160 North Craig Street, Suite 210
Pittsburgh, PA 15213
Phone: 412.683.3004
Fax: 412.683.3005
perlin@cybgen.com

April 1, 2015

Jerry D. Varnell, Contract Specialist
Procurement Section, Department of Justice
Federal Bureau of Investigation
935 Pennsylvania Avenue, N.W.
Washington, District of Columbia 20535
Phone: 703.632.7500
Fax: 703.632.8480
Jerry.Varnell@ic.fbi.gov

Re: Solicitation Number PR-0018507

Dear Mr. Varnell,

The attached documentation is in response to the March 31, 2015 posting of the FBI's
Notice of Intent for a sole source contract with NicheVision Forensics for STRmix software
manufactured by the New Zealand company ESR.

Cybergenetics is a small American business located in Pittsburgh, PA. Our company
innovated accurate TrueAllele® computer interpretation of complex DNA evidence,
including mixtures. Cybergenetics has commercially supplied TrueAllele Casework
products and services in the United States for over five years. TrueAllele user software
runs on Macintosh and Windows computers, including Windows 7.

After you review the attached documentation, I would respectfully request that you
withdraw the sole source contract for STRmix, and initiate a competitive bid process.


Sincerely,

Mark W. Perlin, PhD, MD, PhD
Chief Scientific and Executive Officer
Cybergenetics (registered in SAM)

**Re: FBI Notice of Intent for Sole Source Procurement of Foreign DNA Technology**

The Federal Bureau of Investigation (FBI) has issued a Notice of Intent (Solicitation Number PR-0018507) to procure DNA interpretation technology (STRmix) manufactured in New Zealand through a sole source contract. However, a better solution (TrueAllele) is available from Cybergenetics, an American small business, and so the proposed sole source procurement is inappropriate.

**Cybergenetics TrueAllele® Casework System**

Mixtures arise when two or more individuals contribute their DNA to a biological evidence item. Crime laboratories generate informative data from these mixtures, but manual data review is often uninformative. For fifteen years, tens of thousands of mixture items have been discarded as evidence due to manual review limitations.

Fifteen years ago Cybergenetics (Pittsburgh, PA) developed TrueAllele® Casework, a computerized solution to the DNA mixture problem. TrueAllele objectively separates a lab's electronic data into the genetic types (or, "genotypes") of each person who contributed their DNA to the mixture. TrueAllele then compares evidence and reference genotypes to calculate a match statistic.

TrueAllele is highly reliable. Seven published validation studies establish how well the computer identifies true contributors, excludes non-contributors, and gives reproducible results (Attachment A). United States courts have accepted TrueAllele after admissibility challenge in six states (Attachment B). The New York and Virginia forensic science commissions have recognized TrueAllele as reliable. No other mixture analysis approach is as extensively validated or widely accepted.

TrueAllele improves criminal justice in the United States. Crime laboratories use TrueAllele to interpret their mixtures. Hundreds of TrueAllele case reports have been filed across twenty three states. Prosecutors have introduced TrueAllele evidence in dozens of criminal trials in state, federal and military courts. TrueAllele provides scientific identification for challenging DNA evidence in crimes of murder, rape, child abuse and terror. TrueAllele reanalyzed victim remains in the World Trade Center disaster.

**FBI Technology Requirements**

The FBI's technology requirements are described in the Notice of Intent. Addressing each one in turn:

*1. new algorithms and biological and statistical strategies*

Cybergenetics published such algorithms and strategies[1] in 2001, and elaborated them further in subsequent papers (Attachment A). These methods may be "new" to the FBI or New Zealand, but they are old hat in the rest of the forensic science community.

---

[1] Perlin MW, Szabady B. "Linear mixture analysis: a mathematical approach to resolving mixed DNA samples." *J Forensic Sci.* 2001;46(6):1372-7.

*2. enable full utilization of all DNA typing results*

Cybergenetics TrueAllele makes full use of the DNA typing data, as described in many papers and presentations[2].  However, New Zealand's product does not fully consider all the DNA data and possible solutions.

*3. including those encountered in the most challenging forensic samples*

TrueAllele has been shown to solve the most challenging forensic samples in numerous cases and studies.  STRmix does not have this capability; for example, it cannot even resolve mixtures containing five or six people.

*4. automates the manual interpretation process that examiners perform*

TrueAllele automates all steps of the DNA mixture interpretation process to give accurate and reliable answers.  STRmix requires manual steps (e.g., re-calibration) that impede such full automation.

