

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2102236	(X3) Date Survey Completed 12/09/2024
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
D0000	A proficiency testing desk review survey was performed on December 4, 2024, the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 review of CASPER report 155 and graded results from the College of</p>

	<p>American Pathologists (CAP), the laboratory failed to successfully participate in four out of five Proficiency Testing (PT) events in the subspecialty Routine Chemistry for the analyte Sodium (NA). Refer to D2096.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CASPER 155 report and graded results from College of American Pathologists (CAP), the laboratory failed to achieve satisfactory performance (80% or greater) for four out of five events in the subspecialty Routine Chemistry for the analyte Sodium (NA). The findings include: 1) A Review of the CASPER 155 report revealed the following: a) The laboratory scored 0% for NA in event 2-2023. b) The laboratory scored 60% for NA in event 3-2023. c) The laboratory scored 60% for NA in event 2-2024. d) The laboratory scored 0% for NA in event 3-2024. 2. A review of CAP graded results confirmed the above failed PT events.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CASPER 155 report and graded results from College of American Pathologists (CAP) the Laboratory Director (LD) failed to provide overall management and direction to laboratory personnel to ensure that the Proficiency Testing (PT) surveys are performed satisfactorily and in compliance with Clinical Laboratory Improvement Amendments (CLIA) regulations. The findings include: 1. The LD failed to ensure PT surveys are performed satisfactorily and in compliance with CLIA regulations. Refer to D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on a review of the CASPER 155 report and graded results from College of</p>

American Pathologist (CAP) the Laboratory Director (LD) failed to ensure successful participation in a Department of Health and Human Services (DHHS) approved Proficiency Testing (PT) program for four out of five PT events for the analyte Sodium (NA) resulting in subsequent unsuccessful performance. Refer to D2096.