Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2166017	06/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
National Blood Testing Partners	1625 Rock Mountain Boulevard Suite R, Stone Mountain, GA	

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 validation survey was conducted at National Blood Testing Partners on June 25, 2025, by federal surveyors from the CMS CLIA Survey Branch. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to be compliance with condition-level CLIA requirements.The following standard-level deficiencies were found during the CLIA validation survey completed on June 25, 2025.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) (d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory records, and interview with staff, the laboratory failed to provide their clients instructions for transporting specimens for 17 out of 26 tests. Findings included: 1. Review of the laboratory's procedure QAM.2.1 (version 4) Quality Manual on June 25, 2025, found the following on page 17: "7.2 Sample Management The laboratory provides written instructions for specimen collection and transport." 2. Review of the laboratory's reference document 177735.467 (version 4) Specimen Transport and Storage Requirements available to clients found the following: "1. Test ... Blood Grouping Reagents ...Sample Type - EDTA ...Acceptable Transport Temperature - not specified in package insert ... 2. Test ...Antibody Screen ... Sample Type - EDTA ... Acceptable Transport Temperature - not specified in package insert ... 3. Test ... cobas Babesia ... Sample Type - Whole blood ... Acceptable Transport Temperature - not specified in package insert ... 21. Test ... Cholesterol ...Sample Type - Serum or EDTA ... ... Acceptable Transport Temperature - not specified in package insert ... 22. Test ...Total Protein ... Sample Type - Serum or

	EDTA ... ... Acceptable Transport Temperature - not specified in package insert ..." The above is a sample of the 17 out of 26 tests listed in the reference document that did not have instructions for specimen transportation. The following is a list of the 17 tests that did not have transport requirements for the laboratory's clients on the Specimen Transport and Storage Requirements reference document: Blood Grouping (ABO/Rh) Antibody Screen Elecsys Anti-HBsAg II Elecsys HIV Duo Elecsys Anti-HCV II Elecsys Anti-HTLV 1/ II Elecsys Anti-HBc II Elecsys Chagas Cobas MPX (Multiplex HIV, HCV, HBV NAT) cobas WNV TP System (Syphilis) CMV cobas Babesia LABScreen (Trademark) (HLA-AB) Cholesterol Total Protein Automated Rapid Plasma Reagin (RPR) Test for Syphilis 3. Review of the laboratory's test volume records, according to the Centers for Medicare and Medicaid (CMS)-116 form, revealed the following annual test volumes for the laboratory: a. Histocompatability - 8,008 b. Microbiology - 1,525,347 c. Diagnostic Immunology - 7,733,342 d. Chemistry - 677,211 e. Immunohematology - 1,086,297 4. During interview on June 25, 2025, at approximately 12:30 pm, the Quality Manager confirmed the above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer package insert and interview with staff, the laboratory failed to follow the manufacturer's instructions to validate BD Vacutainer EDTA blood collection tubes for use in immunohematology test for 2 out of 2 test systems. Findings included: 1. Review of the BD Vacutainer EDTA blood collection tubes manufacturer's package insert on June 25, 2025, found the following: " INTENDED USE ...BD Vacutainer K2EDTA Blood Collection Tubes may be used for immunohematology testing, such as ABO blood grouping and Rh typing. The performance characteristics of these tubes have not been established for immunohematology testing in general, therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions. 2. During interview on June 56, 2025, at approximately 12:30 pm, the Quality Manager stated the laboratory did not establish performance specifications for BD Vacutainer EDTA blood collection tubes used in testing for ABO/Rh typing and antibody screen for their NEO Iris analyzers. 3. The laboratory's annual volume of ABO/Rh, antibody screen and antibody identification tests is 1,086,297.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test

reports.

