

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2131019	(X3) Date Survey Completed 12/17/2021
Name of Provider or Supplier Axis Clinicals Llc	Street Address, City, State 1711 Center Ave W, Dilworth, MN	
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 Center for Medicare and Medicaid Services reports and proficiency testing reports from the College of American Pathologists (CAP), the laboratory failed to successfully participate in proficiency testing for Beta human chorionic gonadotropin (BHCG) testing under the specialty of Chemistry. Findings are as follows: 1. The CASPER Report 0155D, reviewed on 12-10-21, indicated the the laboratory failed to successfully participate in BHCG testing in 2021. Unsatisfactory PT performance in BHCG testing was obtained in the following</p>

events. -2021 1st event 20% -2021 3rd event 0% 2. The CASPER Report 0155D indicated the laboratory failed to obtain a BHCG PT score of at least 80 percent in two out of three consecutive testing events in 2021. See D2087 and D2096. .

D2087

ROUTINE CHEMISTRY
CFR(s): 493.841(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

. Based on a review of proficiency testing (PT) reports from the College of American Pathologists (CAP), the laboratory failed to obtain a PT score for Beta human chorionic gonadotropin (BHCG) testing of at least 80 percent which resulted in unsatisfactory performance for the analyte. Unsatisfactory PT performance for BHCG testing was obtained in the following events. -2021 1st event 20% -2021 3rd event 0%

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D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

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 a review of proficiency testing (PT) reports from the College of American Pathologists (CAP) provider, the laboratory failed to achieve successful performance for Beta human chorionic gonadotropin (BHCG) testing in two out of three consecutive PT events. Findings are as follows: The laboratory failed BHCG testing in two out of three consecutive PT events. Two out of three consecutive PT failures for the same analyte constitutes unsuccessful performance. PT reports from CAP listed the following unsatisfactory BHCG scores. -2021 1st event 20% -2021 3rd event 0% .