

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0899072	(X3) Date Survey Completed 05/22/2019
Name of Provider or Supplier Mitchell Medical Center	Street Address, City, State 1209 10th Street, Port Huron, MI	
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
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: . Based on procedure review, record review, and interview with technical consultant #1 (TC1), the laboratory failed to manually check the instrument calculated parameters for the very low density lipoprotein (VLDL), low density lipoprotein (LDL) and the glomerular filtration rate (GFR) annually for 2 (2017 and 2018) of 3 years reviewed. Findings include: 1. Procedure review for "LIS Policy" states "At least one time per year the LIS will be checked to validate VLDL, LDL, and GFR calculations. Five patients will be checked to make sure the results are being calculated correctly." 2. Record review revealed a lack of documentation for the annual calculation checks for 2017 and 2018. 3. An interview with TC1 on May 22, 2019 at 9:40 am confirmed the annual calculation checks were not performed and documented in 2017 and 2018. .</p>