

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2102236	(X3) Date Survey Completed 10/25/2022
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	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) evaluation records, work records and interview with Technical Consultant (TC) the laboratory failed to participate in PT for events A-B 2022 General Chemistry/Therapeutic Drugs and VITD-B 2021 25-OH Vitamin D with the College of American Pathologists.</p>
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local</p>

laboratory requirements.

This STANDARD is not met as evidenced by:

Based on surveyor review of the laboratories NJ State License, Proficiency Testing (PT) and interview with the State of New Jersey Proficiency Provider Program lead, the Laboratory Director (LD) failed to be in compliance with New Jersey Administrative code N.J.A.C. 8:44-2.5(b)3. The finding includes: 1. N.J.A.C. 8:44-2.5 (b)3. states Laboratories shall: iii. Maintain records of all proficiency testing results in surveys in which they participate and make such records, including results, interpretations and cumulative performance data routinely available to the Department of Health and Senior Services. 2. The LD failed to make PT data routinely available to the Department of Health and Senior Services.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Competency Assessment (CA) records and interview with the Technical Consultant (TC) the laboratory failed to follow its policies and procedures for assessing the competency of Testing Personnel (TP) who perform Endocrinology, Hematology, and routine chemistry testing from 11/12/16 to the date of survey. The findings include: 1. The laboratory failed to use all the required elements applicable to Endocrinology, Hematology and Routine Chemistry for assessing the competency of TP. The laboratory did not use: a. #4 assessment of test performance through proficiency testing, blind sampling or previously analyzed specimens 2. The CA did not include evaluation of TP specifically for Endocrinology, Hematology and Routine Chemistry. 3. The TC confirmed on 10/25/22 at 10:00 am the laboratory did not use the follow the CA 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:

a) Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC) it was revealed that the laboratory failed to review code 20 "No appropriate target/response could not be graded" results obtained for Chemistry, Hematology and Endocrinology PT performed with the College of American Pathologists (CAP) in the calendar years 2020, 2021 and 2022 The finding includes: 1. Code 20 results were received for all analytes for "Hematology Auto Differentials,FH1" three events in 2021 and events FH1-A 2022 and FH1-B 2022. 2. Code 20 Results where received for Triglycerides Samples CHM-11 through 15 in event C-C 2021 General chemistry/therapeutic Drugs. 3. Code 20 results where received for Thyroid Stimulating Hormone samples CHM-06 through 10 in event C-B

	<p>2021 General Chemistry/Therapeutic Dugs 4. The TC confirmed on 10/25/22 at 10:30 am that the laboratory failed to evaluate code 20 PT results. b) Based on surveyor review of the Proficiency Testing (PT) records and interview with the TC it was revealed that the laboratory failed to review code 11 "Unable to Analyze. Documentation to be provided by laboratory" results obtained for Chemistry performed with the College of American Pathologists (CAP) in the calendar years 2020, 2021 and 2022 The finding includes: 1. Code 11 result were received for Thyroid Stimulating Hormone samples CHM-01 through 05 event C-A 2021 General Chemistry/Therapeutic Drugs. 2. The TC confirmed on 10/25/22 at 10:30 am that the laboratory failed to evaluate code 11 PT results.</p>
<p>D5215</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>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).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to verify the accuracy of Chemistry and Hematology test results obtained from the College of American Pathologists (CAP) for the calendar years 2021 and 2022. The findings include: 1. The laboratory received a 100 but results were received a code 20. 2. There was no documented evidence the laboratory verified: a. "Hematology Auto Differentials, FH1" three events in 2021 and events FH1-A 2022 and FH1-B 2022 all analytes. 3. There was no documented evidence the laboratory verified: a. Thyroid Stimulating Hormone event C-B 2021 General Chemistry/Therapeutic Dugs 4. The TC confirmed on 10/25/22 at 10:20 am accuracy of the PT results were not verified</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Technical Consultant (TC), the laboratory failed to follow all procedures written for proficiency testing review and review of unacceptable controls from 11/12/19 to the date of the survey. The findings include: 1. There was no documented evidence the logs in the PM labeled "Review of Controls for Unacceptable Results" and "Investigation of Proficiency test scores less than 100%" were used. 2. The TC confirmed on 10/25/22 at 10:30 am that the laboratory did not follow the PM.</p>
<p>D5411</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p>

