Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0718726	07/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Worcester Internal Medicine	416 Belmont 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	A CLIA COLA validation survey was conducted for the Worcester Internal medicine, Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview the laboratory had implemented test systems and procedures that were high complexity and were not under the management and direction of a laboratory director who qualified under 493.1443 of this subpart as evidenced by the following: Sysmex KX21N hematology analyzer: a) In October of 2020 the laboratory implemented the Sysmex KX21N hematology analyzer. The lab attempted to get Sysmex reagents for the analyzer but, because it was not purchased from the company directly, the company would not sell the required reagent to them. b) According to the technical consultant interviewed on 7/25/23, the laboratory purchased off brand reagents from another company and was utilizing the hematology analyzer using the off brand reagents for patient testing and reporting. The utilization of off brand reagents is a modification of the test system and therefore considered high complexity. At the time of the survey, the laboratory was not under the direction of a laboratory director who qualified under high complexity testing. Urine culture screens: a) A review of twenty seven (27) patient reports for testing performed between 4/2/21 and 7/10/23 revealed that for one (1) of the twenty seven (27) reports the lab reported 1000 mixed on a urine culture screen (laboratory accession # 82116).

	The reporting of mixed culture growth is considered high complexity. At the time of the survey, the laboratory was not under the direction of a laboratory director who qualified under high complexity testing.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation on 7/25/23 at 12:36 PM, the laboratory director failed to provide a safe environment environment in which employees are protected from chemical and biological hazards as evidenced by the following: a) On the day of the survey in the presence of the technical consultant, it was observed that there were two fire extinguishers on the floor that were no mounted and secured. b) On the day of the survey in the presence of the technical consultant, it was observed that the laboratory area where testing was performed was carpeted creating a potential biohzard. .