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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D2088097 | (X3) Date Survey Completed 09/06/2024 |
| Name of Provider or Supplier Genomind, Inc | Street Address, City, State 2200 Renaissance Blvd, Suite 100, King Of Prussia, PA | |
| 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 |
|---------------------------|---|
| D6123 | <p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Preventative Maintenance Program policy, maintenance records and interview with General Supervisor (GS) #1, the Technical Supervisor (TS) failed to perform and document the review of maintenance records for 12 of 12 months in 2023 and 2 of 8 months in 2024 when pharmacogenomics (PGx) testing was performed. Findings include: 1. The laboratory's Preventative Maintenance (PM) Program policy states, "All preventive maintenance log forms are reviewed monthly by the Laboratory Director or designee. This will be completed within the first 10 business days of the month, and documented with initials and date". 2. On the day of survey, 09/06/2024, the laboratory failed to provide documentation of the monthly review by the Laboratory Director or designee for maintenance performed in April and July of 2024 for the following equipment: - Open Array Plate press #4 (s/n 285890859) - Sorval ST-8 Centrifuge (s/n 41917923) 3. Further review of monthly PM records revealed no documentation of the annual review of maintenance performed from January - December of 2023 on the Sorval ST-8 Centrifuge (s/n 41917923), Proflex Thermal Cycler #1, #2, #3 and #4 and ABI QuantStudio 12K Flex AccuFill 2 (s/n 230820371). 4. GS #1 (CMS 209 personnel #4) confirmed the findings above on 09/06/2024 at 11:52 am.</p> |