



# STATE OF NEW YORK DEPARTMENT OF HEALTH

Wadsworth Center

The Governor Nelson A. Rockefeller Empire State Plaza

P.O. Box 509

Albany, New York 12201-0509

Antonia C. Novello, M.D., M.P.H., Dr.P.H.  
*Commissioner*

Dennis P. Whalen  
*Executive Deputy Commissioner*

September 28, 2004

Dear Colleague:

In July of 2003, laboratories and assisted reproductive technology (ART) providers were notified that a New York State laboratory permit would be required for facilities performing preimplantation genetic diagnosis (PGD) on single cells derived from embryos by molecular genetic and/or cytogenetic techniques. Since that announcement was made, laboratories in the process of obtaining a permit have been authorized on a case-by-case basis to provide PGD for specimens collected in New York State.

The purpose of this letter is to announce that two laboratories have successfully completed the licensure process and are approved to provide PGD services effective October 1, 2004. Laboratories performing PGD are being held to the same quality standards as other clinical laboratories, including certification of the laboratory director, review of procedures and method validation data, on-site facility survey and participation in our proficiency testing program (when available).

Effective October 1, 2004, Reprogenetics in West Orange, NJ, is approved to offer PGD screening for chromosome aneuploidy and rearrangements by fluorescence in situ hybridization (FISH) plus molecular genetic testing for single gene defects and histocompatibility matching by PCR. A second laboratory, Genzyme Genetics in Pasadena, CA, is approved to only offer PGD screening for chromosome aneuploidy by FISH. After a reasonable transition period, authorization to refer IVF specimens from New York to PGD laboratories that do not hold permit will not be allowed. The only exceptions anticipated are cases when continuity of diagnostic procedures is medically or technically justified or when an approved laboratory can not provide the PGD test required by the patient. Therefore, we urge ART programs to contact the approved PGD providers (details provided in an enclosure) to make arrangements for future testing.

If you have any questions or require further assistance, you may contact Deirdre Astin, Assistant Director, Clinical Laboratory Evaluation Program, at (518) 402-2974.

Sincerely,

A handwritten signature in black ink that reads "Ellis Jacobs".

Ellis Jacobs, Ph.D., DABCC  
Director, Clinical Laboratory Evaluation Program

Enclosure  
EJ:lm



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## Laboratories Approved to Provide Preimplantation Genetic Diagnosis (PGD)

<b>Effective Date</b>	October 1, 2004	October 1, 2004
<b>Lab ID Number:</b>	8106	3356
<b>Laboratory:</b>	Reprogenetics, LLC 101 Old Short Hills Road Ste 501 West Orange, NJ 07052	Genzyme Genetics 11 West Del Mar Boulevard Pasadena, CA 91105
<b>Director:</b>	Santiago Munné, Ph.D.	Jin-Chen C. Wang, M.D
<b>Telephone:</b>	973-322-6333	800-255-1616
<b>Approved Tests:</b>		
<b>Prenatal Cytogenetics</b>	Aneuploidy for chromosomes 13, 15, 16, 17, 18, 21, 22, X, Y by fluorescence in situ hybridization (FISH)  Chromosome translocations by FISH	Aneuploidy for chromosomes 8, 9, 13, 15, 16, 18, 21, 22, X, Y by fluorescence in situ hybridization (FISH)
<b>Genetic Testing - Molecular</b>	Single Gene Defects by PCR  Histocompatibility (HLA) by PCR	Not applicable

For additional information concerning clinical laboratory approval for preimplantation genetic diagnosis, contact:

Deirdre Astin, M.S.	Assistant Director, Clinical Laboratory Evaluation Program	518- 402-2974
Michele Caggana, Sc.D.	Director, Genetic Testing Quality Assurance Program	518-474-6271
Ann M. Willey, Ph.D., J.D.	Director, Cytogenetics Quality Assurance Program	518-474-6796