

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D0711692	<b>(X3) Date Survey Completed</b>  08/19/2019
<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>D2087</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by:                      **This is a repeat deficiency as cited on the 09/07/2017 CLIA inspection** Item 1: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to attain a proficiency testing (PT) score of at least 80 % (percent) of acceptable responses for the analyte albumin (Alb) which resulted in three out of five acceptable results or a score of 60 % for the third testing event of 2018. All patient Alb testing performed in this laboratory from June 2018 (last successful Alb score for the 2nd event 2018) through March 2019 (next successful Alb score for the 1st event 2019) had the potential to be affected by this unacceptable PT analyte score. Findings Include: 1. Review of the laboratory's 2018 and 2019 College of American Pathologists (CAP) PT documentation, provided on the date of the inspection, revealed an Alb analyte testing score of 60% for the third testing event of 2018. 2. Review of the laboratory's PT evaluation revealed the unacceptable results to be clerical errors with reporting the ALT results instead of the Alb results as listed below: PT Alb ALT Alb Result Expected Specimen Result Result Reported Result                      CHM-14 3.2 162.0 162.0 2.8-3.5 CHM-15 3.7 134.0 134.0 3.3-4.1 3. The GS confirmed the laboratory did not achieve a PT analyte testing score of at least 80% for Alb and stated their PT evaluation revealed their clerical error and the Alb results achieved were within CAP's expected range for the third testing event of 2018. The interview occurred on 08/19/2019 at 10:15 AM. Item 2: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to attain a proficiency testing (PT) score of at least 80 % (percent) of acceptable responses for the analyte total bilirubin (Tbil) which resulted in two out of five acceptable results or</p>

a score of 40 % for the second testing event of 2019. All patient Tbil testing performed in this laboratory from March 2019 (last successful Tbil score for the 1st event 2019) through date of inspection had the potential to be affected by this unacceptable PT analyte score. Findings Include: 1. Review of the laboratory's 2018 and 2019 College of American Pathologists (CAP) PT documentation, provided on the date of the inspection, revealed an analyte testing score of 40% for Tbil for the second testing event of 2019. 2. Review of the laboratory's PT evaluation revealed the unacceptable results and the evaluation of the re-run PT specimens as listed below: PT Tbil Result Tbil Expected Specimen Achieved/Reported Re-Run Result CHM-06 0.5 1.0 0.8-1.7 CHM-07 0.8 1.6 1.2-2.1 CHM-09 0.5 0.8 0.7-1.6 3. The GS confirmed the laboratory did not achieve a PT analyte testing score of at least 80% for Tbil for the second testing event of 2019 and stated their PT evaluation included a review of Tbil quality control and calibrations, a review of all patient Tbil testing and a review of the policies and procedures. The interview occurred on 08/19/2019 at 10:15 AM.