

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1068135	(X3) Date Survey Completed 10/11/2023
Name of Provider or Supplier Wfhn Pediatrics - Kernersville Sports Complex	Street Address, City, State 861 Old Winston Rd Ste 103, Kernersville, 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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2020, 2021, 2022, and 2023 API (American Proficiency Institute) proficiency testing records 10/11/23, the laboratory failed to test proficiency samples in the same manner that patient specimens are routinely tested. Review of the "Complete Blood Counts" procedure revealed "... A result that is considered a critical will be repeated before reporting, ...". Review of the "PROFICIENCY TESTING" policy revealed "... Proficiency testing specimens are tested in the exact same manner as a patient specimen ...". Review of 2020, 2021, 2022, and 2023 API proficiency testing records revealed the laboratory failed to repeat testing on proficiency samples with critical low values for hemoglobin. Examples: 1. 2020 3rd Hematology test event - sample HEM-13 not repeated. 2. 2021 1st Hematology test event - sample HEM-02 not repeated. 3. 2022 2nd Hematology test event - sample HEM-08 not repeated. 4. 2023 2nd Hematology test event - sample HEM-10 not repeated.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES 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 semiannually during the first year the individual tests patient specimens.

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 laboratory's POC (Point-of-Care) Coach 10/11/23, the technical consultant failed to perform and document competency evaluations semiannually for 1 of 6 testing personnel (TP #5). Review of the laboratory's "PERSONNEL" policy revealed "This laboratory will maintain personnel records for each position held. ... Personnel records will include: ... Competency assessments - competency will be reviewed semi-annually the first year and annually thereafter. ..." Review of personnel records revealed that TP #5 was hired in February 2021. There was no documentation that TP #5's competency was evaluated twice during the first year of testing patient specimens. During interview at approximately 1:00 p.m., the POC Coach stated that they didn't realize TP #5 needed to be evaluated semiannually because TP #5 had worked at the laboratory before, had left, and was re-hired in February 2021.

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 laboratory's POC (Point-of-Care) Coach 10/11/23, the technical consultant failed to perform and document annual competency evaluations for 5 of 6 testing personnel (TP #1, TP #2, TP #3, TP #4, TP #6) in 2020, 2021, and 2022 and 1 of 6 testing personnel (TP #5) in 2022 only. Review of the laboratory's "PERSONNEL" policy revealed "This laboratory will maintain personnel records for each position held. ... Personnel records will include: ... Competency assessments - competency will be reviewed semi-annually the first year and annually thereafter. ..." Review of personnel records revealed: 1. TP #1 (hired in March 2007) - the only competency evaluation available was performed in January 2023. 2. TP #2 (hired in September 2014) - the only competency evaluation available was performed in January 2023. 3. TP #3 (hired in August 2011) - the only competency evaluation available was performed in January 2023. 4. TP #4 (hired in July 2017) - the only competency evaluation available was performed in February 2023. 5. TP #5 (hired in February 2021) - the only competency evaluation available was performed in January 2023. 6. TP #6 (hired in August 2010) - the only competency evaluation available was performed in February 2023. During interview at approximately 12:55 p.m., the POC Coach confirmed there was no documentation of competency evaluations during 2020, 2021, and 2022.