*5. significantly reduces analysis time*

TrueAllele's parallel processing lets a lab resolve hundreds or thousands of DNA mixtures each day in an automated workflow that significantly reduces analysis time.  The STRmix less automated workflow has manual steps that may increase analysis time.

*6. removes all elements of subjectivity*

TrueAllele resolves DNA mixtures without any knowledge of a comparison reference genotype, thus is entirely objective.  STRmix uses the comparison reference in its calculations, and is therefore a subjective approach.

*7. has been demonstrated to promote consistent interpretations*

TrueAllele has been demonstrated to give consistent match statistics in dozens of validation studies and on hundreds of complex DNA mixtures.  STRmix can give different answers based on how an analyst sets their input parameters.

*8. resolve previously unresolved mixed DNA profiles*

TrueAllele is regularly used to resolve previously unresolved mixed DNA profiles, and can be applied to any DNA mixture, always giving an answer.  When STRmix cannot resolve a DNA mixture, it just says there is no solution.

*9. DNA mixtures of up to four individuals*

---

[2] http://www.cybgen.com/information/presentations/page.shtml

TrueAllele resolves DNA mixtures without any limitation on the number of contributing individuals; one validation paper shows its operation on five contributor mixtures (Attachment A). The STRmix limitation to four individuals is not practical for modern casework, where evidence (e.g., handguns) often have DNA from more than four people.

*10. fully continuous approach for DNA profile interpretation*

TrueAllele is a fully continuous approach to interpreting DNA evidence that uses all of the available electronic data. However, STRmix uses threshold parameters that discard data, and drop-out parameters that concoct data, and so may not actually be "fully continuous".

**Sole Source Authority, FAR 6.302-1(a)**

The authority of FAR 6.302-1 sole source procurement requires that for "supplies or services may be considered to be available from only one source" there must be "a unique and innovative concept" or "capability". The 48 CFR 2.10 definition of "unique and innovative" has four components, *all* of which must be satisfied:

*(i) Is the product of original thinking submitted confidentially by one source;*

Relative to the FBI's procurement requirements for mixture interpretation (as reviewed above), the long-standing American TrueAllele product is "the product of original thinking," not the recent New Zealand's STRmix software.

*(ii) Contains new, novel, or changed concepts, approaches, or methods;*

Cybergenetics expended fifteen years of American innovation in developing the new and powerful methods implemented in the TrueAllele DNA mixture interpretation product. STRmix is one of several recent foreign software programs to enter that landscape.

*(iii) Was not submitted previously by another; and*

For over ten years Cybergenetics has informed the FBI that TrueAllele solves the FBI DNA lab's mixture problem. Cybergenetics visited the FBI DNA lab several times, and gave multiple presentations on TrueAllele mixture analysis to the FBI's Scientific Working Group on DNA Analysis Methods (SWGDAM). Moreover, Cybergenetics reanalyzed the FBI's DNA mixture data in Commonwealth of Pennsylvania v. Kevin Foley, with the FBI analyst attending the 2009 homicide trial where TrueAllele results were introduced as evidence.

*(iv) Is not otherwise available within the Federal Government.*

Cybergenetics has worked with federal prosecutors on resolving DNA mixture evidence in cases in Massachusetts, Pennsylvania and Virginia. TrueAllele is available to, and used by, the Federal Government.

**Sole Source Application, FAR 6.302-1(b)**

The application of FAR 6.302-1 sole source procurement is considered appropriate in certain situations, including:

*(1) When there is a reasonable basis to conclude that the agency's minimum needs can only be satisfied by unique supplies or services available from only one source or only one supplier with unique capabilities*

The facts show that Cybergenetics is the only source having the unique capabilities specified by the FBI's requirements for DNA mixture interpretation. There is no showing that the New Zealand supplier uniquely meets these needs. Therefore, a sole source FBI contract with Cybergenetics for its TrueAllele solution may be appropriate.

*(2) The existence of limited rights in data, patent rights, copyrights, or secret processes*

Cybergenetics has United States patents for automated genotyping and mixture analysis (Attachment C). The first patent was filed in 1994. The most recent patent issued in 2014. A sole source FBI contract with the American innovator Cybergenetics for its TrueAllele solution may therefore be appropriate.

**Conclusion**

The FBI's Notice of Intent says that "Based on market research conducted and contacts made with knowledgeable individuals within the government and related industry, it has been determined the FBI's requirement can only be provided by NicheVision Forensics as they are the sole US distributor of STRmix."

