

# News Release



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## FOR IMMEDIATE RELEASE

### CELERA AND COLLABORATORS PRESENT DATA SUPPORTING THE SUITABILITY OF A PROTOTYPE FRAGILE X ASSAY FOR POPULATION SCREENING

*Prototype assay found to be rapid and precise with 100 percent concordance with existing analyses and with minimal "hands on" time*

**ALAMEDA, CA – March 27, 2009** – Celera Corporation (NASDAQ:CRA) and its collaborators at the University of Utah and ARUP Laboratories today announced that data from a feasibility study using its prototype Fragile X screening assay will be presented as a poster entitled, "A rapid assay suitable for Fragile X population screening", at the 2009 American College of Medical Genetics annual meeting in Tampa, FL. Fragile X syndrome is the most common cause of inherited mental retardation<sup>1</sup>. Key findings of this study were that the prototype assay was found to detect expanded alleles in all pre-mutation and full mutation patients with 100 percent sensitivity in both genders, in addition to identifying all non-expanded alleles in patients with 100 percent specificity. The study also found the prototype requires minimal hands-on time, is rapid, robust, runs on an existing instrument (ABI PRISM® 3100) and fits well into the workflow of a clinical laboratory. Celera believes these combined findings support the suitability for further development of this prototype assay as a means of performing high throughput population screening for Fragile X syndrome.

The Fragile X prototype assay combines a single PCR "chimeric" primer with Celera's general purpose reagents and fragment analysis on a capillary electrophoresis genetic analyzer. The new primer set, available as an analyte specific reagent, is designed to distinguish between normal and expanded *FMR1* (Fragile X mental retardation) genotypes using extracted DNA from whole blood or dried blood spots.

The causative mutation in 99 percent of cases of Fragile X syndrome is expansion of the CGG (cytosine-guanine-guanine) triplet repeat in the *FMR1* gene, which resides in the X chromosome. The CGG expansion can be categorized into four classes based on the size of the repeat: normal (5-44 repeats), intermediate-grey zone (45-54 repeats), pre-mutation (55-200 repeats), and full mutation (greater than 200 repeats). Pre-mutation repeats may expand to full mutations in the next generation. Females that have either a pre-mutation or full mutation repeat length alleles are carriers, and some females with full mutations are affected. Males that inherit a full mutation repeat allele exhibit developmental disabilities.

As part of the current study, Celera and its collaborators identified the presence of expanded *FMR1* alleles in 132 samples (59 pre-mutation, 71 full-mutation, 2 mosaics) and normal *FMR1* alleles in 73 samples. There was a 100 percent concordance with previously obtained results from PCR and Southern blot analyses. Thirteen samples that were assayed in triplicate for within-run and between-run variability gave consistent

results. Celera believes this study demonstrates that considerable laboratory technician time could be saved by referring only non-normal outcomes for additional tests through PCR-acrylamide gels and Southern blotting.

“This prototype assay appears to be suitable for population screening to identify pre-mutation carrier females and affected newborns,” said Elaine Lyon, Ph.D., Associate Professor of Pathology at the University of Utah and Medical Director of Genetics at ARUP Laboratories, and the lead author on the poster. “Population screening requires a rapid and robust assay with high sensitivity and specificity, and suitable for high-throughput analysis. The results we obtained were reproducible and agreed well with our in-house method.”

“We’re pleased with the findings of this study using our prototype assay as we believe they support our findings that this assay allows a more efficient PCR method for detecting Fragile X carriers and affected individuals compared to current procedures,” said Michael Zoccoli, Ph.D., General Manager of Celera’s Products business.

This prototype assay can be used in conjunction with Celera’s existing Fragile X assay, which is a PCR assay that co-amplifies a novel gender-specific gene simultaneously with the trinucleotide CGG repeat region within the *FMR1* gene. Empirical data generated through external collaborations has shown that the PCR can amplify *FMR1* expansions that contain > 1000 CGG repeats, and the fragment analysis can accurately size up to 230 repeats on the ABI PRISM® 3100. Previous internal studies have demonstrated results for amplification of normal and pre-mutation triplet repeats in the *FMR1* gene, which were sized on the ABI PRISM 3100. Also included is amplification of a novel gender gene that can be used to confirm the gender of the individual associated with the sample, which serves as an aid in assessing the X chromosome copy number.

