Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 34D1048049	**(X3) Date Survey Completed** 09/07/2021
Name of Provider or Supplier Kintegra Pediatric Medicine - Hudson	**Street Address, City, State** 991 W Hudson Boulevard, Gastonia, 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	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of North Carolina Division of Health Service Regulation (NCDHSR) records, review of 2020 and 2021 glucose quality control (QC) records, review of glucose testing result records and interview with practice manager 9/7/21, the laboratory failed to notify the North Carolina Division of Health Service Regulation (NCDHSR) prior to performing SARS-CoV-2 of their intent to perform testing, failed to ensure authorized Fact Sheets for patients and providers were included with SARS-CoV-2 test reports and failed to perform QC as required on 6 of 6 Evencare G3 blood glucose monitors for 2 of 2 years, 2020 and 2021. Approximately 6,360 glucose test results were reported when QC was not performed as required. 1. The laboratory failed to notify NCDHSR of their intent to perform SARS-CoV-2 testing prior to performing patient testing. Findings: The laboratory began SARS-CoV-2 testing utilizing the BinaxNOW COVID-19 Ag Card test system in March of 2020. Review of NCDHSR records revealed no notification for the performance of SARS-CoV-2 testing prior to performing patient testing. Review of manufacturer's instructions for the BinaxNOW COVID-19 Ag Card test system revealed on Page 8 "CONDITIONS of AUTHORIZATION for LABORATORY and PATIENT CARE SETTINGS...Authorized laboratories using your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing...". Interview with practice manager at approximately 2:30 p.m. confirmed the laboratory began testing for SARS-CoV-2 in March of 2020. 2. The laboratory failed to ensure authorized Fact Sheets for patients and providers were included with SARS-CoV-2 test reports. Findings: The laboratory

	performs SARS-CoV-2 testing utilizing the BinaxNOW COVID-19 Ag Card test system. Review of manufacturer's instructions for the BinaxNOW COVID-19 Ag Card test system revealed on page 8 "CONDITIONS of AUTHORIZATION for LABORATORY and PATIENT CARE SETTINGS...Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets...". Interview with practice manager at approximately 2:20 p.m. confirmed the laboratory failed to include authorized Fact Sheets with the BinaxNOW COVID-19 Ag Card test result reports. 3. The laboratory failed to perform QC as required on 6 of 6 Evencare G3 blood glucose monitors for 2 of 2 years, 2020 and 2021. Approximately 6,360 glucose test results were reported when QC was not performed as required. Findings: Review of manufacturer's instructions for the Evencare G3 blood glucose monitoring system revealed under "CONTROL SOLUTIONS SHOULD BE USED WHEN:... Using a new bottle or box of EVENCARE G3 Blood Glucose Test Strips...At least once per week to verify that the meter and test strips are working properly...". Review of QC records for the months of January and October of 2020 and June and August of 2021 revealed the following: a. January of 2020 QC was performed 4 times; 1/16, twice on 1/22, and 1/23. It is unclear which of the 6 glucose monitors the QC was performed on, and also if it was for a new bottle of QC material, a new box of EVENCARE G3 Blood Glucose Test Strips or a weekly QC as required. QC should have been performed and documented approximately 24 times in the month, once a week for each of the 6 glucose monitors in use. b. October of 2020 QC was performed 3 times; all three times on 10/13. It is unclear which of the 6 glucose monitors the QC was performed on, and also if it was for a new bottle of QC material, a new box of EVENCARE G3 Blood Glucose Test Strips or a weekly QC as required. QC should have been performed and documented approximately 24 times in the month, once a week for each of the 6 glucose monitors in use. c. June of 2021 QC was performed 2 times; 6/3 and 6/8. It is unclear which of the 6 glucose monitors the QC was performed on, and also if it was for a new bottle of QC material, a new box of EVENCARE G3 Blood Glucose Test Strips or a weekly QC as required. QC should have been performed and documented approximately 24 times in the month, once a week for each of the 6 glucose monitors in use. d. August of 2021 QC was performed 2 times on 8/6. It is unclear which of the 6 glucose monitors the QC was performed on, and also if it was for a new bottle of QC material, a new box of EVENCARE G3 Blood Glucose Test Strips or a weekly QC as required. QC should have been performed and documented approximately 24 times in the month, once a week for each of the 6 glucose monitors in use. Review of glucose testing result records for January and October of 2020 and June and August of 2021 revealed approximately 1,061 glucose test results were reported during the four month period of review. Approximately 6,360 glucose test results were reported in 2 of 2 years, 2020 and 2021, when QC was not performed as required. Interview with practice manager at approximately 2:15 p.m. confirmed the laboratory had 6 Evencare G3 blood glucose monitors in use. She also confirmed that QC was not performed as required, she stated "QC is performed with each shipment of test strips".