

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0642547	(X3) Date Survey Completed 12/19/2024
Name of Provider or Supplier Mn Clinical Laboratory	Street Address, City, State 1330 Arrow Hwy, La Verne, CA	
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	A proficiency testing desk review survey was performed on 12/19/2024, the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; Laboratory Director.
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 review of the Certificate and Survey Provider Enhanced Reporting (CASPER) - 0155D and AAB-Medical Laboratory Evaluation records (2024-2 and 2024-3), the laboratory failed to successfully participate in a proficiency testing</p>

	<p>program approved by HHS for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA, the laboratory failed to successfully participate in the subspecialty of Toxicology and analytes: Carbamazepine, Digoxin, Lithium, Phenobarbital, Phenytoin, and Valproic Acid resulting in unsuccessful performances. Refer to D2118 and D2119.</p>
<p>D2118</p>	<p>TOXICOLOGY CFR(s): 493.845(f)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and AAB-Medical Laboratory Evaluation program report, the laboratory failed to achieve satisfactory performance for two consecutive events (2024 second & third testing events) for the following analytes: The findings include: 1. Carbamazepine - 0% 2024 second testing event, Carbamazepine - 0% 2024 third testing event. 2. Digoxin - 0% 2024 second testing event, Digoxin - 0% 2024 third testing event. 3. Lithium - 0% 2024 second testing event, Lithium - 0% 2024 third testing event. 4. Phenobarbital - 0% 2024 second testing event, Phenobarbital - 0% 2024 third testing event. 5. Phenytoin - 0% 2024 second testing event, Phenytoin 0% 2024 third testing event. 6. Valproic Acid - 0% 2024 second testing event, Valproic Acid - 0% 2024 third testing event. AAB-Medical Laboratory Evaluation confirmed the above findings.</p>
<p>D2119</p>	<p>TOXICOLOGY CFR(s): 493.845(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on desk review of Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and AAB-Medical Laboratory Evaluation reports, the laboratory failed to achieve satisfactory performance for consecutive proficiency events in 2024 for specialty Toxicology: The laboratory received the following scores: 1. The laboratory received the following scores: 0% for the 2024-2 Toxicology, 0% on the 2024-3 Toxicology. A review of the 2024 proficiency testing scores from AAB-Medical Laboratory Evaluation confirms the above findings.</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>

This CONDITION is not met as evidenced by:
Based on a proficiency testing desk review of the CASPER 0155D report and AAB-Medical Laboratory Evaluation records for 2024-2 and 2024-3 proficiency events, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on a proficiency testing desk review of the CASPER 0155D report and AAB-Medical Laboratory Evaluation records for 2024-2 and 2024-3 events, the laboratory director failed to ensure successful participation in an HHS proficiency testing program. Refer to D2118 and D2119.