

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2262146	(X3) Date Survey Completed 03/26/2025
Name of Provider or Supplier Dialogix Laboratories	Street Address, City, State 570 Nevada St Ste E, Redlands, 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 as performed on 3/25/2025, the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES D2016 - 42 C.F.R. 493.803 Condition: Successful [proficiency testing] participation; and D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity 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 review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER) - 0155D report and American Proficiency Institute (API) records (for the laboratory's 2024-1, 2024-2, 2024-3, and 2025-1 proficiency testing</p>

	<p>events), the laboratory failed to successfully participate in an approved HHS proficiency testing program for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA. See D2084 and D2096.</p>
<p>D2084</p>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(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 review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER) 0155D report and the American Proficiency Institute (API) records, the laboratory failed to achieve satisfactory performances for the analyte AFP (Tumor Marker). The findings include: AFP (Tumor Marker) 20% - 2024 first testing event; AFP (Tumor Marker) 20% - 2024 third testing event; AFP (Tumor Marker) 0% - 2025 first testing event. The above 2024 & 2025 American Proficiency Institute (API) scores resulted in subsequent unsuccessful AFP (Tumore Marker) performance.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D report and laboratory's American Proficiency Institute (API) records, the laboratory failed to achieve satisfactory performance for the analytes: Cholesterol, HDL and Triglycerides. The findings include: Cholesterol, HDL 0% - 2024 second testing event: Cholesterol, HDL 20% - 2024 third testing event: Cholesterol, HDL 0% - 2025 first testing event: Triglycerides 60% - 2024 first testing event; Triglycerides 0% - 2024 third testing event; Triglycerides 0% - 2025 first testing event. The above 2024 & 2025 American Proficiency Institute (API) scores resulting in subsequent unsuccessful Cholesterol, HDL and Triglycerides performances.</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> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the laboratory's CASPER 0155D report</p>

and API records for 2024-1, 2024-2, 2024-3, and 2025-1 proficiency testing 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)

(e)(4)(i) 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 laboratory's CASPER 0155D report and American Proficiency Institute records for 2024-1, 2024-2, 2024-3, and 2025-1, the laboratory director failed to ensure successful participation in an HHS proficiency testing program. Refer to D2084 and D2096.