Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0718726	04/23/2019
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. .
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency testing record review and confirmed through an interview on 4/23/19 at 10:21 AM with one testing person, the laboratory failed to ensure that one (1) out of two (2) testing personnel tested proficiency testing samples as evidenced by the following: 1. A review of proficiency testing record attestation statements for calendar years 2017, 2018, and 2019 (seven testing events) revealed that only one of the personnel performing moderate complexity testing was also performing proficiency testing samples (documented signature on the attestation form). Records of proficiency testing for testing person number 2 only started in calendar year 2019. 2. Testing person number 1 interviewed confirmed that she was the only person routinely performing proficiency testing samples up until 2019. .
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or

	produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview , the laboratory failed to check each batch of media for sterility, its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response before or concurrent with initial use as evidenced by the following: a) The laboratory performs urine culture screens utilizing Uricult microbiological media paddles. b) A review of bacteriology quality control records for calendar year 2018 and 2019 (fifteen and a half (15 and 1/2) months of laboratory operation) revealed that the laboratory failed to check each lot number or shipment of Uricult microbiological media for its ability to support growth and, as appropriate, select or inhibit specific organisms. c) Testing person number 1 confirmed in an interview on 4/23/19 at 11:30 AM that the Uricult microbiological media had not been checked for it's ability to support growth and, as appropriate, select or inhibit specific organisms. .
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, 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 two (2) laboratory technologists, it was observed that there was no permanently mounted eyewash which would provide fifteen minutes of continuously flowing water near the laboratory area. b) Testing person number 1 confirmed in an interview on 4/23/19 at 9: 49 AM that there was no permanently mounted eyewash available in the facility. .