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ArmedXpert™ v3.0.8.21/27

Contents

1. Summary/Introduction

Description

ArmedXpert (AX) is a software program that assists the user in deconvoluting mixtures and performing frequency calculations on STR profiles imported from Genemapper ID-X. AX is intended as a tool for the analysis of 1- 2- and 3-contributor profiles

AX performs statistical calculations as directed by the user, but performs no analysis itself. Like Popstats, AX utilizes the NIST population database and supports random match probability (RMP), combined probability of inclusion (CPI/CPE), and relatedness calculations. In addition, AX supports unrestricted, restricted and modified random match probabilities (uRMP, rRMP, mRMP). The application of RMP to mixture profiles increases statistical power by taking into consideration information on number of contributors, limiting certain genotypes and by compensating for potential dropped alleles

AX employs a proportional allele sharing model to help deconvolute mixtures. From the relative peak heights, AX calculates the proportion of each contributor. This is then factored in to the ranking of potential allele combinations at loci with overlapping alleles. The user then evaluates this information and makes a determination.

Overview of Software (Settings = Supporting Documentation 1)

1. DNA profile to be interpreted is imported into AX.

2a. Complete single source profiles can be immediately subject to statistical calculation and exported to CODIS.

2b. AX's support of RMP permits the use of loci with dropout, even though the exact genotype cannot be ascertained.

3. Two-and 3-person mixtures can be interpreted using proportion windows. Some profiles can be deconvoluted.

Validation Steps

1. The pre-programed data and mathematical functions of AX were checked by direct comparison to values obtained from Popstats. To check AX calculations not supported in Popstats, the expected formulae were calculated in an Excel spreadsheet.

2. To thoroughly establish the estimated range of stochastic amplification to be expected in casework mixtures, a set of 225 known-contributor mixture samples were created and analyzed.

3. Some of the electropherograms from the set of 225 mixtures were analyzed with AX to check the software settings and help draft procedures.

4. The verification and functionality of the AX software, user-entered parameters and draft procedure were checked using a set of the mixture electropherograms that had not been included in the original analysis.

Authorized Staff to Participate in the Validation

Steve Wiechman	David Miller
Andrea Weisenburger	Emily Feldenkris
Katharine Dailey	

Versions and Install

ArmedXpert™ v3.0.8.5 was initially validated on a stand-alone computer in January, 2017. Several interim developmental versions were validated during the next 2.5 years. Finally, AX v3.0.8.27 was installed onto the BCI network accessible at both London and Richfield laboratories. A Functional testing and performance check were conducted on the network install. The software was found to function the same on the stand-alone computer and on the network from multiple laboratory- and home-based network connections.

2. Regression testing between Popstats and AX. **(Supporting documentation 2)**

Population Database Check

Allele frequencies for the NIST Revised 1036 US Population Dataset for the Caucasian, African American, and Hispanic population groups are stored in both Popstats and AX. They were manually compared by SMW. AX frequencies can be viewed in the Options/Interpretation/Frequency menu by selecting the Review Frequencies button. Popstats frequencies were reviewed by opening the text file corresponding to the selected ethnic group/locus combination in the Popstats /NIST/STR folder. Frequency values used in calculations were confirmed to be the same in both programs. The display differed in that Popstats lists the actual observed frequency of all alleles and AX displays the 5/2N minimum allele frequency where applicable. Both programs apply the 5/2N minimum value as needed.

AX-Popstats Frequency Calculation Comparison

Frequencies for 3 single-source profiles and 3 mixtures were calculated in both AX and Popstats. Upon importing the data file, AX automatically generates the value whereas Popstats requires the user to key in each allele. Popstats displays 4 decimals in the result and AX was set to display four as well. For most results, differences occurred in the 4th decimal. These differences were traced to differences in display where Popstats rounds from the 5th significant figure and displays 4 whereas AX displays 5 decimals.

