

TOMA - Advanced Biomedical Assays Spa

Via F. Ferrer 25/27 - 21052 Busto Arsizio (VA) - Tel 0331 652911 ra. - Fax 0331 652919 - www.tomalab.com  
C. F. e P.IVA 00772010120 - CCIAA Varese REA 155894 - Capitale Sociale € 250.000 I.V.



Istituto certificato:

ISO 9001:2008 (n° cert. 194315)

ISO 15189:2007 (n° cert. 194315/A)

SIGUCert 2009 certificato dei laboratori di citogenetica e genetica molecolare (n° cert. 004)

Inserito nell'Albo del MIUR dei laboratori di ricerca altamente qualificati (art. 14 D.M. 593/2000)

September 06, 2010

*John V. Ilekis, PhD*

*Health Scientist Administrator,*

*Program Scientist, Genomic & Proteomic Network for Preterm Birth Research,*

*National Institutes of Health,*

*Eunice Kennedy Shriver National Institute of Child Health and Human Development,*

*Center for Developmental Biology and Perinatal Medicine,*

*Pregnancy and Perinatology Branch,*

*Room 4B03C, 6100 Executive Blvd.*

*Rockville, MD 20852*

*Re: GWAS Data Submission Certification*

*International Standard Cytogenomic Array (ISCA) Consortium*

*CNV Atlas TOMA, Advanced Biomedical Assays IRB File #0000001*

Dear Dr. Ilekis,

As the designated Chief Executive Officer for TOMA Advanced Biomedical Assays ("TOMA"), I am writing this letter to certify that the data submission for the ISCA Consortium CNV Atlas is consistent with all applicable laws and regulations as well as institutional policies;

- The appropriate research uses of the data and the uses that are specifically excluded by the informed consent documents are delineated.
- The identities of research participants will not be disclosed to the NIH GWAS data repository.
- The TOMA IRB review referenced above has verified that:

The submission of data to the NIH GWAS data repository and subsequent sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;

The investigator's plan for de-identifying datasets is consistent with the standards outlined in the policy;

The IRB has considered the risks to individuals, their families, and groups or populations associated with data submitted to the NIH GWAS data repository; and The genotype and phenotype data to be submitted were collected in a manner consistent with 45 C.F.R. Part 46.

Please contact me if you have any questions.

Sincerely,

**Federico Maggi, PhD**

*Diagnostic Laboratory CEO, Sanitary Director and President*

*Institutional Official for TOMA, Advanced Biomedical Assays*

A handwritten signature in blue ink, appearing to read "Federico Maggi", written over a horizontal line.

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