

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0694973	(X3) Date Survey Completed 01/05/2023
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 on 3/8/22 for 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 a second occurrence of unsuccessful proficiency testing performance for the specialty of Immunohematology (D (Rho) typing), the following Condition level deficiencies were deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. Condition 42 CFR 493.1403 - Laboratory Director. .
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:</p>

Based on record review on 1/5/23 of calendar years 2021 and 2022 proficiency testing results (three testing events), the laboratory failed to successfully participate (achieve a score of 100 percent) in the American Proficiency Institute (API) proficiency testing program for the specialty of Immunohematology (D (Rho) typing) as evidenced by the following: First Unsuccessful Occurrence: The laboratory achieved a score for Immunohematology (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 the first occurrence of unsuccessful performance for the specialty of Immunohematology (D (Rho) typing) . Second Unsuccessful Occurrence: The laboratory achieved a score for Immunohematology (D (Rho) typing) of eighty (80) percent for the second testing event of 2022 and a score of eighty (80) percent for the third testing event of 2022 resulting in the second occurrence of unsuccessful performance for the specialty of Immunohematology (D (Rho) typing) . Based on this evidence the laboratory failed to undertake the appropriate training and/or technical assistance necessary to correct the problem of unsuccessful proficiency testing performance for the specialty of Immunohematology (D (Rho) typing). Refer to D2163. .

D2163

ABO GROUP AND D(RHO) TYPING
CFR(s): 493.859(g)

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.

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 an over all testing event score of at least 100 percent for all Immunohematology analytes leading to a second unsuccessful performance for the specialty of Immunohematology (D (Rho) typing) as evidenced by the following specialty scores obtained: 1. 2021 API testing event 3 - Immunohematology score of sixty (60)%. 2. 2022 API testing event 2 - Immunohematology score of eighty (80)%. 3. 2022 API testing event 3 - Immunohematology score of eighty (80)%. The scores were confirmed in a telephone conversation with the technical consultant on 1/4/23. .

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on the deficiencies cited herein, the laboratory director failed to ensure that effective remedial action was instituted in response to unsatisfactory proficiency testing results resulting in repeated unsuccessful performance for the specialty of Immunohematology (D (Rho) typing). Refer to D2016 and D2163.