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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>34D2138778                 | <b>(X3) Date Survey Completed</b><br><br>10/20/2022 |
| <b>Name of Provider or Supplier</b><br><br>Durham Women's Clinic   | <b>Street Address, City, State</b><br><br>7780 Brier Creek Parkway, Suite 330, 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>  |
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| <b>D5417</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(d)</p> <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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor observation and testing personnel interview 10/20/22, the laboratory failed to dispose of expired potassium hydroxide (KOH) reagent that had exceeded their expiration date. Findings: Surveyor observed the following two bottles of KOH reagent that had exceeded their expiration dates and were available for use. 1. One bottle of KOH reagent, Troy Biologicals Lot # 17312 expiration date 11/8/19, on the counter top beside microscope. 2. One bottle of KOH reagent, HealthLink Lot #9301 expiration date 10/28/21, in the cupboard above microscope. During observation TP confirmed the two bottles of KOH reagent had exceeded their expiration dates. The TP promptly disposed of the reagents to ensure they would not be available for use.</p> |
| <b>D6046</b>              | <p>TECHNICAL CONSULTANT RESPONSIBILITIES<br/>CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of personnel records, review of 2020, 2021 and 2022 testing personnel (TP) competency records and interview with laboratory director (LD) 10/20</p>   |

/22, the technical consultant (laboratory director) failed to perform the yearly competency assessments for all TP. Findings: Review of personnel records revealed TP #3 and TP #4 have a high school diploma and do not meet the qualifications to serve as technical consultant and evaluate the competency of TP. Review of 2020, 2021 and 2022 TP competency records revealed the following: 1. TP #3 evaluated the competency of TP #4 in 2020, 2021 and 2022, TP #6 in 2021, TP #7 in 2022 and TP #10 in 2021 and 2022. 2. TP #4 evaluated the competency of TP #2 in 2022, TP #3 in 2021 and TP #8 in 2021 and 2022. Interview with LD at approximately 12:30 p.m. confirmed the TP #3 and TP #4 have high school diplomas. The LD stated they were not aware that only someone who qualifies as a technical consultant could evaluate the competency of TP.