

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2207862	(X3) Date Survey Completed 08/01/2023
Name of Provider or Supplier Mhg Physician Services - Massachusetts, Pllc	Street Address, City, State 500 Harrison Avenue Flr 3r, Boston, 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 MHG Physician Services - Masssachusetts. PLLC 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 Routine Chemistry and Hematology specialties, 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 an off-site proficiency testing desk review for calendar years 2022 and 2023,</p>

the laboratory failed to successfully participate (achieve a score of 80 percent or more) in the American Proficiency Institute (API) proficiency testing program for the specialties of Routine Chemistry and Hematology resulting in unsuccessful proficiency testing performance for the two specialty areas. Refer to D2089 and D2123. .

D2089

ROUTINE CHEMISTRY

CFR(s): 493.841(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on record review of calendar years 2022 and 2023 proficiency testing results (three testing events), the laboratory failed to return proficiency testing results for the third testing event of 2022 and the second testing event of 2023 as evidenced by the following: a) A review of the the American proficiency Institute (API) proficiency testing results for the third testing event of 2022 and the second testing event of 2023 revealed that the laboratory received a score of zero (0) percent for all chemistry analytes for failure to participate. b) The laboratory's failure to participate in the above Routine Chemistry testing events was confirmed through a telephone interview on 7/28/23 with the American Proficiency Testing (API) proficiency testing program. .

D2123

HEMATOLOGY

CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on record review of calendar years 2022 and 2023 proficiency testing results (three testing events), the laboratory failed to return proficiency testing results for the third testing event of 2022 and the second testing event of 2023 as evidenced by the following: a) A review of the the American proficiency Institute (API) proficiency testing results for the third testing event of 2022 and the second testing event of 2023 revealed that the laboratory received a score of zero (0) percent for all hematology analytes for failure to participate. b) The laboratory's failure to participate in the above

Hematology testing events was confirmed through a telephone interview on 7/28/23 with the American Proficiency Testing (API) proficiency testing program.