Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2134301	01/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Manhattan Specialists Cente, Llc	202 Research Drive, Manhattan, KS	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) from the provider American Academy of Family Physicians (AAFP) Proficiency Testing performed 2/2/2020 to 1/19/2022 and interview with testing personnel #3 (TP#3), the laboratory director (LD) failed to attest on two of six events and testing personnel failed to attest on six of six events that proficiency testing samples were handled in the same manner as patient samples. Findings: 1. Review of the attestation pages for PT from AAFP revealed no signature of the LD or designee was present on AAFT-PT 2021-A and AAFP-PT 2021-C. 2. Review of the attestation pages for PT from AAFP revealed that no testing personnel (TP) signatures were present on: a. AAFT-PT 2020-A, AAFT-PT 2020-B, and AAFT-PT 2020-C b. AAFT-PT 2021-A, AAFT-PT 2021-B and AAFP-PT 2021-C. 3. Interview with the TP#3 on 1/19/22 at 11:30 a.m. confirmed, the LD failed to attest on two of six events and TP failed to attest on six of six events that proficiency testing samples were handled in the same manner as patient samples.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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. This STANDARD is not met as evidenced by: Based on an absence of thermometer function check records or certificates of accuracy, protocols for thermometer function checks and interview with the TP#3, the laboratory failed to define and perform a function check protocol for one of one thermometers. Findings: 1. No documentation was available for function checks on one of one thermometers at the time of survey. 2. No documentation was available for the certification of accuracy (NIST traceable) on one of one thermometers at the time of survey. 3. Protocols for the function checks of thermometers were not made available at the time of survey. 4. Interview with TP#3 on 1/19/22 at 11:45 a.m. confirmed, the laboratory failed to define and perform a function check protocol for one of one thermometers.