| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D2105680 | 07/23/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Bio Genetisys Inc | 471 W Lambert Rd Ste 104, Brea, CA | |

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 |
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| **D2123** | HEMATOLOGY<br>CFR(s): 493.851(c)<br><br>(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the College of American Pathology (API) proficiency testing (PT) records for the first event of 2025 (Q1-2025), three (3) randomly chosen patient test results, and interview with the laboratory director (LD) and testing personnel (TP) the laboratory failed to participate in a testing event which is unsatisfactory performance and results in a score of 0% for the testing event. The findings included: 1. The laboratory registered with API for the PT for MHO2 (Leukemia Only) and NGS Hematology Malignancies (Hematology Malignancies) for the year 2025. 2. The LD and TP affirmed on the day of the survey July 23, 2025, 11:30 a.m. that the laboratory did not receive the PT samples in a timely matter on April 2025 and that API had sent the laboratory a letter with a new delivery date of May 19, 2025. 3. The LD confirmed by a written statement that the API- PT gave the laboratory and extension to report PT results for Q1-2025 until June of 2025. However, no PT for Q1-2025 results were submitted to API. 4. The laboratory's testing declaration signed and dated by the laboratory director states that the laboratory tested and reported less than 100 test results for Leukemia and Hematologic Malignancies by Next Generation Sequencing during the time PT results were not submitted for API grading. |

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| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.<br><br>This STANDARD is not met as evidenced by:<br>Based on an incomplete procedure for the detection of Hematologic Malignancies and Leukemia by Next Generation Sequencing (NGS) and interview with the laboratory director (LD) and testing personnel (TP) on July 23, 2025, at approximately 1:30 pm, the laboratory failed to establish and follow a written policy and procedure for specimen qualifications such acceptability and rejection criteria. The findings include: 1. The laboratory did not have a written policy and procedure for the detection of Hematologic Malignancies and Leukemia by NSG laboratory test for specimen preparation, storage, preservation, acceptability and rejection of samples for testing. Therefore, the laboratory cannot ensure the reliability of the specimens' tests results. 2. The LD and TP confirmed on 7/23/2025 at approximately 1:40 p.m., that the laboratory did not have a complete written policy and procedures as stated in #1 above. 3. The laboratory's testing declaration form, signed by the laboratory director on 07/18/2025 stated that the laboratory performed less than 100 test for the detection of Hematologic Malignancies and Leukemia by NGS annually. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's observation during the laboratory's tour and interviews with the testing personnel (TP), the laboratory failed to label reagents used in the laboratory to indicate the received date, opening, preparation, and expiration dates when such materials are used. The findings include: 1. Based on the surveyor's observation during the laboratory's tour on July 23, 2025, at approximately 12:15 p.m. no received date, opening date, and preparation labels were used or documented for reagents, water, and buffers used in the laboratory. 2. The laboratory's TP affirmed by interview conducted on July 23, 2025, at approximately 12:30 p.m. that the reagents mentioned in statement #1 were not labeled with the received date, opening, preparation, and/or expiration date. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 100 samples for the detection of Hematologic Malignancies by Next Generation Sequencing using reagents not labeled as regulated. |
| **D6082** | LABORATORY DIRECTOR RESPONSIBILITIES |

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| | CFR(s): 493.1445(e)(1)<br><br>(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyors' review of the College of American Pathologists Proficiency Testing results, laboratory's policies and procedures, randomly selected patient test records, observations during the tour of the facility, and interviews with the laboratory director and testing personnel on July 23, 2025; the laboratory director is herein cited due to failure to ensure that several aspects of the preanalytic, analytical, and postanalytic phases of the laboratory testing were monitored. The findings include See D2123, D5311, D5415. |