### **About Fragile X<sup>1</sup>**

Affected people with Fragile X syndrome have a mutation in the *FMR1* gene in the DNA that makes up the X chromosome. That mutation causes the cell to methylate a regulatory region of the *FMR1* gene. The methylation turns off the *FMR1* gene. Since the gene is turned off, the person doesn't make FMRP (Fragile X mental retardation protein). That lack of this specific protein triggers Fragile X syndrome. Those for whom molecular testing should be considered are individuals with mental retardation, developmental delay, and autism. Additional candidates for testing include those seeking reproductive counseling who have a family history of Fragile X syndrome or undiagnosed mental retardation, as well as fetuses of carrier mothers. Finally, men over age 50 with a late onset, progressive intention tremor and ataxia disorder with dementia could be tested for expanded alleles to distinguish from Parkinson's or Alzheimer's disease.

Little information exists for ethnic/racial groups; however, population-based estimates in mixed, African-derived populations suggest that the prevalence of the full mutation may be 1 in 5,000 males. No study has determined the prevalence of the full mutation among females in the general population. However, based on the prevalence of the full mutation in males, 1 in 8-9,000 females in the general population may be affected by the Fragile X syndrome<sup>1</sup>.

### **About Celera**

Celera is a healthcare business delivering personalized disease management through a combination of products and services incorporating proprietary discoveries. Berkeley HeartLab, a subsidiary of Celera, offers services to predict cardiovascular disease risk

and improve patient management. Celera also commercializes a wide range of molecular diagnostic products through Abbott and has licensed other relevant diagnostic technologies developed to provide personalized disease management in cancer and liver diseases. Information about Celera Corporation, including reports and other information filed by the company with the Securities and Exchange Commission, is available at <http://www.celera.com>.

### **About ARUP Laboratories**

ARUP Laboratories is a national clinical and anatomic pathology reference laboratory and an enterprise of the University of Utah and its Department of Pathology. With more than 2,400 employees, ARUP offers in excess of 2,000 tests and test combinations, ranging from routine screening tests to highly esoteric molecular and genetic assays, for patients throughout the country. Rather than competing with its clients for physician office business, ARUP chooses instead to support clients' existing test menus by offering highly complex and unique tests, with accompanying consultative support, to enhance their abilities to provide local and regional laboratory services. ARUP's clients include more than half of the nation's university teaching hospitals and children's hospitals, as well as multihospital groups, major commercial laboratories, group purchasing organizations, military and government facilities, and major clinics. In addition, ARUP is a worldwide leader in innovative laboratory research and development, led by the efforts of the ARUP Institute for Clinical and Experimental Pathology<sup>®</sup>. Further information on ARUP Laboratories can be found at [www.aruplab.com](http://www.aruplab.com).

### **Forward-Looking Statements**

Certain statements in this press release are forward-looking. These may be identified by the use of forward-looking words or phrases such as "believe," "expect," "will," "should," "anticipate," and "intend," among others. These forward-looking statements are based on Celera's current expectations. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, Celera notes that a variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include, but are not limited to, the risks and uncertainties that: (1) Celera is using novel and unproven methods to discover markers for the development of new diagnostic products, which may not be successful; (2) the diagnostic industry is very competitive, and new diagnostic products may not be accepted and adopted by the market; (3) demand for diagnostic products may be adversely affected if users of these products cannot receive adequate reimbursement for these products from third party payors such as private insurance companies and government insurance plans; (4) potential product liability or other claims against Celera as a result of the testing or use of its products; (5) uncertainty of the availability to Celera of intellectual property protection, limitations on its ability to protect trade secrets, the risk to it of infringement claims, and the possibility that it may need to license intellectual property from third parties to avoid or settle such claims; and (6) other factors that might be described from time to time in Celera's filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Celera does not undertake any duty to update this information, including any forward-looking statements, unless required by law.

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1. Crawford DC, Acuña JM, Sherman, SL. (2001) FMR1 and the Fragile X syndrome: Human genome epidemiology review. *Genetics in Medicine*. **3(5)**: 359-371.