

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2260410	(X3) Date Survey Completed 12/19/2024
Name of Provider or Supplier Tekotest Lab Inc	Street Address, City, State 3111 Winona Ave Ste 102, Burbank, 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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on review of the Certificate and Survey Provider Enhanced Reporting (CASPER) - 0155D and American Proficiency Institute records (2024-2 and 2024-3), the laboratory failed to successfully participate in a proficiency testing 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 specialties of Bacteriology and Virology unsuccessful performances. Refer to D2028 and D2064.
D2028	BACTERIOLOGY CFR(s): 493.823(e) 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. 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 American Proficiency Institute program report, the laboratory failed to achieve satisfactory performance for two consecutive events (2024 second & third testing events) for the specialty of Bacteriology: The findings include: 1. Bacteriology - 0% 2024 second testing event, Bacteriology - 0% 2024 third testing event. American Proficiency Institute confirmed the above findings.
D2064	VIROLOGY CFR(s): 493.831(e) 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. 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 American Proficiency Institute program report, the laboratory failed to achieve satisfactory performance for two consecutive events (2024 second & third testing events) for the specialty of Virology: The findings include: 1. Virology - 0% 2024 second testing event, 2. Virology - 0% 2024 third testing event. American Proficiency Institute confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 0155D report and American Proficiency Institute records for 2024-2 and 2024-3 events, the laboratory director failed to ensure successful participation in an HHS proficiency testing program. Refer to D2028 and D2064.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure 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 American Proficiency Institute records for 2024-2 and 2024-3 proficiency events, the laboratory director failed to provide overall management ensuring proficiency testing samples were tested as required under subpart H of this part. See D2028 and D2064.