Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	99D1101256	07/25/2019
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	Federal Jurisdictional Survey (international) The laboratory was found in compliance with standard level deficiencies cited:
D5413	Based on direct observation, lack of documentation, manufacturer's instructions, and interview, the laboratory failed to monitor temperatures and document those conditions in the laboratory as evidenced by: Refrigerator with patient Controls 1. In direct observation on 7/25/2019 @1050 Refrigerator #8 the temperature was not being monitored. The following selected controls were stored in the refrigerator: 22.1.2.3 V529 96.1.1.687V 43.1.31674 43.1.2.1674 2. The laboratory printed out a document from a temperature monitoring system. The temperature was 0 degrees. 3. In interview with the Quality Assurance person she stated. " I think the temperature monitor is 0 degrees C all of the time." The Quality Assurance person called maintenance @1051 and maintenance stated that the temperature monitoring system was not connected. 4.The laboratory did not have a procedure in place at the time of the survey. Room Temperature PCR room 1. In review of the manufacturer's instructions applied Biosystem quick guide, states,"operating temperature 15-30 degrees C" 2. The laboratory could not provide documentation that they took room temperature on a daily basis. The laboratory did not have a procedure in place at the time of the survey. The laboratory labeled them PS 27,31,32,26 Room Temperature storage room 1. In review of the manufacturer's instructions on the box of the Qiagen symphony DNA mini kit reagents states, "store at 15-25 degrees C" 2. The laboratory couldn't provide documentation that they took room temperature on a daily baisis. The laboratory did not have a procedure in place to monitor room temperature at the the time of the survey 3.In direct observation @1053 the following reagents were observed on the shelf: DNA Qiagen Symphony DNA mini kit lot#160050504 expiration date 09-06-2019 DNA Qiagen Symphony DNA mini kit lot#1633010845
D6121	Based on review of the laboratory's procedures, interviews, and lack of documentation, the laboratory failed to have procedures in place for evaluation of competency of staff with 5 of 6 components for 2018 and 2019 as evidenced by: 1. In review of the laboratory's procedures, the laboratory did not have a procedure in place

	to perform competencies. The laboratory did not have procedures for 5 of 6 of the required components: Monitoring the recording and reporting of test results Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records Direct observation of performance of instrument maintenance and function checks; Assessment of problem solving skills. 2. The laboratory couldn't provide documentation for all testing personnel competencies for 2018 and 2019, for all testing personnel listed on the CMS-209 form. 3. In interview with the Laboratory Director and Quality Assurance person, on 7/24/2019 @1221 stated that they don't have competency. The CLIA inspector had to show both individuals the brochure for competencies and where to find it on the CLIA website for further guidance.