

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0947277	<b>(X3) Date Survey Completed</b>  06/25/2024
<b>Name of Provider or Supplier</b>  Laboratory Of Molec Genetics Nidcd-Nih	<b>Street Address, City, State</b>  35a Convent Drive- Room 1f-210 - Msc3729, Bethesda, MD	
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>	An onsite recertification survey was performed on 06/25/2024 under 42 CFR part 493 CLIA regulations. Standard level deficiencies were cited.
<b>D5315</b>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c)</p> <p>The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's written procedure, CLIA certificate, Centers for Medicare &amp; Medicaid Services-116 (CMS-116) database, electronic mail (email), and interview with staff, the laboratory failed to ensure patient specimens were sent to a CLIA-certified laboratory for DNA sequencing. Findings included: 1. Review of the laboratory's written procedure stated, "The LMG switched its testing model for patient samples in 2022 to that of a non-traditional, multiple site testing model. Site 1 is the LMG, which performs the wet chemistry process of PCR/Sanger Sequencing of patient DNA samples and has a CLIA certificate for High Complexity Testing. Site 2 is a local commercial vendor, ACGT, Inc., which has a CLIA certificate of Waiver. Site 2 runs the sequencing plates on a 3730XL or 3730 Genetic Analyzer, generates electropherogram data occurs at Site 1, the LMG. Site 2 does not perform any analysis of the data or send any reports back to patients." 2. During an interview on 06/25/2024 at 10:24 am, the technical supervisor stated treated patient plates are sent to a different laboratory for DNA sequencing in Germantown, MD. 3. The laboratory provided the CLIA certificate for the laboratory that performed DNA sequencing and it was a CLIA certificate of waiver, "CLIA # 14D2035148 ACGT, INC 35 Waltz Dr, Wheeling, IL 60090." 4. During an interview with the laboratory manager and technical supervisor on 06/25/2024 at 2:30 pm, were asked to clarify that the laboratory used for DNA sequencing was in Germantown or in Wheeling, IL. They</p>

confirmed it was in Germantown, MD at 12321 Middlebrook Road, Suite 105. 5. Review of the CMS-116 database did not include a CLIA number for ACGT at 12321 Middlebrook Road, Suite 105, Germantown, MD. 6. The laboratory manager emailed ACGT on 06/25/2024 at 1:30 pm requesting their CLIA number and the vice president replied (06/25/2024 at 2:51 pm), "Our Germantown facility does not possess its own CLIA accreditation as it is a research grade Sanger sequencing facility. All clinical services are provided from our Wheeling, Illinois headquarters and lab ..."  
Word Key: LMG - Laboratory of Molecular Genetics DNA - Deoxyribonucleic acid PCR - polymerase chain reaction

**D5413**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of the laboratory's temperature records, direct observation, manufacturer's instructions, and interview with the Technical Supervisor, the laboratory failed to set freezer and refrigerator temperature ranges in accordance to storage requirements of the manufacturer for 1 of 1 Applied Biosystems BigDye Terminator V3.1 Cycle Sequencing Kits and 1 of 1 Applied Biosystems BigDye Terminator V1.1 Sequencing Buffer. Findings Included: 1. A review of the laboratory's Rees Scientific manufacturer's ranges for the freezer '004 1F210 (-20)' showed a temperature range set for -30C lower limit and -10C upper limit; for the refrigerator '003 1F210 (+4)' a temperature range set for 0C lower limit and 8C upper limit. 2. During a tour of the laboratory at 9:34am, the following reagents were found: [Freezer 004 1F210] - One box of Applied Biosystems BigDye Terminator V3.1 Cycle Sequencing Kit, Lot 2912514, expiration date 2025-05-31, manufacturer storage temperature requirement -25C to -15C. [Refrigerator 003 1F210] - One box of Applied Biosystems BigDye Terminator V1.1 Sequencing Buffer, Lot 2312322, manufacturer storage temperature requirement 2C to 8C. 3. In an interview in the laboratory on 6/25/24 at 10:09am, the Technical Supervisor corroborated that the temperature ranges set on the Rees Scientific monitoring system for freezer 004 1F210, and refrigerator 003 1F210 where the reagents were located, were beyond manufacturer's specifications. II. Based on direct observation, manufacturer's instructions, and interview with the Technical Supervisor, the laboratory failed to ensure temperature specifications were being monitored and documented for 1 of 1 Quality Biological Molecular Biology Water. Findings Included: 1. During a tour of the laboratory on 6/25/24 at 9:34am, one box of Quality Biological Molecular Biology Water, Lot 725281, expiration 3/2026, manufacturer storage temperature requirement 15C to 30C, was found in the pre-PCR testing area of the laboratory. 2. In an interview in the conference room on 6/25/24 at 1:08pm, the Technical Supervisor verified that the laboratory's facilities management did not monitor the room temperature in the pre-PCR area of the laboratory.

**D5781**

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of refrigerator temperature charts, and interview with the Technical Supervisor, the laboratory failed to communicate and document corrective action when the temperature for the freezer was out for 7 of 18 months. Findings Included: 1. A review of the laboratory's Rees Scientific manufacturer's ranges (-30C to -15C) for the freezer '004 1F210 (-20)' located in 'N4, BG 35A Floor B, G, 1' showed a total of 37 incidents of the temperature being out of range from May 2023 to June 2024, for 7 months between the following dates, with no correct action documented: 5/16/23 - 6/30/23: 7 incidents outside of -30C to -15C range 6/30/23 - 8/14/23: 6 incidents outside of -30C to -15C range 9/28/23 - 11/12/23: 2 incidents outside of -30C to -15C range 4/15/24 - 5/6/24: 3 incidents outside of -30C to -15C range 5/6/24 - 5/27/24: 12 incidents outside of -30C to -15C range 5/27/24 - 6/17/24: 7 incidents outside of -30C to -15C range 2. In an interview in the conference room on 6/25/24 at 12:05pm, the Operations Laboratory Manager explained the laboratory did not keep records of corrective actions beyond the Rees Scientific temperature chart.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

I. Based on review of the Centers for Medicare & Medicaid Services (CMS) - 209 form, laboratory's personnel records, and interview with the Technical Supervisor, the Technical Supervisor failed to perform and evaluate the annual competency for 3 of 3 Testing Personnel (TP) performing high complexity testing. Findings Included: 1. A review of the laboratory's CMS-209 form showed 3 Testing Personnel performing high complexity testing. 2. A review of personnel records in 2023 revealed that no performance or evaluation of annual competency was performed for three TPs. 3. In an interview in the laboratory on 6/25/24 at 1:19pm, the Technical Supervisor confirmed that due to minimal test volume, they were unaware of the annual competency requirements for TPs, and therefore annual competency was not completed.