Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2102236	11/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Integrated Healthcare Pc	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 surveyor review of the Proficiency Testing (PT) evaluation records, work records and interview with Laboratory Manager (LM)) the laboratory failed to participate in PT events "K-B 2023 Ligand-General" and "C-B 2023 General Chemistry/Therapeutic Drugs" with the College of American Pathologists (CAP).
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a

	procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Manager (LM), the laboratory failed to include the dates of initial use and discontinuance for "RPR Card Test N/A" procedure on 11/20/24. The finding includes: 1. The PM had a procedure for serology testing. 2. The laboratory does not performed Serology testing. 3. The LM stated "she did know why" the procedure was in the PM. 4. The PM for "RPR Card Test N/A" had no dates of initial use and discontinuance. 5. The LM confirmed on 11/20/24 at 1:00 pm that the laboratory failed to include the dates of initial use and discontinuance for the aforementioned procedure.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Manager (LM) it was revealed that the laboratory failed to review code 11 "Unable to Analyze. Documentation to be provided by laboratory" results obtained for Chemistry, endocrinology and Toxicology performed with the College of American Pathologists (CAP) in the calendar years 2023, and 2024 The finding includes: 1. Code 11 result were received for event "C-A 2024 General Chemistry /Therapeutic Drugs" as follows. a) Amylase, Serum specimens CHM-01, CHM-02, CHM-03, CHM-04, CHM-05 b) Creatine Kinae specimens CHM-01, CHM-02, CHM-03, CHM-04, CHM-05. c) Pancreatic Amylase specimens CHM-01, CHM-02, CHM-03, CHM-04, CHM-05. d) Triiodothyronine (T3) specimens CHM-01, CHM-02, CHM-03, CHM-04, CHM-05. 2. Code 11 result were received for event "C-B 2024 General Chemistry/Therapeutic Drugs" as follows. a) Pancreatic Amylase specimens CHM-06, CHM-07, CHM-08, CHM-09, CHM-10. 3. Code 11 result were received for event "K-B 2023 Ligand-General" as follows. a) Ferritin specimens K-06, K-07, K-08, K-09, K-10. b) Folate specimens K-06, K-07, K-08, K-09, K-10. c) Vitamin B-12 specimens K-06, K-07, K-08, K-09, K-10. d) Prostate Specific Ag (PSA) specimens K-06, K-07, K-08, K-09, K-10. e) PSA, Free specimens K-06, K-07, K-08, K-09, K-10. 3. Code 11 result were received for event "C-C 2023 General Chemistry /Therapeutic Drugs" as follows. a) Amylase, Serum specimens CHM-11, CHM-12, CHM-13, CHM-14, CHM-15 b) T3 specimens CHM-11, CHM-12, CHM-13, CHM-14, CHM-15. 3. The LM confirmed on 11/20/24 at 10:30 am that the laboratory failed to evaluate code 11 PT results. Note: This was previously cited.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score

	for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Manager (LM) laboratory failed to verify the accuracy of Chemistry and Endocrinology test results obtained from the College of American Pathologists (CAP) for the calendar years 2023 and 2024. The findings include: 1. The laboratory received a 100% but results were received a code 20 "response was not formally graded due to insufficient peer group data. Please see the participant summary for additional information". 2. There was no documented evidence the laboratory verified code 20 for event "C-A 2024 General Chemistry/Therapeutic Drugs" as follows: a) High-density lipoprotein (HDL) Cholesterol, specimens CHM-01, CHM-02, CHM-03, CHM-04, CHM-05. b) Triglycerides, specimens CHM-01, CHM-02, CHM-03, CHM-04, CHM-05. c) Unsaturated iron-binding capacity (UIBC), specimens CHM-01, CHM-02, CHM-03, CHM-04, CHM-05. 3. There was no documented evidence the laboratory verified code 20 for event "C-B 2024 General Chemistry/Therapeutic Drugs" as follows: a) HDL Cholesterol, specimens CHM-01, CHM-02, CHM-03, CHM-04, CHM-05. b) Triglycerides, specimens CHM-01, CHM-02, CHM-03, CHM-04, CHM-05. c) UIBC, specimens CHM-01, CHM-02, CHM-03, CHM-04, CHM-05. 4. There was no documented evidence the laboratory verified code 20 for event "ESR-A 2024 Erythrocyte Sedimentaion Rate" as follows: a) Erythrocyte Sedimentation Rate (ESR) Specimens ESR-01, ESR-02, ERS-04. 5. There was no documented evidence the laboratory verified code 20 for event "S2-A 2024 Special Immunology" as follows: a) Anti-throglobulin,qu samples S2-03 an S2-04. b) Anti-thyroid perox, qu samples S2-03 an S2-04 6. There was no documented evidence the laboratory verified code 20 for event "S2-B 2024 Special Immunology" as follows: a) Anti-throglobulin, qu samples S2-21 an S2-22. b) Anti-thyroid perox, qu samples S2-21 an S2-22. 7. There was no documented evidence the laboratory verified code 20 for event "C-C 20234 General Chemistry/Therapeutic Drugs" as follows: a) HDL specimens CHM-11, CHM-12, CHM-13, CHM-14, CHM-15. b) Triglycerides, specimens CHM-11, CHM-12, CHM-13, CHM-14, CHM-15. 8. The LM confirmed on 11/20/24 at 10:20 am accuracy of the PT results were not verified Note: This was previously cited
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A) Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Manager (LM), the laboratory failed to follow all procedures written for proficiency testing review 10/25/22 to the 11/20/24. The findings include: 1. There was no documented evidence the log in "Investigation of Proficiency test scores less than 100%" was used. 2. The LM confirmed on 11/20/24 at 10:30 am that the laboratory did not follow the PM. Note: This was previously cited. B) Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Manager (LM), the laboratory failed to follow all procedures written for Quality Controls (QC) review 10/25/22 to the 11/20/24. The findings include: 1. The PM

