Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0122114	09/19/2018
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to maintain the attestation page for KOH and Wet Mount tests performed with the American Academy of Family Physicians (AAFP) in the calendar years 2017 and 2018. The TC confirmed on 9/19 /19 at 2:50 pm that all PT records were not maintained.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with

	the Technical Consultant (TC), the laboratory failed to review and evaluate KOH and Wet Mount PT results obtained from the American Academy of Family Physicians in 2018. The TC confirmed on 9/19/18 at 2:50 pm that the laboratory did not review PT results.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Requisitions (TR) and interview with the Technical Consultant (TC), the laboratory failed to ensure that test requisitions included relevant and necessary information for accurate and reliable testing and reporting from January 2018 to the date of survey. The findings include: 1. A review of ten TR for tests performed on the Cepheid Gene Expert revealed ten of ten did not have the specimen source and collection date recorded. 2. A review of one TR for KOH and Wet Mount did not have the collection date. 3. The laboratory did not document any efforts made to get the information. 4. The TC confirmed on 9/19/18 at 3:10 pm that specimen source and collection date was not on all TR.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Technical Consultant (TC), the laboratory failed to establish a procedure for microscope maintenance at the time of the survey. The TC confirmed on 9/19/18 at 12:40 pm that the laboratory did not establish the above procedure.
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 Records (MR) and interview with the Technical Consultant (TC), the laboratory failed to perform and document maintenance as specified by the manufacturer on the Cepheid Gene Expert analyzer in the calendar year 2018. The findings include: 1. Monthly maintenance was not performed as follows: a. Archive Tests and Purge Results - January, February, April and May b. Archive Tests and Purge Results - March (instrument 810313) c. Replace Fan Filters - February (instrument 810313) 2. The TC confirmed on 9/19/18 at 2:15 pm that preventative maintenance as specified by the manufacturer was not performed.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Technical Consultant (TC), the laboratory failed to perform and document a control on each day of patient testing for KOH and Vaginal Wet Mounts in the calendar years 2017 and 2018. The TC confirmed on 9/19/18 at 1:20 pm that the laboratory did not perform QC each day of patient testing.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control records and interview with the Technical Consultant (TC), the laboratory failed to perform and document quality control each day of patient testing performed on the two Cepheid Gene Experts from January 2018 to the date of the survey. The findings include: 1. The laboratory performed and documented QC once a month. 2. The laboratory ran and reported

	approximately 15 -20 patient results a day. 3. The TC confirmed on 9/19/18 at 1:15 pm that the laboratory did not perform and document quality control on each day of patient testing.
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 Final Report (FR) and interview with the Technical Consultant (TC), the laboratory failed to ensure that the FR included all the required information from January 2018 to the date of survey. The findings include: 1. The FR did not include the correct name of the facility where testing was performed. 2. There was no "Repot Date" on the FR. 3. The TC confirmed on 9/19/18 at 3:00 pm that FR did not have all the required information.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Technical Consultant (TC), the laboratory failed to ensure that the Normal Reference Intervals (NRI) were indicated on the FR for KOH and Wet Mount tests from January 2018 to the date of survey. The TC confirmed on 9/19/18 at 2:55 pm that the NRI were not on the FR.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with

	the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure the laboratory was enrolled in a approved PT program for Trichomonas vaginalis, Chlamydia trachomatis and Neisseria gonorrhoeae tests performed on the Cepheid Gene Expert analyzer in 2018. The TC confirmed on 9/19/18 at 2:30 pm that the laboratory was not enrolled in PT.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files and interview with the Technical Consultant (TC), the Laboratory Director failed to have education documented for two out of threeTesting Personnel (TP) from January 2018 to the date of the survey. The TC confirmed on 9/19/18 at 1:30 pm that all TP did not have education records.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Technical Consultant (TC), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements at the time of the survey. The TC confirmed on 9/19/18 at 2:10 pm that a CA procedure was not established.