

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0684540	(X3) Date Survey Completed 05/26/2021
Name of Provider or Supplier Stanly County Health Department	Street Address, City, State 1000 North First Street, Suite 3, Albemarle, NC	
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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedure, review of 2018, 2019, 2020 and 2021 CAP(College of American Pathologists) PT(proficiency testing) records and interview with TP(testing personnel) 5/26/21, the laboratory failed to document evaluation of all proficiency testing results received. Findings: The laboratory's "Proficiency Testing" policy and procedure states, "...9. Upon receiving Proficiency Testing Results all results: graded, ungraded, and any unacceptable will be reviewed using the Participant Summary report. 10. Any failed, missed or unacceptable result will be reviewed and documented following the Policy and Procedure for Missed or Failed Proficiency Testing." Review of 2018, 2019, 2020, and 2021 CAP PT records revealed the laboratory failed to document evaluation of all unacceptable PT results. Examples: 1. 2018 D5-C event: 1 of 5 Gram Stain morphology challenges incorrect with no evaluation documented; 2. 2019 D5-A event: 1 of 5 Gram Stain morphology challenges incorrect with no evaluation documented; 3. 2019 D5-C event: 3 of 5 Gram Stain morphology challenges incorrect with no evaluation documented; 4. 2020 D5-A event: 3 of 5 Gram Stain morphology challenges incorrect with no evaluation documented; 5. 2020 D5- B event: 3 of 5 Gram Stain morphology challenges incorrect with no evaluation documented; 6. 2020 D5- C event: 1 of 5 Gram Stain morphology challenges incorrect with no evaluation documented; 7. 2021 D5-A event: 1 of 5 Gram Stain morphology challenges incorrect with no evaluation documented. At approximately 11:55 a.m., TP #2 and TP #3 stated they are reviewing the summaries from CAP but the reviews were not documented.</p>

They also confirmed the Missed and Failed PT investigation form is not being completed for any morphology challenge responses that are incorrect. Deficiency previously cited 8/1/18.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's QA(quality assessment) policies and procedures and review of QA records 5/26/21, the laboratory failed to follow written policies and procedures to monitor, assess, and correct problems identified with PT(proficiency testing) performance. Findings: The laboratory's "Quality Systems Assessment" policy and procedure states, "1. Select one or more systems each quarterly and evaluate components or processes for compliance...6. As a part of the Quality Systems Assessment, Proficiency test results will be reviewed to ensure that appropriate action has been taken for any missed or failed proficiency test results. This is to be documented on the Quality Systems Assessment Checklist." Review of the laboratory's QA records revealed the laboratory completed the "Quality Systems Assessment Checklist" on 12/27/18, 4/25/19, 1/3/20, and 5/24/21. Review of the "Quality Systems Assessment Checklist" revealed the QA program failed to identify and correct the problems in the laboratory for PT performance(See D5211). For example: A response of "Compliant" was given on the 12/27/18 checklist and a response of "Not applicable" was given on the 5/24/21 checklist for question, "Were incorrect results(graded and ungraded) investigated and corrective action taken?" There was no documentation to indicate the incorrect morphology challenge PT results were investigated or that corrective action was taken.