Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0122114	02/27/2020
Name of Provider or Supplier	**Street Address, City, State**	
Henry J Austin Health Center Inc	321 N Warren Street, Trenton, NJ	

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
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on surveyor observation of the area where Molecular testing was performed and interview with the Nurse Coordinator (NC), the laboratory failed to have a unidirectional workflow for specimen preparation, reagent preparation, product detection and amplification from June 2019 to the date of the survey. The NC confirmed on 2/27/20 at 2:00 pm the laboratory did not have a unidirectional work flow.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of the Maintenance Record (MR) and interview with the Nurse Coordinator (NC), the laboratory failed to perform and document maintenance as specified by the manufacturer on the Cephid GeneXpert analyzer used for Microbiology tests from 10/2/19 to 10/8/19. The finding includes: 1. A review of the MR revealed there was no documented evidence daily maintenance was performed in the time period stated above. 2. Approximately 10 to 15 samples were run per day. 3.

	The NC confirmed on 2/27/20 at 1:35 pm that maintenance as specified by the manufacturer was not performed.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Report (TR) and interview with the Nurse Coordinator (NC), the laboratory failed to include the test report date for Bacteriology tests from 6/5/19 to the date of survey. The NC confirmed on 2/27/20 at 2:00 pm that the test report date was not on the TR.