Based on the information provided herein, clearly this determination was incomplete and incorrect. Cybergenetics can provide the FBI's requirement, and probably do so with superior technology at a lower cost.

The Notice also states "Information received will be considered solely for the purpose of determining whether or not to conduct a competitive procurement."

There may be a genuine basis for the FBI's having *Cybergenetics provide TrueAllele technology on a sole source basis*. But there is no foundation for any other sole source arrangement. Barring a sole source arrangement with Cybergenetics, the FBI should proceed with a competitive procurement process.

For fifteen years, the FBI and other American crime labs have misinterpreted or discarded vital DNA evidence in tens of thousands of criminal cases. The result has been criminal injustice, government waste, and needless victimization. Cybergenetics solved the DNA mixture problem fifteen years ago, providing highly reliable TrueAllele technology that is used throughout the United States. The FBI can help rectify this public safety threat by learning about TrueAllele, and adopting Cybergenetics technology in its laboratory.

**Attachment A**

**Peer-reviewed TrueAllele validation papers**

*laboratory data*

• Perlin MW, Sinelnikov A. An information gap in DNA evidence interpretation. *PLoS ONE*. 2009;4(12):e8327.

• Ballantyne J, Hanson EK, Perlin MW. DNA mixture genotyping by probabilistic computer interpretation of binomially-sampled laser captured cell populations: combining quantitative data for greater identification information. *Science & Justice*. 2013;52(2):103-14.

• Perlin MW, Hornyak J, Sugimoto G, Miller K. TrueAllele® genotype identification on DNA mixtures containing up to five unknown contributors. *Journal of Forensic Sciences*. 2015;*in press.*

• Greenspoon SA, Schiermeier-Wood L, and Jenkins BC. Establishing the Limits of TrueAllele® Casework: A Validation Study. *Journal of Forensic Sciences*. 2015;*in press.*

*casework data*

• Perlin MW, Legler MM, Spencer CE, Smith JL, Allan WP, Belrose JL, Duceman BW. Validating TrueAllele® DNA mixture interpretation. *Journal of Forensic Sciences*. 2011;56(6):1430-1447.

• Perlin MW, Belrose JL, Duceman BW. New York State TrueAllele® Casework validation study. *Journal of Forensic Sciences*. 2013;58(6):1458-66.

• Perlin MW, Dormer K, Hornyak J, Schiermeier-Wood L, and Greenspoon S. TrueAllele® Casework on Virginia DNA mixture evidence: computer and manual interpretation in 72 reported criminal cases. *PLoS ONE*. 2014:9(3):e92837.

**Attachment B**

**TrueAllele admissibility outcomes in the United States**

• California trial court admitted TrueAllele into evidence in People v. Dupree Langston, Kern County, case number BF139247B, January 10, 2013.  (Kelly-Frye)

• Louisiana trial court admitted TrueAllele into evidence in State v. Chattley Chesterfield and Samuel Nicolas, Parish of East Baton Rouge, case 01-13-0316 (II), November 6, 2014. (Daubert)

• New York trial court admitted TrueAllele into evidence in People v. John Wakefield, Schenectady County, indictment number A-812-29, February 11, 2015.  (Frye)

• Ohio trial court admitted TrueAllele into evidence in State v. Maurice Shaw, Cuyahoga County, case number CR-575691, October 10, 2014.  (Daubert)

• Pennsylvania Superior Court affirmed TrueAllele admissibility ruling in Commonwealth v. Kevin Foley, Indiana County 2009 trial, establishing a statewide Pennsylvania precedent; 2012 PA Super 31, No. 2039 WDA 2009, filed February 15, 2012.  (Frye)

• Virginia trial court admitted TrueAllele into evidence in Commonwealth v. Matthew Brady, Colonial Heights County, case number CR11000494, July 26, 2013.  (Spencer-Frye)

**Attachment C**

**Cybergenetics patents on automated genotyping and mixture interpretation**

• US8898021 - Method and system for DNA mixture analysis.

• EP1229135 - Method and system for DNA mixture analysis.

• US6807490 - Method for DNA mixture analysis.

• US6750011 - Method and system for genotyping.

• US6054268 - Method and system for genotyping.

• US5876933 - Method and system for genotyping.

• US5580728 - Method and system for genotyping.

• US5541067 - Method and system for genotyping.