

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D2105934	<b>(X3) Date Survey Completed</b> 05/05/2022
<b>Name of Provider or Supplier</b> Wfhn Medical Plaza North Elm	<b>Street Address, City, State</b> 3903 North Elm Street, Suite 101, Greensboro, 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>D6017</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(ii)</p> <p>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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2020, 2021, and 2022 API (American Proficiency Institute) proficiency testing records and interview with TP (testing personnel) #1 on 5/5/22, the laboratory director failed to ensure proficiency testing results were returned in the required timeframes. Findings: Review of 2020, 2021, and 2022 API proficiency testing records revealed that TP #2 (a provider) participates in proficiency testing for the KOH (potassium hydroxide) testing performed by the laboratory. TP #2 is the only TP that performs this test. Review of 2020, 2021, and 2022 API proficiency testing records revealed that the laboratory failed to submit results to API and reported a "test problem" for: 1. 1 of 3 events in 2020 (3rd Microbiology); 2. 3 of 3 events in 2021 (1st, 2nd, 3rd Microbiology); 3. 1 of 1 event in 2022 (1st Microbiology). Proficiency testing records indicated that the provider was not available to read the slides and submit the results to API for 4 of the 5 events when the laboratory noted a "test problem". The provider reviewed the slides after the submission deadline and documented the results. During interview at approximately 2:00 p.m. TP #1 stated that TP #2 is in the laboratory on a very limited basis, so TP #2 is not always available to perform the proficiency testing and submit the results before the deadline.</p>
<b>D6054</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p>

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 personnel records and interview with TP (testing personnel) #1 on 5/5/22, the technical consultant (laboratory director) failed to perform and document annual competency evaluations for 1 of 2 TP (TP #1) during 2020 and 2021. Review of personnel records for TP #1 revealed a 2022 competency evaluation. There were no records of a competency evaluation for TP #1 in 2020 or 2021. During interview at approximately 11:45 a.m., TP #1 confirmed that she did not have a competency evaluation in 2020 or 2021.