Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	99D1101256	07/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mogen Body Genetics Lab	6b, Kiryat Mada St. Har Hozvim, Not Available, FN	

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	A remote recertification survey was performed on 07/29/25 and 07/30/25. Standard-level deficiencies cited.
D5209	Based on review of Centers for Medicare and Medicaid (CMS) Personnel Form 209, personnel records, and interview with the Quality Assurance (QA) Manager, the laboratory failed to perform competency assessment in 2024 for one of two Technical Supervisors based on job responsibilities. Findings included: 1. Review of the submitted CMS 209 form, signed and dated by the laboratory director on 07/23/25, listed two Technical Supervisors (TS). 2. In an interview on 07/23/25 at 2:20 am (US CST), the QA Manager stated Technical Supervisors were assessed annually based on job responsibilities. 3. Review of 2024 personnel records for Technical Supervisors revealed no annual competency assessment based on job responsibilities for one of two Technical Supervisors (TS #2). 4. In an interview on 07/29/25 at 2:36 am (US CST), the QA manager confirmed the findings. Word Key US CST = United States Central Standard Time
D5413	I. Based on manufacturer's instructions, environmental records, and interview with Technical Supervisor #1 (TS #1), the laboratory failed to ensure the manufacturer's requirements for humidity for 12 of 12 months. Findings included: 1. TS #1 confirmed on 07/30/25 at 01:14 am (US CST), the laboratory performed mutation analysis (genetic screening) allele specific polymerase chain reaction (ASP) using Applied Biosystems 2720 Thermocyclers. 2. Review of manufacturer's user guide section, "Environmental Considerations" stated, "Maintain a noncondensing relative humidity between 20-80%.". 3. Review of 2024 environmental logs revealed no evidence of documentation or monitoring of humidity. 4. In an interview on 07/30/25 at 2:00 am (US CST), TS #1 confirmed the laboratory failed to ensure the manufacturer's requirements for humidity. II. Based on manufacturer's instructions, environmental records, and interview with Technical Supervisor #2 (TS #2), the laboratory failed to ensure the manufacturer's requirements for Flow Cell cartridges for seven of seven days. Findings included: 1. TS #2 confirmed on 07/30/25 at 03:10 am, the laboratory performed Next Gen Sequencing (NGS) using the following: a.

	Illumina NextSeq 550 instrument b. NextSeq 500/550 High Output Flow Cell Cartridges 2. Review of manufacturer's instructions "Contents and Storage" stated: b. NextSeq 500/550 High Output Flow Cell Cartridge - storage requirement of 2C to 8C 3. Review of environmental records from 06/01/25 through 06/07/25 revealed temperatures warmer than the manufacturer's requirement for seven of seven days. a. 06/01/25 - documented temperature 9.6C b. 06/02/25 - documented temperature 9.0C c. 06/03/25 - documented temperature 9.5C d. 06/04/25 - documented temperature 9.4 C e. 06/05/25 - documented temperature 9.6C f. 06/06/25 - documented temperature 9.6C g. 06/07/25 - documented temperature 9.3C 4. In an interview on 07/30/25 at 03: 30 am (US CST), TS #2 confirmed the laboratory failed to ensure the manufacturer's storage requirements. III. Based on manufacturer's instructions, environmental records, and interview with Technical Supervisor #2 (TS #2), the laboratory failed to ensure the manufacturer's requirements for reagent cartridges for four of six days. Findings included: 1. TS #2 confirmed on 07/30/25 at 03:10 am, the laboratory performed Next Gen Sequencing (NGS) using the following: a. Illumina NextSeq 550 instrument b. NextSeq 500/550 High Output Reagent Cartridges 2. Review of manufacturer's instructions "Contents and Storage" stated: b. NextSeq 500/550 Reagent Cartridges - storage requirement of -25C to -15C 3. Review of environmental records from 06/02/25 through 06/07/25 revealed temperatures warmer than the manufacturer's requirement for four of six days. a. 06/02/25 - documented temperature -11.4C b. 06/03/25 - documented temperature -14.0C c. 06/06/25 - documented temperature -14.0C d. 06/07/25 - documented temperature -11.6C 4. In an interview on 07/30/25 at 03:25 am (US CST), TS #2 confirmed the laboratory failed to ensure the manufacturer's storage requirements. Key Word US CST = United States Central Standard Time
D5775	Based on record review and interview with Technical Supervisor #1 (TS #1), the laboratory failed to perform instrument comparison studies at least twice a year for one of one year (2024). Findings included: 1. In an interview on 07/30/25 at 01:14 am (US CST), TS#1 confirmed that the laboratory performed mutation analysis (genetic screening) allele specific polymerase chain reaction (ASP) using nine Cleaver Scientific Electrophoresis instruments. Instrument Serial Numbers: G-22 - MS100730007 G-26 - MS100713015 G-28 - MS101208093 G-29 - MS100713015 G-30 - MS101208092 G-33 - MS100713012 G-37 - MS101208095 G-96 - MS180523072 G- 97 - MS180523008 2. Review of laboratory's 2024 comparison studies revealed one comparison study (performed on 10/07/24). 3. In an interview on 07/30/25 at 1:30 am (US CST), TS #1confirmed the laboratory failed to perform comparison studies at least twice a year as indicated above. Key Word US CST = United States Central Standard Time
D6128	Based on review of Centers for Medicare and Medicaid (CMS) Personnel Form 209, personnel records, and interview with the Quality Assurance (QA) Manager, the Technical Supervisor failed to perform competency assessment in 2024 for one of five testing persons performing high complexity testing at least annually. Findings included: 1. Review of the submitted CMS 209 form, signed and dated by the laboratory director on 07/23/25, revealed Testing Person #1 (TP #1) listed to perform high complexity testing. 2. Review of 2024 personnel records for five testing persons performing high complexity testing revealed no annual competency assessed for TP #1. 3. In an interview on 07/29/25 at 2:08 am (US CST), the QA manager confirmed the findings. Key Word US CST = United States Central Standard Time