

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D2180550	<b>(X3) Date Survey Completed</b>  11/05/2021
<b>Name of Provider or Supplier</b>  Manhattan Medical Group, Llc	<b>Street Address, City, State</b>  202 Research Drive, Manhattan, KS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 the review of proficiency testing (PT) records, the laboratory failed to successfully participate in PT from American Proficiency Institute (API) under the specialties: 1. Routine Chemistry for the regulated analytes: pCO2 Blood Gas. See D2096. 2. Hematology for the regulated analytes overall score derived from: Prothrombin time, Hematocrit (HCT) and Hemoglobin (HGB). See D2130.</p>
<b>D2096</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p>

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 desk review of PT scores from the provider API under Routine Chemistry for the regulated analyte pCO<sub>2</sub> and phone interview revealed the following: 1. Second Event Chemistry 2021 revealed a score of 60% for pCO<sub>2</sub>. 2. Third Event Chemistry 2021 revealed a score of 0% for pCO<sub>2</sub>. 3. Phone interview with the lab manager on 11/4/21 at 2:00 p.m. confirmed, the laboratory failed to achieve an acceptable score of 80% or higher for two of three consecutive testing events on the regulated analyte pCO<sub>2</sub>.

**D2130**

**HEMATOLOGY**

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of PT scores from the provider API under the specialty Hematology for the regulated analytes of hematocrit (HCT), hemoglobin (HGB) and prothrombin time, and phone interview revealed the following: 1. Second Event Hematology 2021 revealed an overall score of 66% derived from 100% HCT, 100% HGB and 0% prothrombin time. 2. Third Event Hematology 2021 revealed an overall score of 0% derived from 0% HCT and 0% HGB. 3. Phone interview with the lab manager on 11/4/21 at 2:00 p.m. confirmed, the laboratory failed to achieve an acceptable score of 80% or higher for two of three consecutive testing events on the specialty Hematology.