

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1093662	(X3) Date Survey Completed 09/19/2024
Name of Provider or Supplier Integrated Health Concepts, Llc	Street Address, City, State 1615 Bluff City Hwy, Bristol, TN	
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 a review of the Centers for Medicare and Medicaid Services CASPER Report 155 (CMS 155) and the laboratory's proficiency testing (PT) evaluation reports, the laboratory failed to maintain satisfactory participation for two out of three proficiency testing events in 2023 and 2024, resulting in initial unsuccessful participation for the red blood cell (RBC) analyte. (See D2130)</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of the CMS 155 and the laboratory's American Proficiency Institute (API) PT evaluation reports, the laboratory failed to maintain satisfactory performance for two out of three test events for the red blood cell (RBC) analyte, resulting in initial unsuccessful PT occurrence. The findings include: 1. A review of the CMS 155 report revealed the following unsatisfactory RBC scores: - 2023 Event three: 20% - 2024 Event two: 20% 2. A review of the laboratory's API PT evaluation report revealed the following unsatisfactory RBC scores: - 2023 Event three: 20% - 2024 Event two: 20%