

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0392965	(X3) Date Survey Completed 12/03/2024
Name of Provider or Supplier Ssm Health Dean Medical Group - N High Point Rd	Street Address, City, State 752 N High Point Rd, Madison, 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), PT samples for KOH (potassium hydroxide) testing from three of five events and PT samples for Scabies testing from four of six events were sent to and tested at one of two other laboratories, Laboratory A and Laboratory C, and were not tested at this laboratory. Results were submitted to the AAB-Medical Laboratory Evaluation (AAB-MLE) PT program under this laboratory's (Laboratory B) account for all events. Findings include: 1. The Laboratory A Dermatology area and Laboratory C each received PT materials for KOH and Scabies tests from Laboratory B during 2023 and 2024. 2. Results from PT sample testing in the dermatology area of Laboratory A and Laboratory C were reported as results for Laboratory B's account to AAB-MLE, the PT provider. 3. Laboratory B performed KOH testing on patient dermatology samples and performed scabies testing. Laboratory B was enrolled in the AAB-MLE PT program for this testing. 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), Staff A transported AAB-Medical Laboratory Evaluation (AAB-MLE) PT samples for KOH (potassium hydroxide) and Scabies tests from this laboratory, Laboratory B, to either Laboratory A or Laboratory C for three of five KOH testing events and four of six Scabies testing events. 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 2023 and 2024 showed testing personnel in this laboratory, Laboratory B, performed KOH PT testing on samples from event two in 2023 and event one in 2024 and performed Scabies PT in event one in 2023 and event one in 2024. Records showed Laboratory B received five events for KOH testing and six events for Scabies testing in 2023 and 2024. i. Proficiency records from AAB-MLE showed Scabies PT samples were tested at the following laboratories: Event one 2023: Laboratory B Event two 2023: Laboratory C Event three 2023: Performing Laboratory not identified on PT records Event one 2024: Laboratory B Event two 2024: Laboratory A Event three 2024: Laboratory A ii. Proficiency records from AAB-MLE showed KOH PT samples were tested at the following laboratories: Event two 2023: Laboratory B Event three 2023: Laboratory A Event one 2024: Laboratory B Event two 2024: Laboratory A Event three 2024: Sample K12 Laboratory A Event three 2024: Sample K11 Laboratory C iii. Review of the AAB-MLE submission reports showed the CLIA number of the laboratory as that of Laboratory B. 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 752 North High Point Rd, Madison, Wisconsin 53717. 3. Interview with Staff A on December 3, 2024, at 12:50 PM and 3:30 PM confirmed Staff A transported PT samples from Laboratory B to Laboratory A or Laboratory C when the PT was not performed at Laboratory B. Further interviewed confirmed staff at Laboratory B performed patient KOH testing on dermatology samples and performed Scabies testing. 4. Email communication with Staff A on December 4, 2024, at 12:48 PM revealed the Scabies test for event three 2023 was performed at Laboratory A.