and procedure, reagent log documentation of reagents, solutions and stains utilized, to include the products, lot numbers and the expiration dates along with the laboratory's indated Methanol and HemaQuik stain from the TS. The TS stated the laboratory did not have a labeling policy and procedure and did not have a reagent log established. The TS further confirmed the Methanol and HemaQuik stain were utilized for mdiff testing procedures performed and they were expired. The interview occurred on 02/14/2024 at 11:35 AM.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on record review and an interview with the Technical Supervisor (TS), the Laboratory Director failed to ensure that one out of seven testing personnel (TP) was trained and had demonstrated that they could perform complete blood count (CBC) testing procedures on the Sysmex xs1000i in the specialty of Hematology reliably to provide and report accurate results prior to performing patient testing. This deficient practice had the potential to affect 108 out of 108 CBC tests performed by TP#7 from 07/12/2023 through 02/14/2024. Findings Include: 1. Review of the laboratory's "CLIA Competency Assessment" policy and procedure, approved by the Laboratory Director on 12/05/2021, provided on the date of the inspection, found the following instructions: "Evaluating and documenting competency of personnel responsible for testing is required prior to independent testing in any specialty...the individual tests patient specimens." 2. Review of the laboratory's competency assessment documentation for 2022, 2023 and 2024 did not find any training or demonstration of competency documentation for TP#7 prior to independent CBC testing on the Sysmex xs1000i test system. 3. The Inspector requested the laboratory's 2023 training and initial demonstration of competency documentation for TP#7 from the TS. The TS confirmed that the laboratory did not conduct and document training or initial demonstration of competency for TP#7 for the testing procedures performed on the Sysmex xs1000i test system and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/14/2024 at 8:25 AM.

**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 record review and an electronic mail (email) interview with the General Supervisor (GS), the Laboratory Director failed to ensure that approved policies and procedures were available for any aspect of the testing process. This deficient practice had the potential to affect 310,464 out of 310,464 test procedures performed from the last CLIA inspection on 02/09/2022 through 02/14/2024. Findings Include: 1. Review of the laboratory's "Crystal Clinic, Inc. Laboratory Standard Operating Procedures" manual, approved by the Laboratory Director via signature and date on 12/05/2021 and provided on the date of the inspection, did not find any mention of labeling instructions for reagents, solutions and stains. 2. The Inspector requested the laboratory's labeling policy and procedure from the General Supervisor (GS) via an email on 02/15/2024 at 8:57 AM. 3. An email from the GS on 02/16/2024 at 8:57 AM confirmed the laboratory did not have a labeling policy and procedure established, however the TS composed one on the date of the inspection after the Inspector exited the inspection. It was titled "Policy for Labeling of Reagents, Solutions and Stains", was unapproved by the Laboratory Director via signature and date and was found in the pocket of the maintenance manual.