

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2024372	(X3) Date Survey Completed 06/30/2021
Name of Provider or Supplier Rainbow Pediatrics - Hoke County Location	Street Address, City, State 142 Paraclete Drive, Suite 102, Raeford, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Laboratories eligible for a certificate of waiver must- (1) Follow manufacturer's instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory procedures, review of personnel training records, review of instructions for use (IFU) and interview with testing personnel (TP #1) 6/30/21, the laboratory failed to ensure the manufacturer's instructions for the SARS-CoV-2 testing performed were for the correct test system, failed to follow manufacturer's instructions for the Quidel Sofia SARS-CoV-2 testing performed to ensure 6 of 6 testing personnel (TP) had received appropriate training, and failed to ensure authorized Fact Sheets for patients and providers were included with SARS-CoV-2 test result reports. The laboratory began performing SARS-CoV-2 testing using the Quidel Sofia-SARS Antigen Fluorescent Immunoassay (FIA) on 5/5/21. 1. The laboratory failed to ensure the manufacturer's instructions on site for the SARS-CoV-2 testing performed were for the correct test system. Findings: Review of laboratory procedures revealed manufacturers' instructions for the Quidel Sofia Influenza A + B FIA test. There were no manufacturer's instructions for the Quidel Sofia-SARS Antigen FIA test on site at time of survey. Interview with TP #1 at approximately 12:50 p.m. confirmed that the laboratory did not have the correct manufacturer's instructions for the SARS-CoV-2 testing performed. She stated those were the instructions that came with the boxes when the test system arrived at the facility. She also confirmed the laboratory began testing for SARS-CoV-2 on 5/5/21. 2. The laboratory failed to ensure 6 of 6 TP received appropriate training for the performance</p>

of SARS-CoV-2 testing. Findings: Review of IFU for Quidel Sofia-SARS Antigen FIA revealed on page 15 "Conditions of Authorization for the Laboratory...All operators using your product must be appropriately trained in performing and interpreting the results of your product,...". Review of personnel training records revealed no documentation of training for the performance of the Quidel Sofia-SARS Antigen FIA testing for 6 of 6 TP. Interview with TP #1 at approximately 11:15 a.m. confirmed the laboratory had no documentation of TP training for the SARS-CoV-2 testing performed. She stated that everyone was trained but they did not realize they needed to have documentation of the training. 3. The laboratory failed to ensure authorized Fact Sheets for patients and providers were included with SARS-CoV-2 test result reports. Findings: Review of IFU for Quidel Sofia-SARS Antigen FIA revealed on page 15 " "Conditions of Authorization for the Laboratory...Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets." Interview with TP #1 at approximately 9:45 a.m. confirmed the laboratory failed to provide authorized Fact Sheets with test result reports. She stated they were unaware the Fact Sheets needed to be included with test result reports.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:
 Based on review of TP personnel records and interview with TP #1 6/30/21, the technical consultant (TC)(laboratory director) failed to ensure 1 of 6 TP received training for the Medonic hematology analyzer installed 12/10/18. Findings: Review of TP #2 personnel records revealed no documentation of training for the Medonic hematology analyzer installed 12/10/18. Interview with TP #1 at approximately 11:15 a.m. confirmed there was no documentation of training for TP #2 for the Medonic hematology analyzer. She stated that TP #2 was trained but she was unsure what happened to the documentation.