

ACCURACY OF GENDER TEST KITS IN QUESTION

The modern-day equivalent of old wives' tales, they can have far greater consequences than inappropriately colored nurseries.

By Karen Kaplan, Los Angeles Times Staff Writer

Amid the tumult of the delivery room, Rohit and Geeta Jain were calm about one thing: Their new baby was sure to be a boy.

Six months earlier, the Jains had spent more than \$300 for a test that screened a minute quantity of Geeta's blood for traces of male DNA. The testing company said it was 95% accurate in determining the sex of a baby, even as early as the eighth week of pregnancy.

After six hours in the delivery room, Rohit gaped as his wife gave birth to a daughter.

"There's only two choices—either it's a boy or a girl," said Rohit, 35, a computer scientist in the Vancouver, Canada, suburb of Surrey. "I couldn't fathom how it could be wrong."

Like scores of other expectant parents, the Jains had stumbled into a corner of the booming genomics industry and discovered that the claims of some genetic entrepreneurs have gone beyond what science can provide.

Marketing directly to consumers, the new crop of companies has jumped into a realm of dubious science, mining DNA to offer information on ethnic heritage, long-lost relatives, personalized dieting plans—even the sports for which one is best suited.

The tests are loosely based on legitimate scientific research, much of which has been funded by the National Institutes of Health, among others. But often, the companies' claims of accuracy have not been backed up by independent laboratory analysis.

Thousands of consumers have bought tests—and analysts say the number will only grow as entrepreneurs find more ways to market the mysteries of the human genome.

The Federal Trade Commission, which protects consumers from false and misleading advertising, has warned buyers to be skeptical of at-home genetic tests, which are now unregulated.

In most cases, customers have no way of judging if their test results are accurate. But if a prenatal gender test is wrong, parents will surely find out.

The tests, scientists say, are the latest incarnation of old wives' tales about salty food cravings, hairy legs and belly shapes denoting the sex of the impending baby. This time, the predictions are being sold with the patina of cutting-edge genetic technology.

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A host of companies, such as Acu-Gen Biolab Inc. of Lowell, Mass., and Consumer Genetics Inc. of Sunnyvale, Calif., have been selling the tests for \$249 and up. Critics say they are banking on most disgruntled parents being too happy—or too busy—with their new child to file for a refund.

The consequences aren't merely financial.

"I wouldn't have had an abortion, but there are women out there who experience really big disappointment," said Jolene Sodano, a stay-at-home mother in Nazareth, Pa., whose daughter was mistakenly identified as a boy. "They really want to give their husbands the little boy they want, or a little girl, and they will abort based on these results."

More than 100 women have filed a lawsuit against Acu-Gen and its owner, Chang-ning Wang, that is pending in federal court. At least one customer has been questioned by the FBI. Wang has repeatedly declined to discuss the scientific validity of the test.

"It made me very angry at myself for believing this gibberish," said Mandana Kouroshnia, a Redlands dentist who joined the suit after her test incorrectly predicted a boy. "I made a fool out of myself."

RIPE FOR EXPLOITATION

The rise of direct-to-consumer genetic tests has come with surprising speed after the decoding of the human genome in 2000. Today, about 1,400 different types are being sold to consumers.

In the past, virtually all testing was done in medical laboratories for diagnostic purposes, such as searching for the mutations in the BRCA1 gene that are related to breast cancer.

But the development of faster and cheaper machines to sequence specific genes quickly gave entrepreneurs an opportunity.

Any trivial genetic quirk can be ripe for exploitation. Consumer Genetics, for example, offers a \$139 test called CaffeineGEN that screens for a DNA variant that causes caffeine to be metabolized slowly and is associated with an increased risk of miscarriages and nonfatal heart attacks. The company is also developing a test for a gene variant that might allow people to lower their cholesterol levels through moderate wine consumption.

Both tests are based on documented genetic aberrations, but there has been no proof that they can accurately predict health outcomes.

The gender tests got off to a splashy start in June 2005, when Acu-Gen's Baby Gender Mentor was featured on NBC's "Today" show. Holly Osburn, then seven weeks pregnant,

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went on the morning program to find out whether her third baby would be another girl or her first boy. On live TV, she appeared to force a smile after being told to expect a daughter.

The company's website said its \$275 test was able to detect fetal genetic material as early as five weeks after conception with up to 99.9% accuracy.

Other companies soon began popping up. Consumer Genetics introduced its \$195 Pink or Blue test in 2006, promising on its website 95% accuracy just seven weeks after conception. The company has sold more than 3,500 kits, said Lily Nguyen, the company's product manager for Pink or Blue.

It may seem a frivolous use of DNA. But the genetic tests are relatively inexpensive, and some parents figure there is no harm in learning the sex of their baby a little earlier than the usual 10 to 16 weeks needed for traditional medical tests, such as ultrasound.

For the Jains, the test was for more than mere curiosity.

Geeta discovered the Pink or Blue test on the Internet after an unexpected pregnancy presented the couple with a dilemma.

She wanted to keep the baby, but Rohit wasn't sure. With two daughters already, the family's finances were a bit strained. Could they really afford a third child?

Geeta countered with another question: What if the baby were a boy?

In traditional Indian culture, sons are prized because they will grow up to manage the family resources and support their parents in old age, even lighting their funeral pyres.

All Geeta had to do was prick a finger and mail a sample of dried blood to the company's laboratory.

"I don't know anything about biology, but it looked like it should be true," Rohit said. "It's DNA. It cannot be wrong."

The results arrived in March and stated that the baby was a boy. Geeta was ecstatic. Over the summer, she traveled to India for three weeks and offered prayers of thanks for the son she was carrying.

