Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2102236	(X3) Date Survey Completed 12/11/2023
Name of Provider or Supplier Integrated Healthcare Pc	Street Address, City, State 5600 Kennedy Blvd, West New York, NJ	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on an office review of the CASPER reports 153 and 155 and proficiency testing provider reports, the laboratory failed to achieve 80% or more in two out of three events for Routine Chemistry and Toxicology testing with the College of American Pathologists (CAP). .
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte

	in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on an office review of the CASPER reports 153 and 155 and Proficiency Testing (PT) provider reports, the laboratory failed to achieve at least 80% for the Lactate Dehydrogenase (LDH) and Sodium (NA) tests. The finding includes: 1) The laboratory scored 0% for Sodium in event C-2023 with the College of American Pathologists (CAP). 2) The laboratory scored 60% for Sodium in event B-2023 with the CAP. 3) The laboratory scored 0% for LDH in event C & B-2023 with the CAP.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on an office review of the CASPER reports 153, 155 and the performance summary form College of American Pathologists (CAP), 2023 Rountine Chemistry tests event B. The laboratory failed to participate in CAP aforementioned Proficiency Testing (PT) event of 2023 for Routine Chemistry tests.
D2111	TOXICOLOGY CFR(s): 493.845(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on an office review of the CASPER reports 153, 155 and the performance summary form College of American Pathologists (CAP), 2023 Toxicolgy test event C. The laboratory failed to participate in the CAP aforementioned Proficiency Testing (PT) event of 2023 for Toxicolgy test.
D2118	TOXICOLOGY CFR(s): 493.845(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on an office review of the CASPER report 153 and 155 and Proficiency Testing (PT) provider reports, the laboratory failed to achieve a score of at least 80% or more for Lithium. The finding includes: The laboratory scored 0 % in event 2-2023 and 0% in event 3-2023 PT events with the College of American Pathologists.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on an office review of the laboratory's performance in Proficiency Testing (PT) surveys, the laboratory director failed to provide appropriate direction to the laboratory personnel to ensure that the PT surveys are performed satisfactorily and compliance with the CLIA regulations are maintained.