| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 05D2262146 | 12/19/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Dialogix Laboratories | 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 |
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| **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** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the Certificate and Survey Provider Enhanced Reporting (CASPER) - 0155D and American Proficiency Institute records (2024-1 and 2024-3), the laboratory failed to successfully participate in a proficiency testing program |

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| | 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 analyte AFP (Tumor Marker) resulting in unsuccessful performance. Refer to D2084. |
| **D2084** | GENERAL IMMUNOLOGY<br>CFR(s): 493.837(f)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Proficiency Institute program report, the laboratory failed to achieve satisfactory performance for two consecutive events (2024 first & third testing events) for the analyte AFP (Tumor Marker): The findings include: 1. AFP (Tumor Marker)Bacteriology - 20% 2024 first testing event, 2. AFP (Tumor Marker)Bacteriology - 20% 2024 third testing event. American Proficiency Institute confirmed the above findings. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on a proficiency testing desk review of the CASPER 0155D report and American Proficiency Institute program records for 2024-1 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<br>CFR(s): 493.1407(e)(4)(i)<br><br>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;<br><br>This STANDARD is not met as evidenced by:<br>Based on a proficiency testing desk review of the CASPER 0155D report and American Proficiency Institute program records for 2024-1 and 2024-3 events, the laboratory director failed to ensure successful participation in an HHS proficiency testing program. Refer to D2084. |