This STANDARD is not met as evidenced by:
I. Based on direct observation, review of manufacturer instructions, and confirmed in an interview with the General Supervisor (GS) # 8 according to the Centers for Medicare and Medicaid (CMS)-209 form, the laboratory failed to ensure monitoring and documentation of temperatures for 1 of 1 Biorad IPS Microplate Incubator. Findings Included: 1. During a tour of the laboratory on 6/25/2025 at 2:30 PM, one Biorad IPS Microplate incubator (S/N# 6476) was observed in the confirmatory syphilis blood donor screening section with no documentation of temperature recordings, as part of the methodology of the Trinity Biotech Captia T-Pallidum test system. 2. Review of the Trinity Biotech Captia Syphilis test system manufacturer instructions, stated the following assay procedural step: "5. Seal the strips and holding frame with a plate sealer and incubate at 37 (+/- 1) degree C for 60 (+/- 5) minutes." 3. In an interview, GS #8 confirmed that the incubator temperature was only observed while testing, but not recorded and documented. 47272 II. Based on observation, manufacturer's instructions, freezer temperature records, and interview with general supervisor# 13 (GS#13), the laboratory failed to ensure the storage of 15 of 15 boxes for seven of seven days according to manufacturer's storage instructions. Findings include: 1. On 06/25/25, GS#13 verified the laboratory used the One Lambda LABScreen for donor HLA Antibody testing. 2. Observation on 06/25/25 at 11:30 am of the Thermoscientific TSX Series freezer revealed 15 boxes of One Lamda LABScreen boxes (lot# 025) with a manufacturer's requirement of -65C or colder. 3. Review of the iSenix records (laboratory's electronic monitoring system) from 06/15 /25 through 06/21/25 revealed the laboratory failed to store 15 of 15 boxes for seven of seven days according to manufacturer's storage instructions of -65C or colder as follows: a. 06/15/25 - minimum freezer temperature reading -28.95C b. 06/16/25 - minimum freezer temperature reading -29.12C c. 06/17/25 - minimum freezer temperature reading -29.24C d. 06/18/25 - minimum freezer temperature reading -29.20C e. 06/19/25 - minimum freezer temperature reading -32.28C f. 06/20/25 - minimum freezer temperature reading -32.21C g. 06/21/25 - minimum freezer temperature reading -32.29C 4. Interview on 06/25/25 at 11:45 am with GS#13 confirmed the findings above. 5. The laboratory performs approximately 757 donor HLA Antibody testing annually. III. Based on laboratory's written policy and procedure, manufacturer's instructions, room temperature record review, and interview with general supervisor#13 (GS#13), the laboratory failed to ensure the room temperature followed the manufacturer's storage instructions for four of five days. Findings include: 1. On 06/25/25, GS#13 verified the laboratory used the One Lambda PE-Conjugated Anti-Human IgG for donor HLA Antibody testing. 2. Review of the laboratory's written policy and procedure titled, "GTPM.3.1 (version 16.0) Perform Donor HLA Antibody Testing" section "Reagent Requirements" stated, "Store PE-conjugated anti-human IgG at 2 to 8C; ... .Centrifuge solution if it is not completely clear after standing for 1 to 2 hours at room temperatures (20 to 25C) ....". 3. Review of the One Lambda product insert section, "I. For each test batch, test a negative control serum (e.g. OLI cat. # LS-NC or equivalent) to establish background values. To complete the test in a 1.5 ml microcentrifuge tube" set number seven stated, "7. Add 100l of 1XPE-conjugated anti-human IgG to each tube. Vortex and then incubated in the dark for 30 minutes at 20-25C with gentle shaking.". 4. Review of the iSenix records (laboratory's electronic monitoring system) from 05/28/25 through 06/01/25 revealed temperatures below 20C for four of five days as follows: a. 05/29/25 - minimum temperature reading 19.41C b. 05/30/25 - minimum temperature reading 19.30C c. 05/31/25 - minimum temperature reading 19.18C d. 06/01/25 -

	minimum temperature reading 19.04C 5. Interview on 06/25/25 at 11:55 am with GS#13 confirmed the findings above. 6. The laboratory performs approximately 757 donor HLA Antibody testing annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 laboratory's written policy and procedure, Cobas Cholesterol manufacturer's instructions, review of performance specification records, and interview with the quality assurance director, the laboratory failed to verify the manufacturer's enitre reportable range for one of one instrument. Findings include: 1. On 06/24/25, the quality assurance director verified the laboratory director approved the Roche Cobas c503 analyzer for use on 09/24/24. 2. Review of the laboratory's written policy and procedure titled, "177735.782 CHOL - c503" section, "14.1.4 Result Interpretation and Review" stated, " ....The cobas c503 instrument is configured with the analytical range of 3.87mg/dL-800mg/dL and is programmed in settings under the applications tab (CHOL) under analytical parameters.". 3. Review of the Roche Cobas CHOL 2, Cholesterol Gen.2, manufacturer's instructions stated the following: a. Section "Assay" stated, "The performance of applications not validated by Roche is not warranted and must be defined by the user." b. Section, "Limits and ranges" and "Measuring range" stated, 3.87 - 800 mg/dL 4. Review of the laboratory's performance specification records revealed the laboratory verified a reportable range of 7.230 - 828.667 mg/dL. 5. Interview on 06/24/25 at 01:15 pm with the quality assurance director confirmed the laboratory failed to verify the the manufacturer's claim of 3.87 mg/dL as indicated in their written policy and procedure. 6. The laboratory performs approximately 266,310 cholesterol tests annually.