

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D0711692	<b>(X3) Date Survey Completed</b>  09/01/2022
<b>Name of Provider or Supplier</b>  David R Mandel Md Inc	<b>Street Address, City, State</b>  6551 Wilson Mills Road, Suite 106, Mayfield Village, OH	
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>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 record review and an interview with the sole Testing Personnel (TP), the laboratory failed to successfully participate in a Proficiency Testing (PT) program for the urea testing performed under the subspecialty of routine chemistry. All patients who had urea testing in this laboratory from the first testing event of 2022 on 03/23/2022 to 06/23/2022 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to achieve a PT score of 80% (percent) for the analyte urea in the first and second PT events in 2022 in the specialty of Chemistry. (Refer to D2096)</p>

**D2096**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(f)

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 record review and an interview with the sole Testing Personnel (TP), the laboratory failed to achieve a Proficiency Testing (PT) score of 80% (percent) for the analyte urea in the first and second PT events in 2022 in the specialty of Chemistry. All patients who had urea testing in this laboratory from the first testing event of 2022 on 03/23/2022 to 06/23/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's 2022 College of American Pathologists (CAP) PT documentation revealed the analyte urea was scored of 20% for for the first testing event and 40% for the second testing event of 2022. 2. The TP confirmed the laboratory did not achieve satisfactory PT performance for the analyte urea in the first two consecutive testing events in 2022. The interview occurred on 08 /04/2022 at 1:27 PM.