

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0667196	(X3) Date Survey Completed 09/23/2021
Name of Provider or Supplier Shamrock General Hospital	Street Address, City, State 1000 South Main, Shamrock, TX	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, records of calibration checks, and interview, the laboratory failed to have a procedure to define the frequency of calibration checks for two of two pipettes used in the laboratory to reconstitute controls and calibrators for chemistry testing performed on the Vitros 350. Findings follow. A. Review of the laboratory's policies and procedures did not show a procedure for the pipette calibration checks. B. Review of the calibration checks from 2019 - survey date, September 23, 2021 showed one calibration check performed on 01/20/2021 for one MLA Macro Pipette for the volume of 3000 uL. C. Interview with the Technical Consultant on September 23, 2021 at 1410 hours in her office confirmed one calibration check was performed in the last two years, that they rotate usage between the two pipettes, and they do not have a policy and procedure in place for the calibration check.</p>