Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2135860	10/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Walpole Medical Center, Pc	841 Main Street, Walpole, MA	

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	A CLIA recertification survey was conducted for the Walpole Medical Center, PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: . Based on record review and confirmed through an interview with the laboratory consultant on 10/25/2022 the laboratory failed to verify the accuracy of analytes assigned a proficiency testing score that did not reflect laboratory test performance as evidenced by the following: The surveyor reviewed the American Proficiency Institute (API) proficiency testing results for calendar years 2020, 2021, and 2022 (four testing events). The review revealed that the proficiency testing service did not grade analyte results for Cocaine and Opiates for the first testing event of 2021. There was no documented self-grading performed by laboratory personnel for the above listed ungraded proficiency testing results. The laboratory consultant confirmed in an interview on 10/25/2022 at 12:00 PM that ungraded proficiency testing results had not been addressed. The laboratory performs 400 Cocaine and 600 Opiates tests annually. .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the laboratory failed to meet the the applicable analytic systems requirements in 493.1251 through 493.1283 as evidenced by the following: The laboratory failed to perform accuracy studies with their validation of the four new drug tests: Amphetamines, Benzodiazepines, Bupenorphine, and Oxycodone prior to patient testing on the Medica EasyRA analyzer. This is a repeat deficiency. Refer to D5421. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory consultant on 10/25/2022 the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer of a new test system before reporting patient test results as evidenced by the following: The surveyor reviewed the validation studies for the four new drug tests implemented on 8/18/2022 on the Medica EasyRA analyzer. The review revealed that the laboratory did not perform accuracy studies with their validation of the four new drug tests prior to patient testing. The four new drug tests implemented were Amphetamines, Benzodiazepines, Bupenorphine, and Oxycodone. The laboratory consultant confirmed through interview on 10/25/2022 at 11:15 AM that the laboratory failed to perform accuracy studies prior to reporting patient test results for the four new drugs tested on the Medica EasyRA analyzer. The laboratory performs 6,000 Toxicology tests annually. This deficiency was cited at the last CLIA survey performed on 10/01/2020.