

QUALIFYING GAMETE DONORS

What Standard-Setters Expect

January 2006

PURPOSE

1. To compare expectations of three groups establishing American standards for qualifying oocyte donors in medical practice: American Society of Reproductive Medicine (ASRM), U.S. Food and Drug Administration (FDA) and New York State Department of Health (NYS). ASRM publishes “guidelines” or recommended standards of practice; the data here is from *Fertility and Sterility* 77 (suppl 5), June 2002. The FDA regulations are Part 1271 of title 21 of the Code of Federal Regulations. NYS has published and enforces regulations for donors provided to physicians in that state (www.health.state.ny.us/nysdoh/phforum/nycrr10.htm and enter “Title 52”).
2. To enable licensed health care professionals to review the standard evaluation [*] of donors on the panel provided by Xytex. Xytex medically qualifies gamete donors for all indicated items [*], whether recommended or essential, and performs FDA and NYS repeat testing.

USE

By means of plus marks [+], the chart designates the various tests that each standard-setting agency specifies as essential, i.e., mandatory. In a few instances, an agency will highly recommend a non-essential test, and this is indicated by a plus in parenthesis [(+)]. Furthermore, NYS requires that four lab tests be repeated on donors within one month of each donation (HIV-1 and 2, HBV and HCV); these are indicated by double plus [++]. Xytex pre-evaluates all indicated items [*], whether recommended or essential, and performs NYS required repeat testing [**].

DONOR CRITERIA 2006	ASRM	FDA	NYS	XYTEX	EXPLANATORY NOTES
History					
Age (y), sperm donor	18-39		<44	18-40	<p>Xytex donors may be as young as 18 years old, which is their legal age of majority. Systems review is obviously important in consideration of infectious diseases, neurologic diseases and genetic diseases. Special attention is given to hepatitis, rabies and spongiform encephalopathies. Sexual history includes frequency, number of partners, sex of partners and conceptions. STI history includes questions about travels to endemic areas, blood transfusions, transplants and risky behaviors. Social history includes tobacco, alcohol and other recreational drug use and exposure to radiation and toxins. Xytex donors are asked detailed genetic history for family members (first and second degree) over four generations: children, siblings, parents and grandparents. Consideration is given to major malformations (e.g. cardiac, spinal), autosomal dominant and X-linked disorders with symptomatic onset at ages greater than the donor's, autosomal dominant with reduced penetrance and autosomal recessive disorders. Evaluation of genetic history is by a certified genetic counselor.</p>
Age (y), egg donor	21-34		≤34	18-31	
System Review	+	+	+	*	
Neuro-degenerative		+	+	*	
Neuro-infectious		+	+	*	
Sexual	+	+	+	*	
STI	+	+	+	*	
Social				*	
Genetic (Family) First Degree	+		+	*	
Second Degree			+	*	
Psychological					
Essay				*	<p>ASRM recommends psychological evaluation of oocyte donors and requires consultation "for individuals in whom there appears to be factors that warrant further evaluation." Xytex recognizes a genetic component of personal behavior and therefore offers three assessments: the donor's personal essay, interview by a licensed psychologist following the ASRM protocol and the California Personality Inventory (CPI), a standardized test. The CPI is a two-hour written assessment of personality. The focus is on personality rather than diagnosis of pathology (as provided by MMPI), but the CPI discloses personality aberrations without assigning a diagnostic label. The CPI is a thorough instrument in contrast to cursory tests such as the Meyers-Briggs and the Keirsey Temperament. The CPI must be supervised and interpreted by a licensed psychologist.</p>
Interview Sperm donor				*	
Egg donor	+			*	
Test (CPI)				*	
Physical Exam					
General (including STI) Sperm donor	+	+	+	*	<p>Interestingly, NYS and FDA, but not ASRM require physical exams of donors. The emphasis of these physical exam is to disclose infectious disease (including sexually transmitted encephalopathies) rather than evaluating fertility. The Xytex donor is evaluated for both.</p>
Egg donor		+	+	*	
Neuro		+	+	*	
Pelvic, egg donor		+	+	*	

DONOR CRITERIA 2006	ASRM	FDA	NYS	XYTEX	EXPLANATORY NOTES
Lab					
ABO/Rh	+		+	*	<p>All standard-setters require laboratory testing of oocyte donors for major STIs. NYS also requires oocyte donors to be re-tested for HIV 1 & 2, HBV and HCV within one month of each donation; an Ovations donor is re-tested within 14 days of retrieval. Additionally, ASRM and NYS require laboratory testing for a few genetic disorders when indicated by ethnic/racial classification.</p> <p>Importantly, NYS and FDA both adamantly require testing to be performed by a clinical laboratory certified by the federal agency CMS; an exempt physician office laboratory is not acceptable. CMS regulation specifies personnel qualification and recurrent training in addition to on-site inspections. Xytex testing is performed by CMS regulated laboratories.</p>
CBC				*	
Syphilis serol	+	+	+	*	
N. gonorrhea Sperm donor	+	+	+	*	
Egg donor		+			
C. trachomatis culture Sperm donor	+	+	+	*	
Egg donor		+		*	
PAP-HPV, egg donor				*	
HIV 1 & 2, Ab or NAT	+	+	++	**	
HBV surf Ag	+	+	++	**	
HBV core Ag or NAT				*	
HCV Ab	+	+	++	**	
HTLV-I Sperm donor		+	+	*	
Egg donor			+	*	
HTLV-II Sperm donor		+		*	
Egg donor		+		*	
CMV Ab Sperm donor		+		*	
Egg donor				*	
Trichomonas				*	
Sickle Cell	+		+	*	
Thalassemia (alpha & beta)	+		+	*	
Cystic Fibrosis	+		+	* (86 alleles)	
Tay Sachs	+		+	*	
Canavan	+		+	*	

DONOR CRITERIA 2006	ASRM	FDA	NYS	XYTEX	EXPLANATORY NOTES
Lab continued					
Gaucher				*	
Karotype Sperm donor	(+)			*	
Egg donor	(+)			(*)	
Documentation, Consent					
Documentation consent	+	+	+	*	All standard setters require documentation of donors' consent, and results of all evaluations. Xytex maintains these permanent records that potentially may be of value to offspring having need of additional medical information.

Adapted from *XytexXtra*, Spring 2004