The Jains had no reason to doubt the test until their daughter Anika was born. Though incorrect results are usually revealed during routine ultrasound exams, fear of gender selection prevents many Canadian doctors from revealing a baby's sex.

After the initial shock and a tinge of sadness, the family quickly bonded with Anika, Rohit said, adding that they never bothered to seek a refund. "Anybody can start this business

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and keep half of the money even if they refund for wrong results, according to the law of probability,” he noted.

The reasons for taking the tests are as varied as the families that buy them.

Erin Rivera, a homemaker in Zephyrhills, Fla., took the test in her ninth week so she could share the news as soon as possible with husband Anthony, who was deployed in Afghanistan with the Army National Guard.

“Horrible as it sounds, in case anything had happened to him, I would have liked to let him know he was having a son or a daughter,” said Rivera.

The test was right. They had a boy.

Adinda DeBoevere, a mother of three boys in Novato, Calif., wanted a girl so badly that she and her husband spent \$25,000 on in-vitro fertilization so that doctors could select female embryos to implant in her womb.

“You keep on asking, ‘Did it work? Did they put the right embryo in?’ “ she said. To find out, the former criminologist took a DNA test when she was 10 weeks along.

The test said a boy. They had a girl.

SCIENTIFIC STUDIES

A baby’s gender is determined by one of the 23 pairs of chromosomes in the human genome. Mothers always contribute an X chromosome. If the father provides another X, the baby is a girl. If the father supplies a Y, the baby is a boy.

Scientific studies have found that a pregnant woman’s blood contains a small amount of fetal DNA, and the gender tests claim they can detect signs of the Y chromosome even if the embryo is no bigger than a grain of rice.

The problem is that divining traces of DNA from maternal blood is not simple.

Science has tried for more than a decade to find a simple and accurate way to determine gender early—and largely failed, using the most advanced technology available.

In a 2004 study, five medical centers in a National Institutes of Health consortium received identical blood samples from 100 women who were 10 to 20 weeks pregnant.

The centers used the same method to look for Y chromosomes in the maternal blood, but none was able to detect all of the 35 fetuses known to be male. According to the study, the detection rates ranged from 31% to 97%.

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Italian researchers published a study in 2005 demonstrating that they could correctly identify 98.7% of boys and 100% of girls by looking for male DNA in maternal blood drawn during the first trimester. But their method required a relatively large blood sample—10 milliliters—that was processed within a few hours.

The companies, in contrast, require just three to 10 drops of dried blood, which can take days to arrive through the mail.

Laura Cremonesi, senior author of the Italian study, said that she doesn't know anything about the companies' laboratory procedures and has no idea if their methods would work.

Nguyen, of Consumer Genetics, said the Pink or Blue test is more sensitive than the one used in Italy because it looks for a DNA marker that is 100 times bigger.

"There's more of it, so it's easier to spot," Nguyen said. For competitive reasons, she wouldn't give any specifics about the particular sequence of male DNA that the company searches for.

She didn't know how many customers had complained of an incorrect result, but she acknowledged that early versions of the test didn't make it clear that women had to be at least seven weeks' pregnant before taking it and that DNA from their husbands could contaminate the results.

Acu-Gen's website lists dozens of clinical studies that it says corroborate its approach, though none of them involved the specific DNA sequence that Acu-Gen says it uses in Baby Gender Mentor and none reported accuracy as high as 99.9%.

A woman who answered the company's phone said she was "not interested" in discussing the test's accuracy. Other calls and e-mails to Acu-Gen were not returned. In court filings, the company denied "any wrongdoing and any liability" in connection with incorrect test results.

Diana W. Bianchi, a medical geneticist at Tufts-New England Medical Center in Boston who worked on the 2004 NIH study, said that little or nothing is known about the companies' methods.

"There's no evidence that they've undergone any quality assessment," she said. "As best as I can tell, anybody can set up a virtual shingle and open for business."

Complaints about the companies and the lawsuit against Acu-Gen have prompted Bianchi and others to call for federal regulation of the industry.

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Currently, the tests are not regulated by the Food and Drug Administration because they aren't used to diagnose a medical condition, said spokeswoman Karen Riley.

Gail Javitt, law and policy director of the Genetics and Public Policy Center at Johns Hopkins University, said that gender tests could be considered diagnostic because some diseases are sex-specific. Nearly all patients with Duchenne muscular dystrophy or the blood clotting disorder hemophilia, for instance, are males.

Bianchi added that there is more at stake than just lost money or disappointment.

"As a physician, I'm most concerned not that someone has painted the nursery the wrong color, but what are the medical consequences of someone taking this test?" she said. An incorrect result could lead to "unnecessary amniocentesis and other procedures that carry a risk of miscarriage."

Melissa Alberti-Araujo subjected her newborn daughter, Nadine, to a battery of tests after she called Acu-Gen to complain that her test results had been wrong. She said Wang came on the line and insisted Nadine had male DNA.

"We panicked," said Alberti-Araujo, who is studying to be a family therapist in Three Rivers, Calif., and joined the class-action suit against the company.

"We did an ultrasound to make sure she didn't have testicles stuck up in there or anything. She was fine, but it was real emotional for us."

The feelings can linger.

Plaintiff Anissa Iverson, who works as an office manager at Disney Studios in Burbank, mourned when she discovered that the baby she expected to be a girl was a boy.

She had already washed and folded more than \$500 worth of clothes for the daughter, to be named Sydney. When she and her husband realized they would be having a son, they changed the baby's name to Zachary.

Iverson later became pregnant again, this time with a girl. The clothes bought for Sydney came out of storage, but the name could not be resurrected.

"I felt like Sydney had died," she said. "It was a tainted name."

Instead, she named her daughter Courtney.

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