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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>34D0655039                   | <b>(X3) Date Survey Completed</b><br>07/15/2025 |
| <b>Name of Provider or Supplier</b><br>Wfuhs Hla/Immunogenetics Laboratory   | <b>Street Address, City, State</b><br>145 Kimel Park Drive, Suite 250, Winston-Salem, NC |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
|---------------------------|---|
| <b>D0000</b>              | A federal surveyor from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted a validation survey on July 15, 2025. The following standard level conditions were cited.  |
| <b>D5317</b>              | <p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b><br/>CFR(s): 493.1242(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory policy and interview with laboratory staff, the laboratory failed to make available to clients written instructions for specimen collection, specimen storage and conditions for specimen transportation for 3 of 3 months (random review) in 2025. Findings included: 1. Review of the laboratory's policy named "GP 03 - Sample Requirements Policy (NCBH)", document number 51507, revision date 04/03/2025, revealed the policy failed to provide instructions for the collection of specimens, storage of the specimen at the clients' facility and the conditions for transport of specimens to the laboratory. 2. During interview on July 15, 2025, at approximately 2pm, the Laboratory Manager and the Quality Assurance staff confirmed the laboratory failed to provide the laboratory's clients with instructions for the collection of specimens, storage of specimens at the clients' facility and the conditions for transport of specimens to the laboratory. The laboratory performs 22,649 histocompatibility tests annually.</p> |
| <b>D5413</b>              | <b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b><br>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:

Based on observation, review of laboratory records, review of manufacturer instructions and interview with laboratory staff, the laboratory failed to maintain temperature requirements as specified by the manufacturer for one of one month. Findings included: I. During tour of the Freezer Room (Tag 1306913), two MiSeq analyzers were observed (Serial numbers M05941 and M08494) in use. a. Review of the temperature log for the KP Freezer Room tag #1306913 (monitored by Cetani) for July 15, 2025, from 12am until 3pm, found the temperature fluctuated below 18C. The Cetani temperature log provided to the surveyor indicated the temperature had the following upper and lower limits: "Ambient Temp (15 to 30C, 30 min) (15.0C, 30.0 C)". b. Review of the MiSeq Site Prep Guide, Document #15027615, vs 01, stated "Temperature ...Operating Conditions 19C to 25C ...". c. During interview on July 15, 2025, at approximately 2pm, the Laboratory Manager and Quality Assurance staff confirmed the above findings. II. During tour of the main laboratory, two CytoFLEX analyzers were observed (Serial numbers AS48353 and BE32044) in use. a. Review of the temperature logs (monitored by Cetani) for the Main Lab Middle Tag 2644505 found the following upper and lower limits: "Ambient Temp (15 to 30C, 30 min) (15.0 C, 30.0C)". b. Review of the CytoFLEX instrument installation guide on page A-4, found the following: "CytoFLEX: Ambient temperature : 15-27C with fluctuations of no more than 2C per hour". c. During interview on July 15, 2025, at approximately 2pm, the Laboratory Manager and Quality Assurance staff confirmed the temperature levels in the laboratory failed to comply with the manufacturer's specifications for operation. The laboratory performs 22,649 histocompatibility tests annually.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

(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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview, the laboratory failed to establish specimen storage and transportation requirements for eight of eight laboratory developed tests. Findings included: 1. The Form CMS 116, laboratory application

form, provided to the surveyor on July 15, 2025, included the following tests: Class I HLA Typing Class II HLA Typing Class I HLA Ab Screen Class II HLA Ab Screen Class I HLA Ab ID Class II HLA Ab ID T-cell Flow-cytometric crossmatch B-cell Flow-cytometric crossmatch 2. The Laboratory Manager confirmed on July 15, 2025, at approximately 2pm that all testing performed in the laboratory is laboratory developed testing and not approved by the Food and Drug Administration (FDA) for clinical testing. 3. The surveyor requested and did not receive documentation of specimen stability studies for the storage and transportation of specimens to the laboratory to ensure the integrity of the specimen for accurate and reliable test results. The laboratory performs 22,649 histocompatibility tests annually.