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

a) Based on surveyor review of the Bio-Rad Liquid Assayed Multiquel Instructions For Use (IFU), Quality Control records (QC) and interview with the Technical Consultant (TC), the laboratory failed to follow the IFU for Uric Acid and Magnesium from 12/9/21 to the date of survey. The findings include: 1. Uric Acid was coded with a for all three levels of QC on the Bio-Rad Liquid Assayed Multiquel assay sheet Lot # 45910. 2. The IFU for Uric Acid states " - The data required to establish the means and acceptable ranges for this assay were not obtained due to limited assignment participation. If your facility is interested in participating in the Value Assignment Program for this assay, please contact your local Bio-Rad office." 3. Magnesium was coded for all three levels of Bio-Rad Liquid Assayed Multiquel assay sheet Lot # 45910. 4. The IFU for Magnesium states "Data is not available at this time. Please inquire." 5. There was no documented evidence that the above mentioned procedures were performed. 6. The TC confirmed on 10/25/22 at 12:50 pm that the laboratory did not follow the IFU. b) Based on surveyor review of the Streck Para 12 Extend IFU, QC records and interview with the TC, the laboratory failed to follow the IFU for "Multi-parameter Assayed Hematology Control" from 8/18/22 to the date of survey. The findings include. 1. The IFU stated that the control materials matrix was not compatible with the Cell-Dyn 1700. 2. The TC confirmed on 10/25/22 at 1:50 pm that the laboratory did not follow the IFU. c) Based on surveyor review of the Streck Cal-Chex IFU, Calibration Verification record (CVR) and interview with the TC, the laboratory failed to follow the IFU for "Hematology Calibrator" from 1/27 /21 to the date of survey. The findings include. 1. The IFU stated that the Calibration materials matrix was not compatible with the Cell-Dyn 1700. 2. The TC confirmed on 10/25/22 at 1:50 pm that the laboratory did not follow the IFU.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

a) Based on surveyor review of the Quality Control (QC) Records and interview with the Technical consultant (TC), the laboratory used expired QC material for Hematology testing from to 9/5/22 to the date of survey. The findings include: 1. QC material expiration date changes once opened. 2. The laboratory was unaware that Streck Paras 12 Extend QC material was stable for 30 days after opening. 3. Streck Para 12 Extend Level 1- Lot 21850422, 2 - 21850423, 3- 21850424 QC opened 7/8/22 expired 9/5/22. 4. Approximately ten patients were run per day. 5. The TC confirmed on 10/25/22 at 11:00 am that the laboratory used expired QC material.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on surveyor review of Calibration (CAL) records, Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to perform Calibration at least once every six months for Hematology Tests performed on the Cell-Dyn 1700 analyzer in the calendar years 2021 and 2022. The findings include: 1. A review of Cal records revealed that the calibration material used was not designed for the Cell-Dyn 1700 for calibration performed in the second half of 2021 and all of 2021. 2. The TC confirmed on 10/25/22 at 10:32 am that the laboratory failed to perform Cal once every six months.

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, Quality Control (QC) records, Patients Work Records (PWR) and interview with the Technical Consultant (TC) the laboratory failed to have available Corrective Action (CA) procedures for QC and flagged PWR from on the date of survey. The TC confirmed on 10/25/22 at 12:00 pm that the laboratory failed have available Corrective Action (CA) procedures.

