Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2140140	10/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Inova Biocore Research Laboratory	3300 Gallows Road, Ihvi 3rd Floor I-3102, Falls Church, VA	

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	An announced CLIA recertification survey was conducted at INOVA Biocore Laboratory on October 18, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
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 a review of the laboratory's policies and procedures, linearity check /analytical measure range (AMR) records for the Roche e602 chemistry analyzer, and

	interviews, the laboratory failed to follow their six (6) month linearity check/AMR verification procedure for the analyte NTProBNP during the twenty-two (22) months reviewed. Findings include: 1. During a tour of the laboratory on October 18, 2022 at approximately 9:00 AM, the surveyor noted the laboratory performs NTProBNP testing on the Roche e602 chemistry analyzer. 2. Review of the laboratory's policies and procedures revealed a protocol, "General Quality Control and Calibration Protocol", that stated "V. Calibration Procedure (CHM.13000)...f. Linearity Check or AMR Verification...AMR Check and verification must be verified every 6 months after a method is initially placed in service or after initiation of patient testing." 3. Review of the laboratory's linearity check/AMR records from January 2021 to the date of the survey, October 18, 2022, revealed the following linearity check/AMR records for NTProBNP: 06/21/2021, 12/17/2021, 7/28/2022 (greater than 6 months), 10/15/2022. The surveyor requested to review the linearity check/AMR records for 06 /2022. The laboratory provided no documentation to review. 4. An exit interview with the Laboratory Manager on October 18, 2022 at approximately 12:30 PM confirmed the findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: A. Based on a tour, review of policies and procedures, maintenance documents, lack of documentation, and an interview, the laboratory failed to document function checks for the Rees Scientific temperature monitoring system's alarm system quarterly per their policy in 2021 until the date of the survey, October 18, 2022. Findings include: 1. During a tour of the laboratory on October 18, 2022 at approximately 9:00 AM, the surveyor noted the laboratory uses the Rees Scientific temperature monitoring system to monitor the temperature of the laboratory's reagent/ specimen refrigerators and freezers. 2. Review of the laboratory's procedures revealed a policy, "Temperature Monitoring", that stated "VI. Quality Control A. Quarterly verification for refrigerator and freezer alarm: 1. Adjust the temperature via Rees Monitoring or open the handle in order to make the alarm go off..." 3. Review of the laboratory's 2021 and 2022 maintenance documentation revealed the following quarterly alarm verification records for the Rees temperature monitoring system: March 2021(refrigerators /freezers), October 2021(refrigerators/freezers), 6/2022 (refrigerators) and 7/2022 (freezers). The surveyor requested to review the June 2021, December 2021, and March 2022 Rees quarterly alarm verification records. The laboratory provided no other documentation to review. 4. An exit interview with the Laboratory Manager on October 18, 2022 at approximately 12:30 PM confirmed the findings. B. Based on a tour, review of policies and procedures, maintenance documents and lack of documentation, the laboratory failed to define function checks and document certification for the Thermo chemical/biological hood prior to the hood's certification expiration date. Date of review January 2021 until the date of the survey, October 18,

