Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0991667	09/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Bedford Research Foundation, Inc	124 South Road, Bedford, 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 recertification survey was conducted for the Bedford Research Foundation, Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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 proficiency testing review and interview, the laboratory failed to properly document the handling of proficiency testing samples as evidenced by the following: a) A review of proficiency testing records for calendar years 2018, 2019, and 2020 (6 testing events) revealed the fact that the program report forms and the attestation statements provided by the proficiency testing program were not signed by the laboratory director and the laboratory technologist performing the testing for all six (6) of the American Association of Bioanalysts (AAB) proficiency testing events reviewed. The general supervisor interviewed on 9/9/20 at 9:20 AM confirmed that the attestation statement for the above events were not signed by the laboratory director and the laboratory technologist. .

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure review and interview the laboratory failed to have a procedure manual which included the following: a) A review of the laboratory procedure manual revealed that there was no quality control section for the Syphilis PCR assay. b) The technical supervisor interviewed on 9/9/20 at 10:45 AM confirmed that that quality control requirements section was missing from the Syphilis PCR procedure. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to to perform validation studies to ensure that it can obtain performance specifications comparable to those established by the manufacturer for a newly introduced test system as evidenced by the following: ASI RPR Test Card a) In August of 2018 the laboratory put into place a RPR (rapid plasma reagin) test for syphilis. b) The laboratory director interviewed on 9/9/20 at 11:45 AM confirmed that no validation of the test method had been performed prior to utilizing it for patient testing and reporting. The laboratory director further stated that she thought the method was waived and therefore no validation studies were required. c) The laboratory performs 80 ASI RPR tests annually. .
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) re-implemented test systems not subject to FDA clearance as evidenced by the following: Syphilis PCR assay a) The laboratory re-implemented the Syphilis PCR assay after a 3 year hiatus of not performing the testing. The laboratory stopped performing the testing in calendar year 2016 and re-implemented the test in June of 2019 according the the general supervisor and laboratory director interviewed on 9/9/20. b) When asked if a revalidation had been performed the laboratory director stated in an interview on 9/9/20 at 11:15 a.m. that no re-validation of the test method had been performed. c) Based on the lack of re-validation of the Syphilis PCR method after a 3 year hiatus of testing there was no assurance that the laboratory's performance specifications for accuracy, precision, analytical sensitivity, and analytical specificity to include interfering substances had not changed. d)The laboratory performs 21 Syphilis PCR assays annually. .
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: . Based on record review and interview the technical supervisor failed to ensure the establishment of the laboratory's test performance characteristics and that the verification of the test procedures performed were adequate for accuracy, precision, sensitivity and specificity, when applicable, prior to implementing two (2) of three (3) new or re-implemented test procedures for patient testing and reporting: a) The technical supervisor failed to ensure that validation studies were performed prior to implementing the test for patient testing and reporting for the ASI RPR card test. Refer to D5421. b) The technical supervisor failed to re-validate the Syphilis PCR assay after a 3 year hiatus of not performing the test. Refer to D5423. .
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least

	semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review interview and interview, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: a) Review of the CMS 209 Laboratory Personnel Report on 9/9/20 revealed that there were two (2) new laboratory technologists hired since the last CLIA recertification survey on 2/28/18. b) Review of personnel competencies for calendar years 2018 and 2019 revealed that there was no documentation of semiannual competency evaluations for one (1) of the two (2) new testing personnel who had been working for over a year. c) The general supervisor confirmed in an interview on 9/9/20 at 8:55 AM that no semiannual competency evaluations had been performed on the one (1) new laboratory technologist.