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 Technical consultant (TC), the laboratory failed to perform corrective action when the Beckman Access 2 had error codes on patient results in October 2022. The findings include: 1. A review of patient WR from 10/22/22 revealed error codes CEX (calibration code expired) and PEX (reagent pack expired) as below: a. Cortisol, Parathyroid Hormone (PTH), Thyroid Stimulating Hormone (TSH3), Vitamin D (VitdA) - CEX b. Free prostate-specific antigen (freePSA) - CEX & PEX 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 10 patients were reported with expired calibrations and 1 patients with an expired reagent. 5. The TC confirmed on 10/25/22 at 2:10 pm that corrective action was not performed. NOTE: This was previously cited 11/12/19

D5809

TEST REPORT
CFR(s): 493.1291(e)

The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

This STANDARD is not met as evidenced by:
Based on survey review of the laboratory Test Menu (TM), Final reports (FR), Test Requisition (TR) and interview with the Technical Consultant (TC) the laboratory failed to make available an accurate list of test methods employed by the laboratory. The findings include: 1) Dehydroepiandrosterone sulfate, Estrodial, Luteinizing Hormone, Progesterone, and Prolactin were listed on the TM but were not being performed by the laboratory. 2) Parathyroid Hormone was not listed on the TM but was being performed by the laboratory. 3) The TC confirmed on 10/25/22 at 2 pm the laboratory failed to make available an accurate list of test methods.

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 Technical Consultants (TC), 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 TC confirmed on 10/25/22 at 1:30 pm the laboratory did not identify problems on the FR. Note: This was previously cited 11/12 /19.

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 surveyor review of the Laboratory records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 10/25/22 to the date of survey. The findings include: 1. The LD failed to ensure that all PT results received were reviewed. Cross refer D6018 2. The LD failed to ensure a Quality Control program was established and maintained. Cross refer D6020. 2. The LD failed to ensure that failed to establish a Quality Assurance plan . Cross refer D6021. 3. The LD failed to ensure that an approved procedure manual was available for FERN and Wet Prep testing. Cross refer 6031. The LD failed to identify problems that may affect test performance, Cross refer D6074 .

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 Technical Consultant (TC), 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 Hematology and Chemistry testing performed with the College of American Pathologists (CAP) in the calendar years 2021 and events A, B, C and A, B in 2022. The TC listed on CMS form 209 confirmed on 10/25/22 at 10:30 am that the CAP PT results were not reviewed.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records, Calibration Material

(CM), QC Manufactures Package Insert (QCMPI), CM Manufactures Package insert (CMMPI), Procedure Manual (PM) and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure that the QC program was maintained for laboratory services provided from 9/9/21 to the date of the survey. The findings include: 1. The laboratory used Hematology QC material with a matrix not supported for the Cell-Dyn 1700. 2. The laboratory used CM with a matrix not supported for the Cell-Dyn 1700. 3. The laboratory failed to establish QC ranges for Magnesium and Uric Acid. 4. The laboratory did not evaluate Hematology proficiency testing for five consecutive PT events in the calendar years 2021 and 2022. 5. The TC confirmed on 10/25/22 at 3:00 pm the the LD failed to ensure that the QC program was maintained. .

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on the surveyor review of the Quality Assessment (QA) policy and interview with the Technical Consultant (TC), the Laboratory Director failed (LD) to failed ensure that the QA program was maintained from 11/12/19 to the date of survey. The finding includes: 1. The QA program did not include Glomerular Filtration Rate (GFR) Laboratory Information System (LIS) calculation check. 2. The LD did not correct citations from the prior survey conducted 11/12/19 survey. 3. The LD failed to ensure the laboratory evaluated all coded Proficiency test results. Cross refer D5211 4. The LD failed to ensure the laboratory to verified the accuracy of Chemistry and Hematology testing. Cross refer D5215 5. The TC confirmed on 6/1/22 at 1:20 pm that the LD did not maintain the QA program.

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 Technical Consultant (TC), the Testing Personnel failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts of Hematology, Endocrinology, and Routine Chemistry QC results performed on the Beckman Coulter Cell-Dyn 1700, Access 2 and AU480 analyzers from 11/12/19 to the date of the survey. The TC confirmed on 10/25/22 at 2:10 PM that trends and shifts were not reviewed.