	2022. 1. During a tour of the laboratory on October 18, 2022 at approximately 9:00 AM, the surveyor noted the laboratory uses a Thermo chemical/biological hood (Serial number 300436603) for the processing of patient specimens. 2. Review of the laboratory's policies and procedures revealed a lack of documentation of a policy for the maintenance and function checks of the laboratory's Thermo chemical/biological hood (Serial number 300436603). 3. Review of the laboratory's maintenance records revealed two hood "Certification Test Reports" that stated "Instrument & Calibration-...All calibrations of all test equipment always expire annually at the end of the month from the date of calibration unless otherwise stated." The "Certification Test Reports" for the Thermo hood (Serial number 300436603) were dated 02/12/2021 (expiration date 02/28/2022) and 08/03/2022 (expiration date 08/31/2023). The surveyor requested to review the "Certification Test Report" for March 2022. The laboratory provided no documentation for review. 4. An exit interview with the Laboratory Manager on October 18, 2022 at approximately 12:30 PM confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of the laboratory's "Performance Improvement and Quality Management Plan", policies and procedures, maintenance documentation, linearity /Analytical Measure Range (AMR) documentation, and interviews, the laboratory failed to follow their established "Performance Improvement and Quality Management Plan" and identify and address analytic issues within the specialty of chemistry (Cross Reference D 5403 and D5435) from January 2021 until the date of the survey October 18, 2022. Findings include: 1. Review of the laboratory's "Performance Improvement and Quality Management Plan", policies and procedures, maintenance documentation, linearity/Analytical Measure Range (AMR) documentation revealed the following analytic issues: -lack of documentation of the every six month verification of the linearity/AMR for NTProBNP (see D5403); -lack of documentation of the laboratory following their established policy for the quarterly alarm checks for the Rees Temperature monitoring system (see D5435 A.); -lack of a policy and documentation of the annual function check/certification of the biological /chemical hood documentation (see D5435 B). 2. Review of the "Performance Improvement and Quality Management Plan" that stated "M. Improvement Mechanisms-1. The Laboratory, in order to implement its Quality Plan, selects external and internal QA monitors to evaluate various areas. The plan is designed to identify problems, categorize, monitor and plan actions for prevention. The Quality Plan will be reviewed and appraised annually for effectiveness. 2. Information to improve processes is gathered from a variety of sources, including the following: Analysis of occurrence trends, Internal audits of the quality system,..." The plan contained an attachment, "Monthly QI Report". 3. Review of the laboratory's "Monthly QI Reports" from January 2021 until September 2022 revealed a lack of documentation of the monthly QI reports from April 2021 until December 2021. On October 18, 2022 at approximately 11:30 AM, the surveyor requested to review

	documentation of the monthly log completion and review. The laboratory provided no documentation for review. 4. An exit interview with the Laboratory Manager on October 18, 2022 at approximately 12:30 PM confirmed the findings.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review the laboratory's policies and procedures, proficiency testing (PT) documentation and an interview, the laboratory director (LD) failed follow the laboratory's established policy to document review of the laboratory's performance in Chemistry PT for four (4) of ten (10) PT events from January 2021 until October 2022. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) BNP-5 2021 (Events 1, 2, 3), 2022 (Event 1 and 2), and CAP CAR 2021(Events 1, 2, 3), 2022 (Event 1 and 2) documentation revealed no documentation of the review of results by the Laboratory Director for: CAP BNP-5 2021 Events 2 and 3; CAP CAR 2021 Events 1 and 3. The surveyor requested to review the documentation of the review of the PT events outlined above. The laboratory provided no documentation for review (No record was available). 2. Review of the laboratory's policies and procedures revealed a policy, "CAP Survey and Proficiency Survey", that stated "V. Procedure... D. Procedure for Review of Proficiency Testing Results: CAP will send evaluated results to the laboratory...The supervisor or Director will review the results and sign. The signed/dated evaluation will be filed in the CAP Survey binder with the original analysis print outs." 3. An exit interview with the Laboratory Manager on October 18, 2022 at approximately 12: 30 PM, confirmed the findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel competency assessment records, laboratory policy and procedures and interview, the technical consultant (TC) failed to follow their established policy and document the semi-annual competency assessment for two (2) of four (4) laboratory testing personnel (TP) from January 2021 to the date of survey on October 18, 2022. Findings include: 1. Review of the CMS 209 revealed five (5) TP identified as responsible for moderate complexity patient testing and revealed: TP A was identified as a new TP in January 2021; and TP B was identified

	as a new TP in November 2020. (See Personnel Code Sheet.) 2. Review of personnel records revealed a lack of documentation of the semi-annual competency assessments for two (2) of the 4 TP needing semi-annual assessments. The surveyor requested to review the semi-annual competency assessments for TP A and B. The laboratory provided no documentation to review. 3. Review of the laboratory's policies and procedures revealed a policy, "General Training and Competency of Personnel" that stated "4. After the initial training, the competency must be assessed semi-annually." The surveyor requested to review the semi-annual competency for TP A and TP B. In an interview on October 18, 2022 at approximately 10:00 AM with the Laboratory Manager (LM), the LM stated they were not the laboratory manager during that time and did not assume the role of LM until January 2022. 4. An exit interview with the Laboratory Manager on October 18, 2022 at approximately 12:30 PM, confirmed the findings.