

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0672012	(X3) Date Survey Completed 10/07/2021
Name of Provider or Supplier Dallas Co Dept Of Health & Human Services	Street Address, City, State 2377 N Stemmons Freeway Suite 003, Dallas, TX	
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 CMS (Centers for Medicare and Medicaid Services) national database and verified with the proficiency testing company, College of American Pathologists (CAP). The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 Successful participation in a proficiency testing program 493.1441 Laboratory Director, (high complexity)
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing records from 2020 (1st, 2nd, and 3rd Events) and 2021 (1st and 2nd Events), it was revealed that the laboratory failed to attain an overall testing event score of at least 80% for the 3rd event of 2020 and 2nd testing event of 2021 for Bacteriology resulting in unsuccessful performance. Findings included: 1. Review of the CMS 0155 report revealed the following results: CAP 2020 - 3rd Event (D3-C 2020) laboratory received an overall unsatisfactory score 66% for Bacteriology. CAP 2021 - 2nd Event (D3-B 2021) laboratory received an overall unsatisfactory score 43% for Bacteriology 2. Review of the laboratory's CAP proficiency testing records revealed the following results: CAP 2020 - 3rd Event (D3-C 2020) laboratory received an overall unsatisfactory score 66% for Bacteriology. CAP 2021 - 2nd Event (D3-B 2021) laboratory received an overall unsatisfactory score 43% for Bacteriology.</p>
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 a review of proficiency testing (PT) records from 2020 (1st, 2nd and 3rd Events) and 2021 (1st and 2nd Events), it was revealed that the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of Bacteriology. Two out of three consecutive unsatisfactory scores result in unsuccessful PT performance. Findings included: 1. Review of the CMS 0155 report revealed the following results: CAP 2020 - 3rd Event (D3-C 2020) laboratory received an overall unsatisfactory score 66% for Bacteriology. CAP 2021 - 2nd Event (D3-B 2021) laboratory received an overall unsatisfactory score 43% for Bacteriology 2. Review of the laboratory's CAP proficiency testing records revealed the following results: CAP 2020 - 3rd Event (D3-C 2020) laboratory received an overall unsatisfactory score 66% for Bacteriology. CAP 2021 - 2nd Event (D3-B 2021) laboratory received an overall unsatisfactory score 43% for Bacteriology.

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 desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6089

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 desk review of proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2028.