

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0402086	(X3) Date Survey Completed 12/04/2019
Name of Provider or Supplier Neighborhood Health Source Central Avenue Clinic	Street Address, City, State 2301 Central Avenue Ne, Minneapolis, 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, College of American Pathologists (CAP) and American Proficiency Institute (API) proficiency testing reports, and email communication with the Technical Consultant (TC), the laboratory failed to successfully participate in proficiency testing (PT) for White Blood Cell Differential testing under the specialty of Hematology. Findings include: 1. The CASPER Report 155, reviewed on December 4, 2019, indicated the unsatisfactory White Blood Cell Differential PT performance was a subsequent - not the first - failure that occurred in calendar year 2019. 2. Based on review of the CAP and API PT reports and email communication with Technical Consultant, the</p>

	<p>laboratory failed to achieve successful PT performance for White Blood Cell Differential testing in three of four consecutive PT events. See D2130.</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <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.</p> <p>This STANDARD is not met as evidenced by: . Based on review of proficiency testing (PT) reports from the College of American Pathologists (CAP) and the American Proficiency Institute (API) and email communication with the Technical Consultant (TC), the laboratory failed to achieve successful PT performance for White Blood Cell Differential testing in two of three consecutive PT events in 2019. Findings include: 1. The CAP and API PT reports, reviewed on December 4, 2019 revealed that the unsatisfactory PT performance was a subsequent - not the first - failure which occurred under the specialty of hematology for White Blood Cell Differential during calendar year 2019 as listed below. 3rd quarter 2018 CAP 0% 1st quarter 2019 API 0% First failure 3rd quarter 2019 CAP 0% Subsequent failure 2. In an email communication on 12/04/2019 at 11:02 AM, the TC confirmed the laboratory lacked participation in the 3rd quarter 2019 hematology PT event because the laboratory missed the submission deadline date.</p>
<p>D6090</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(ii)</p> <p>The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: . Based on a review of proficiency testing (PT) reports from the College of American Pathologists (CAP) and email communication with the Technical Consultant (TC), the Laboratory Director failed to ensure PT results were returned to CAP within the established timeframe. Findings include: 1. The laboratory failed to return their Hematology PT results to CAP prior to the submission deadline for the events listed below. 2018 3rd event 2019 3rd event 2. In an email communication on 12/04/19 at 11:02 AM, the TC confirmed the above finding.</p>