

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2299496	(X3) Date Survey Completed 04/02/2025
Name of Provider or Supplier Cu Medicine Interventional Radiology	Street Address, City, State 9135 S Ridgeline Blvd, Suite 150, Highlands Ranch, CO	
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	Based on an on-site initial certification survey conducted on April 02, 2025, the following condition level deficiencies were cited for CU Medicine Interventional Radiology in Highlands Ranch, Colorado: 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing];
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 a routine desk review of the CMS-155 report for proficiency testing performance and onsite review of proficiency testing evaluation reports from the proficiency testing provider, Wisconsin state laboratory of hygiene, the laboratory</p>

failed to achieve satisfactory performance scores for the Wisconsin state laboratory of hygiene proficiency testing in the specialty of routine chemistry for the following analytes: chloride, creatinine, glucose (non-waived), potassium, sodium, and blood urea nitrogen for two out of three proficiency testing events: event 1 in 2024 and event 3 in 2024 (see D2096), failed to achieve satisfactory performance scores for the Wisconsin state laboratory of hygiene proficiency testing in the specialty of hematology for the analyte: prothrombin time for two consecutive proficiency testing events: event 2 in 2024 and event 3 in 2024 (see D2130).

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a routine desk review of the CMS-155 report for proficiency testing (PT), onsite review of evaluation reports provided by the PT provider, Wisconsin state laboratory of hygiene (WSLH), and an interview with the technical consultant (TC), the laboratory failed to achieve a satisfactory PT score for two out of three PT events in the specialty of chemistry for the following analytes: chloride (Cl), creatinine, glucose (non-waived), potassium (K), sodium (Na), and blood urea nitrogen (BUN) for event 1 in 2024, and event 3 in 2024. Findings include: 1. A review of the CMS-155 Individual Laboratory Profile on February 7, 2025 at 09:41 AM, revealed the laboratory had received a score of 0 for two out of three PT events (event 1 in 2024, and event 3 in 2024) in the specialty of chemistry for the following analytes: Cl, creatinine, glucose (non-waived), K, Na, BUN, resulting in unsuccessful performance. 2. An onsite review of the PT performance summary provided by WSLH, on April 2, 2025, at approximately 10:15 AM, confirmed the laboratory failed to achieve satisfactory testing scores for two out of three PT events in the specialty of chemistry for the following analytes: Cl, creatinine, glucose (non-waived), K, Na, BUN. Scores were 0% in event 1 of 2024, and 0% for event 3 in 2024. 3. An interview with the TC on April 2, 2025, at approximately 10:20 AM, confirmed the laboratory failed to achieve satisfactory testing scores for two out of three PT events in the specialty of chemistry for the following analytes: Cl, creatinine, glucose (non-waived), K, Na, BUN. Scores were 0% in event 1 of 2024, and 0% for event 3 in 2024.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a routine desk review of the CMS-155 report for proficiency testing (PT), onsite review of evaluation reports provided by the PT provider, Wisconsin state laboratory of hygiene (WSLH), and an interview with the technical consultant (TC), the laboratory failed to achieve a satisfactory PT score for two consecutive PT events in the specialty of hematology for the following analyte: prothrombin time (protime) for event 2 in 2024, and event 3 in 2024. Findings include: 1. A review of the CMS-

155 Individual Laboratory Profile on February 7, 2025 at 09:41 AM, revealed the laboratory had received a unsatisfactory scores for two consecutive PT events (60% for event 2 in 2024, and 0% for event 3 in 2024) in the specialty of hematology for the analyte: protime. 2. An onsite review of the PT performance summary provided by WSLH, on April 2, 2025, at approximately 10:15 AM, confirmed the laboratory failed to achieve satisfactory testing scores for two consecutive PT events in the specialty of hematology for the analyte: protime. Scores were 60% in event 2 of 2024, and 0% for event 3 in 2024. 3. An interview with the TC on April 2, 2025, at approximately 10:20 AM, confirmed the laboratory failed to achieve satisfactory testing scores for two consecutive PT events in the specialty of hematology for the analyte: protime. Scores were 60% in event 2 of 2024, and 0% for event 3 in 2024.