

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D1100435	(X3) Date Survey Completed 05/30/2025
Name of Provider or Supplier Quicksilver Scientific Inc	Street Address, City, State 1960 Cherry Street, Louisville, 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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing provider. The facility was found to be out of compliance with the conditions of the CLIA program. The following condition level deficiencies were found to be out of compliance: 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 review of proficiency testing evaluation reports from the proficiency</p>

	<p>testing provider, WSLH Proficiency Testing, the laboratory failed to achieve satisfactory performance scores for the subspecialty of toxicology for the lead analyte, for two consecutive proficiency testing events (event 3 in 2024 and event 1 in 2025), see D2118 and D2119.</p>
<p>D2118</p>	<p>TOXICOLOGY CFR(s): 493.845(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a routine desk review of the CMS-155 report for proficiency testing (PT), and a record review of WSLH PT results, the laboratory failed to achieve a satisfactory score for two consecutive PT events in the subspecialty of toxicology for the lead analyte for event 3 in 2024 and event 1 in 2025. Findings include: 1. A review of the CMS-155 Individual Laboratory Profile on May 30, 2025, at 1:52 PM, revealed the WSLH PT results for lead were 66% in event 3 in 2024, and 0% for event 1 in 2025. 2. A review of the WSLH PT participant evaluation report on May 30, 2025, at 1:54 PM, confirmed the laboratory received a score of 66% for event 3 in 2024, and 0% for event 1 in 2025 for the lead analyte.</p>
<p>D2119</p>	<p>TOXICOLOGY CFR(s): 493.845(g)</p> <p>(g) 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 a routine desk review of the CMS-155 report for proficiency testing (PT), and a record review of WSLH PT results, the laboratory failed to achieve an overall satisfactory score for two consecutive PT events in the subspecialty of toxicology for event 3 in 2024 and event 1 in 2025 . Findings include: 1. A review of the CMS-155 Individual Laboratory Profile on May 30, 2025, at 1:52 PM, revealed the WSLH PT results for the subspecialty of toxicology were 66% in event 3 in 2024, and 0% for event 1 in 2025, resulting in unsuccessful overall performance in the subspecialty of toxicology. 2. A review of the WSLH PT participant evaluation report on May 30, 2025, at 1:54 PM, confirmed the laboratory received a score of 66% for the subspecialty of toxicology for event 3 in 2024, and 0% for event 1 in 2025, resulting in unsuccessful overall performance in in the subspecialty of toxicology.</p>