

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0889196	(X3) Date Survey Completed 10/21/2024
Name of Provider or Supplier Central Clinical Labs Inc	Street Address, City, State 6858 W Archer Ave, Chicago, IL	
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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D - Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to successfully participate in PT for the general immunology analyte Hepatitis B surface antigen (HBsAg) during events one and two of 2024, resulting in unsuccessful PT performance for HBsAg. See D2084.</p>
D2084	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(f)</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.

This STANDARD is not met as evidenced by:

Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D - Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to successfully participate in proficiency testing (PT) for the general immunology analyte Hepatitis B Surface Antigen (HBsAg) during PT events one and two of 2024. Findings include: 1. Review of the CASPER Report 0155D ran on 10/01/2024 identified the initial unsuccessful PT performance for the general immunology analyte HBsAg. GENERAL IMMUNOLOGY HBsAg - EVENT-1, 2024 = 60% - Unsatisfactory HBsAg - EVENT-2, 2024 = 60% - Unsatisfactory 2. Review of the API PT records for event 1 and event 2 of 2024 confirmed the unsuccessful PT performance for HBsAg during these two consecutive PT events.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D - Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory director failed to meet the requirements of this condition. The laboratory director failed to ensure test methods were performed as required to provide accurate and reliable results for the general immunology analyte Hepatitis B Surface Antigen (HBsAg) in 2024. See D6087.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D - Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory director failed to ensure successful participation in an Health and Human Services (HHS) approved PT program for the general immunology analyte Hepatitis B Surface Antigen (HBsAg), resulting in the laboratory's initial unsuccessful PT performance in event one and two of 2024. See D2084.