	states "Make sure there is no shifting in control" 2. There was no documented evidence that laboratory monitored shifts and trends in QC values. 3. The LM confirmed on 11/20/24 at 10:30 am that the laboratory did not follow the PM. C) Based on surveyor review of the PM and interview with the LM, the laboratory failed to maintain complete procedures written for QC review from 10/25/22 to the 11/20 /24. The findings include: 1. The PM did not define a time frame on how and when "Shifting in controls" are monitored. 2. The PM did not define who will review and accept the procedure "Make sure there is no shifting in control". 3. The LM confirmed on 11/20/24 at 10:30 am the laboratory failed to maintain complete procedures written for QC review.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Patient Test Records (PTR) and interview with the Laboratory Manager (LM) the laboratory lacked a Corrective Action (CA) procedure to follow for flagged results for Hematology tests performed on the DxH 520 analyzer from 11/1/23 to 11/20/24. The finding includes: 1. The laboratory did not have a CA procedure available to follow if patient results had flagged results by the DxH 520. 2. Specimen ID 0020597B had a Hemoglobin flagged result as "Suspect Diff". There was no CA procedure implemented by the laboratory to follow to resolve the flagged result. 3. The LM confirmed on 11/20/24 at 11:45 am that the laboratory did not have a CA to follow for flagged patient results.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with Laboratory Manager (LM) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 10/25/22 to 11/20/24. The findings include: 1. The Laboratory failed to have a complete Corrective Action (CA) procedure for Quality Control (QC). 2. The CA procedure stated "control must be in if out of 2SD must be repeated" 3. The CA procedure does not address QC flags. 4. The CA procedure does not address multiple QC failures. 5. The LM confirmed on 11/20 /24 at 11:45 am that the laboratory failed to have complete CA procedure for QC.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)

	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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Manager (LM), the Laboratory Director (LD) failed to ensure that PS procedures performed for Hematology testing performed on the Beckman Coulter DxH 520 analyzer were adequate from 11/1/23 to 11/20/24 . The findings include: 1. There was no acceptability or rejection criteria stated for method comparison, accuracy, precision studies performed on the DxH 520 analyzer. 2. The LM confirmed on 11/20/24 at 11:15 am that PS records were not adequate.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Laboratory Manager (LM), the Laboratory Director (LD) failed to ensure that all PT results received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for Endocrinology and Chemistry testing performed with the College of American Pathologists (CAP) in the calendar years 2023 and 2024 The findings include: 1. Cross refer D5211 2. Cross refer D5215 3. The LM confirmed on 11/20/24 at 10:30 am that not all CAP PT results reviewed. Note: This was previously cited.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Laboratory Manager (LM), the LD failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed

	on the Access 2 and AU480 analyzers from 10/25/22 to 11/20/24. The findings includes: 1. There was no documented evidence that Levy Jennings charts were reviewed by appropriate staff. 2. The QC program is incomplete. Cross refer D5401 3. The LM confirmed on 11/20/24 at 11:35 am, there was no documented evidence trends and shifts were reviewed.