

## **Statement of Work: Methylation Array Testing Services / DNA Methylation EPIC Profile**

**Background:** The USDA ARS Precision Nutrition team at Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University, is conducting a research project on environmental stress and Type 2 diabetes risk in a Hispanic population. The Hispanic population is at high risk of developing Type 2 diabetes, but it is unclear what environmental factors contribute to the risk.

**Project objective:** The primary objective of this work is to examine the changes of the epigenetic status of whole epigenome including 850k methylation sites, from the baseline to the 5-year follow-up and examine the changes of 850K sites and environmental stress in relation to risk of type 2 diabetes. Genomic DNA was isolated from each blood sample that have been collected at the baseline and 5-year follow-up. A set of 96 DNA samples collected at the 5-year follow-up will be sent to the contractor who have conducted DNA methylation profile for other DNA samples from the same group of participants at baseline. The objective of this project is to determine the epigenetic profile of 96 DNA samples from the 5-year follow-up.

**Scope of work:** A set of 96 DNA samples collected during the 5-year follow-up period required epigenomic analysis using the Illumina Methylation EPIC V2 Array. Epigenomic profiling requires registration, tracking, bisulfite conversion, and QC, as well as methylation array testing of samples using the Illumina Methylation EPIC V2 Array. Raw data will need to pass quality control, and batch effects and normalization will be performed on all samples. Beta values for approximately 850,000 probe sets per DNA sample will be calculated and delivered together with the raw data.

**Detailed technical requirements (Contractor Requirements).** USDA ARS will provide 96 extracted genomic DNA samples. The contractor will perform sample registration, tracking, bisulfite conversion and QC, and methylation array testing on the samples using the Illumina Methylation EPIC V2 array. Raw data and any agreed upon supplementary analyses will be delivered using the contractor hosted secure file transfer to which the USDA ARS will be provided access. The contractor will also provide a project summary report. The testing will be performed in a CLIA/CAP accredited laboratory at research grade (RUO) regulatory level. The contractor will complete the epigenomic profile within 9-months. Extension may be granted, with advance notice, to due to research specifications.

There is considerable variation between methylome analysis platforms (i.e., between vendors) due to equipment, reagents, and personal handling. The other DNA samples of the same participants at the baseline were analyzed and processed in the same platform by the same vendor. For the required analysis, we needed these 96 DNA samples to be processed by the same vendor on the same platform. The results of the methylome analysis cannot be integrated and combined for reliable analysis to complete the research project if the service is provided by other vendors. This may render our analytical results and findings unreliable.

**Deliverables.** The contractor will deliver the following results and report to ARS via secure FTPS:

1. Raw IDATs of each sample;
2. Beta values from Illumina Genome Studio after QC;
3. Project Result Report (methods, QC Report, run summary).

**Reporting schedule.** The epigenomic data should be sent via a File Transfer Protocol (FTP). FTPs will be delivered to USDA Representative electronically, or posted on a private server for download within 60 days of sample submission.

**Period of performance.** (Based on Date of Award)

- 9 months.

**Payments:**

All invoices and payment request will be uploaded to the Invoice Processing Platform (IPP), every 30-days or at the end of the project completion. ([ipp.gov](http://ipp.gov))

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