

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0694973	(X3) Date Survey Completed 10/05/2022
Name of Provider or Supplier Healthquarters, Inc	Street Address, City, State 100 Cummings Center Suite 110-E, Beverly, MA	
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 CLIA paper desk review of proficiency testing was conducted for the the Healthquarters, Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Based on evidence of unsuccessful proficiency testing performance for the Immunohematology specialty, the following Condition level deficiency was deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. Refer to D2016. .
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 American Proficiency Institute (API) proficiency testing review for calendar</p>

	<p>years 2021 and 2022 (three testing events), the laboratory failed to successfully participate (achieve a score of 100 percent or more) in a proficiency testing program for the D(RhO) typing analyte. The laboratory achieved a score for D(RhO) typing of sixty (60) percent for the third testing event of 2021 and a score of eighty (80) percent for the second testing event of 2022 resulting in unsuccessful performance for the analyte and the specialty area of immunohematology. Refer to D2162 and D2163. .</p>
<p>D2162</p>	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f)</p> <p>Failure to achieve satisfactory performance for the same analyte 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 record review of calendar years 2021 and 2022 American Proficiency Institute (API) proficiency testing results (three testing events), the laboratory failed to attain a testing event score of at least 100 percent for all immunohematology analytes leading to unsuccessful performance. The laboratory received an overall testing score for D(RhO) typing of sixty (60) percent for the third testing event of 2021 and a score of eighty (80) percent for the second testing event of 2022 resulting in unsuccessful performance for the analyte. .</p>
<p>D2163</p>	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(g)</p> <p>Failure to achieve an overall testing event score of satisfactory for 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 record review of calendar years 2021 and 2022 American Proficiency Institute (API) proficiency testing results (three testing events), the laboratory failed to attain a testing event score of at least 100 percent for the specialty of immunohematology leading to unsuccessful performance. The laboratory received an overall testing score for immunohematology of sixty (60) percent for the third testing event of 2021 and a score of eighty (80) percent for the second testing event of 2022 resulting in unsuccessful performance for the specialty of immunohematology.</p>