Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2187802	04/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Central Lab Partners	124 West Boylston St, Worcester, 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	An initial CLIA certification survey was conducted for the Central Lab Partners laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish performance specifications for one (1) of one (1) newly implemented test systems not subject to FDA clearance as evidenced by the following: Fentanyl Specificity and sensitivity: a) A review of validation studies for the Indiko Plus chemistry analyzer revealed that the laboratory failed to address specificity and sensitivity as part of the validation for the high complexity, non FDA categorized, fentanyl analyte. b) The technical supervisor confirmed in an interview on 4/22/21 at 10:00 a.m. that specificity and sensitivity studies had not been included as part of the validation. The laboratory performs 14,976 fentanyl assays annually. .