

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0392877	(X3) Date Survey Completed 12/03/2024
Name of Provider or Supplier Ssm Health Dean Medical Group - Janesville	Street Address, City, State 3200 E Racine St, Janesville, WI	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of procedures and proficiency testing (PT) records from 2023 and 2024, and interview with the Laboratory Technical Specialist - Point of Care (Staff A), testing personnel in this laboratory received PT materials from Laboratory B and performed a KOH (Potassium Hydroxide) proficiency test in one of five events and a Scabies proficiency test in one of six events for reporting to the AAB-Medical Laboratory Evaluation (AAB-MLE) PT program and did not notify Centers for Medicare and Medicaid Services (CMS) of the receipt of the PT samples from Laboratory B. Findings include: 1. Staff B at this laboratory received PT materials for dermatology KOH and Scabies testing from Laboratory B and did not notify CMS of receipt of the samples. 2. Results from PT samples tested in this laboratory were reported by Laboratory B to AAB-MLE, the PT provider. 3. This laboratory performed patient KOH testing on dermatology samples and Scabies testing and was not enrolled in a PT program for these tests. See D2013.</p>
D2013	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4)</p>

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based on surveyor review of procedures and proficiency testing (PT) records from 2023 and 2024, and interview and email with the Laboratory Technical Specialist - Point of Care (Staff A), testing personnel in this laboratory received PT materials from Laboratory B and performed a KOH (Potassium Hydroxide) test in one of five events and a Scabies test in one of six events for reporting to the AAB Medical Laboratory Evaluation (AAB-MLE) PT program and did not notify Centers for Medicare and Medicaid Services (CMS) of the receipt of the PT samples from Laboratory B. Findings include: 1. The 'QSE-AS-Proficiency Testing Policy', effective date May 19, 1994, stated in the "Points of Emphasis" section, "PT samples must not be sent to another laboratory for testing." 2. Review of PT records from 2024 showed testing personnel (Staff B) in this laboratory, performed KOH PT testing on PT slide 11, a sample received from AAB-MLE by the laboratory at Laboratory B for event three in 2024. i. Review of the AAB-MLE submission reports showed the CLIA number of the laboratory as Laboratory B's CLIA number. The result reports from AAB-MLE showed Laboratory B's CLIA number with the laboratory name, "SSM Health Dean Med CRP" and identified the address of the laboratory as that of Laboratory B. ii. Further review of PT records from 2023 and 2024 showed Laboratory B received five events for KOH testing and six events for Scabies testing in 2023 and 2024. 3. Interviews with Staff A on December 3, 2024, at 12:50 PM and 3:30 PM confirmed Staff A carried PT samples from Laboratory B to this laboratory for testing by Staff B who performed patient KOH and Scabies testing. Further interview confirmed this laboratory did not report the receipt of PT samples from another laboratory to CMS. 4. Email communication with Staff A on December 4, 2024, at 12:48 PM revealed Staff B performed the Scabies test for event 2 in 2023 at this laboratory.