

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D0664927	<b>(X3) Date Survey Completed</b> 02/13/2019
<b>Name of Provider or Supplier</b> Wake County Human Services	<b>Street Address, City, State</b> 10 Sunnybrook Road G-80, Raleigh, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2021</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 CAP (College of American Pathologists) proficiency testing records and interview with the laboratory director 2/13/19, the laboratory received a score of 0% for failure to participate in the 2018 D5-C test event. Review of 2017 and 2018 CAP proficiency testing records revealed the laboratory failed to provide responses for the 2018 D5-C Gram stain module. During interview at approximately 10:50 a.m., the laboratory director stated that the laboratory planned to change proficiency testing testing providers because CAP's Gram stain module included Gram stain challenges that were not applicable to the laboratory because they look for Gram negative diplococci only. He stated they contacted CAP and were told to leave the responses blank for tests not performed by the laboratory. He stated they received a score of 0% because they followed the instructions given to them by CAP.</p>
<b>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p>

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation, review of the laboratory's policies and procedures, and interview with the laboratory director 2/13/19, the laboratory failed to discard supplies that exceeded their expiration date. During a tour of the laboratory at approximately 4:10 p.m., the surveyor observed 2 bottles of Fisherbrand Safranin (lot #413539) with an expiration date of 11/2018 on a shelf, available for use. Review of the policy "Laboratory Quality Assurance Standards" revealed on page 10 "... 8. Handling of reagents, kits, and supplies ... c. It is the responsibility of the laboratory technologist to: ... iii. Assure Proper disposal of all expired and/or contaminated reagents and supplies. ..." During interview at approximately 4:15 p.m., the laboratory director confirmed that the safranin was expired. He stated the bottles should have been discarded.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with the laboratory director 2/13/19, the laboratory director failed to ensure that prior to testing patient specimens 1 of 6 testing personnel (TP #6) received appropriate training and had demonstrated the ability to perform all testing operations reliably to provide accurate patient test results. Review of personnel records for TP #6 revealed she was trained September - November of 2018. There was no documentation available to indicate that the training included Gram stains. Gram stain competency was included in TP #6's February 2019 competency evaluation. During interview at approximately 12:20 p.m., the laboratory director verified that TP #6 was trained to perform Gram stains. He stated the documentation must have been misplaced.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, review of personnel

records, and interview with the former laboratory director 2/13/19, the technical consultant failed to document the performance of annual competency evaluations for 3 of 6 testing personnel (TP #1, TP #2, TP #4). Findings: The "Laboratory Quality Assurance Standards" policy states on page 12"... 4. Standard: Personnel Competency assessment policies (CLIA 493.1235) ... a. ... Laboratory performs competency evaluations on all Medical Technologist and Laboratory Technicians yearly. A new hire will perform competency testing at 6 months, 12 months, and then only once a year. ..." Review of personnel records revealed: 1. TP #1 was trained June - September 2017. A semiannual competency evaluation was documented in February 2018, but there was no documentation that an annual competency evaluation was conducted. 2. TP #2 was trained March - June 2017. A semiannual competency evaluation was documented in February 2018, but there was no documentation that an annual competency evaluation was conducted. 3. TP #4 (trained in August 2015) had annual competency evaluations documented in December 2016 and June 2018. There was no documentation of an annual competency evaluation for TP #4 in 2017. During interview at approximately 2:15 p.m., the former laboratory director stated she was unsure whether the competency evaluations were conducted as required during 2017 and 2018. She stated they had some staff changes and they also installed a new laboratory information system during that time.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:  
Based on review of personnel records 2/13/19 and the deficiency cited at D6065, the laboratory failed to verify that 2 of 6 testing personnel (TP #4, TP #6) met the minimum education requirements for performing moderate complexity testing.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:  
Based on review of personnel records and interview with the laboratory director 2/13/19, the laboratory failed to verify that 2 of 6 testing personnel (TP #4, TP #6) met the minimum education requirements for performing moderate complexity testing.

Findings: Review of personnel records for TP #4 revealed an Associate in Arts degree, Nurse Aide 1 training, and a PBT(ASCP) phlebotomist certification. Personnel records for TP #4 did not include a college transcript, a high school diploma, or a GED (high school graduation equivalency diploma). Review of personnel records for TP #6 revealed an Associate of Arts degree and a Bachelor of Science degree in Health Administration. Personnel records for TP #4 did not include college transcripts, a high school diploma, or a GED. During interview at approximately 12:10 p.m., the laboratory director confirmed that there were no additional education records available for TP #4 and TP #6.