

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0371506	(X3) Date Survey Completed 07/22/2024
Name of Provider or Supplier Macomb Medical Clinic Pc	Street Address, City, State 2405 E 14 Mile Road, Sterling Heights, 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
D0000	An unannounced revisit survey was performed on July 22, 2024 as a follow-up to the May 21, 2024 recertification survey. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined it remains out of compliance with the following Conditions: 493.1250 Condition: Analytic systems 493.1441 Condition: Laboratories performing high complexity testing; laboratory director
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, review of the laboratory's policies and procedures, record review, and interviews, the laboratory failed to provide evidence that they follow manufacturer's instructions for the use of its Drummond pipettes with reusable tips used to perform high complexity routine chemistry testing for two (July 2022 to July 2024) of two years reviewed. Findings include: 1. The surveyor requested the manufacturer's instructions for the use of the Drummond pipettes with reusable tips on 7/22/24 at 1:43 pm and none were made available. 2. Refer to D5403 and D5435</p>
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</p>

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.

This STANDARD is not met as evidenced by:

. Based on observation, record review, and interview with the Technical Consultant, the laboratory failed to establish function check protocol for the use of Drummond pipettes when pipetting patient serum for its Pointe Scientific 180 and Med Test chemistry testing for two (July 2022 to July 2024) of two years reviewed. Findings include: 1. An interview on 7/22/24 at 1:06 pm with the Technical Consultant confirmed the laboratory had not established a protocol for function checks of the reusable pipette tips prior to conducting patient testing. 2. Refer to D5403 and D5411.