Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2102236	11/12/2019
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Consultant (LC), the laboratory director failed to maintain the Work Records (WR) and Attestation Statements (AS) signed by the analyst and laboratory director for Routine Chemistry, Endocrinology, Immunoassay and Hematology tests performed with the College of American Pathologists for events performed in 2018 and 2019. The findings include: 1. The laboratory did not document handling, processing and each step in the testing and reporting of PT sample for: a. General Chemistry - events A,B & C in 2018 and A-2019 b. Immunoassay - Ligand Special Y-B 2018 and Y-A 2019 c. Hematology - Auto Differential FH1 A, B & C 2019 d. Hemoglobin A1C - GHB2 - B2018 & B-2019 2. There were no WR to substantiate reported results for: a. General Chemistry - events A,B & C in 2018 and A-2019. b. Immunoassay - Ligand Special Y-B 2018 and Y-A & B 2019 c. Hematology - Auto Differential FH1 B & C 2018 and FH1 A & C 2019 d. Vitamin - A & B 201825-OH Vitamin D e. Hemoglobin A1C - GHB2 - B2018 & B-2019 3. The LC confirmed on 11/12/19 at 11:15 pm that the laboratory did not maintain all records for PT.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I 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 Consultant (LC), the laboratory failed to verify the accuracy and reliability of Folate, Ferritin, and Vitamin B12 tests twice a year from 9/13/17 to the date of survey. The LC confirmed on 11/12/19 at 11:00 am that the laboratory did not verify the accuracy of above mentioned tests.
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: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Consultant (LC), the laboratory failed to follow the procedure for reviewing results with flags obtained on the Cell Dyne 1700 analyzer used for Hematology testing from 9/13/17 to the date of the survey. The finding includes: 1. The PM stated to review a stained smear to confirm results but a review of ten patient results with flags revealed the laboratory did not make smears. 2. The Testing Personnel stated the laboratory never made blood smears. 3. The LC confirmed on 11 /12/19 at 11:40 am that the laboratory did not follow the procedure for flag review.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the patient Work Records (WR), Final Reports and interview with the Laboratory Consultant (LC), the laboratory failed to perform corrective action when the Beckman Access 2 had error codes on patient results in September 2019. The findings include: 1. A review of patient WR from 9/14/19 - 9/26 /19 revealed error codes CEX (calibration code expired) and LEX (reagent pack

	expired) as below: a. Total Triiodothyronine (T3), Thyroxine (T4), Thyroid peroxidase (TPO) antibody - CEX b. Vitamin B12 and Folate - CEX c. Ferritin - LEX 2. Calibration was not performed on the day of the CEX and LEX flag. 3. There was no documented evidence corrective action was taken. 4. Approximately 40 - 50 patients were reported with expired calibrations and 2 patients with an expired reagent. 5. The LC confirmed on 11/12/19 at 2:10 pm that corrective action was not performed.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR), Work records (WR) and interview with the Laboratory Consultants (LC), the laboratory failed to identify problems on the FR from 9/13/17 to the date of the survey. . The findings include: 1. The flags from the patient's WR were printed on the FR. 2. The LC confirmed on 11/12/19 at 1: 30 pm the laboratory did not identify problems on the FR.