Popstats vs ArmedXpert Calculations

Sample	Database	Popstats CPI	AX CPI	Sample	Database	Popstats RMP	AX RMP
MML/MM 2:1 1.0 ng	C	1.5850E+13	1.5851E+13	AEW 0.5 ng	C	2.5690E+31	2.5691E+31
	AA	1.7600E+14	1.7603E+14		AA	1.9250E+31	1.9245E+31
	H	6.2700E+13	6.2679E+13		H	1.2330E+33	1.2327E+33
PT/SMW 4:1 0.5 ng	C	5.0400E+17	5.0397E+17	LB 1.0 ng	C	4.7920E+29	4.7923E+29
	AA	3.2980E+19	3.2987E+19		AA	1.7530E+32	1.7259E+32
	H	2.3110E+18	2.3109E+18		H	7.2990E+29	7.3006E+29
AS/KBS/LB 1:1:1 1.0ng	C	2,268,000	2,267,500	SMW 0.75 ng	C	1.4710E+30	1.4707E+30
	AA	51,280,000	51,290,000		AA	3.3670E+33	3.3672E+33
	H	2,231,000	2,231,100		H	3.3810E+31	3.3810E+31

Regression testing comparison of frequency calculations performed by Popstats and AX.

Sample Name	Database	ArmedXpert v3.0.8.21 (RMP) stand-alone	ArmedXpert v3.0.8.27 (RMP) network
AEW 0.5ng	Caucasian	2.5691E+31	2.5691E+31
	African Am.	1.9245E+31	1.9245E+31
	Hispanic	1.2327E+33	1.2327E+33
LB 1.0ng	Caucasian	4.7923E+29	4.7923E+29
	African Am.	1.7259E+32	1.7259E+32
	Hispanic	7.3006E+29	7.3006E+29
SMW 0.75ng	Caucasian	1.4707E+30	1.4707E+30
	African Am.	3.3672E+33	3.3672E+33
	Hispanic	3.3810E+31	3.3810E+31

Comparison of calculations for mixed samples between AX v3.0.8.21 on the stand-alone AX workstation in London and AX v3.0.8.27 on the BCI network.

CMF (common message format) file for CODIS uploads. AX was used by SMW to create a CMF file containing a GF positive control. The cmf was recognized by CODIS and the profile was successfully transferred. The allele and specimen information was maintained.

3. Mathematical Verification of AX Statistical Formulas

(Supporting documentation 3)

Microsoft Excel formulas and NIST allele frequencies were used to verify the mathematical equations not supported in Popstats. Concordant values were obtained for all forms of the RMP calculations produced by AX.

Type	Locus	NIST Allele Frequencies				Formula	Excel Result	Allele 1	Allele 2	Allele 3	Allele 4	1	2	AX Result
	D19S433	**13**	**15**					**13**	**15**			**13** **15**		
RMP (Het)		0.2456	0.0804			2pq	**0.0395**	0.2456	0.0804			0.0395		**0.0395**
		0.2548	0.1565				**0.0798**	0.2548	0.1565			0.0798		**0.0798**
		0.2225	0.1356				**0.0603**	0.2225	0.1356			0.0603		**0.0603**
	D10S1248	**13**						**13**				**13** **13**		
RMP (Hom)		0.2339				$p^2+p(1-p)\theta$	**0.0565**	0.2339				0.0565		**0.0565**
		0.3075					**0.0967**	0.3075				0.0967		**0.0967**
		0.2733					**0.0767**	0.2733				0.0767		**0.0767**
	D3S1358	**16**	**18**					**16**	**17**	**18**		**16** **18**	**16** **16**	
Combo		0.3187	0.057			2pq+[p^2+p(1-p)θ]	**0.1401**	0.3187	0.212	0.057		0.0363	0.1037	**0.1401**
(cRMP)		0.2382	0.151				**0.1305**	0.2382	0.2105	0.151		0.0719	0.0586	**0.1305**
		0.2797	0.1229				**0.1490**	0.2797	0.1843	0.1229		0.0688	0.0802	**0.1490**
	SE33	**14**	**16**	**18**	**19**			**14**	**16**	**18**	**19**	**14** **16**	**18** **19**	
Restricted		0.0512	0.0482	0.12	0.127	2pq+2rs	**0.0354**	0.0512	0.0482	0.1199	0.1272	0.0049	0.0305	**0.0354**
(rRMP)		0.0249	0.0402	0.072	0.072		**0.0124**	0.0249	0.0402	0.072	0.072	0.0020	0.0104	**0.0124**
		0.0275	0.0699	0.11	0.089		**0.0235**	0.0275	0.0699	0.1102	0.089	0.0038	0.0196	**0.0235**
	D21S11	**28**	**30.2**	**31.2**	**32.2**			**28**	**30.2**	**31.2**	**32.2**			
Unrestricted		0.2456	0.0175	0.051	0.061	$(p+q+r+s)^2-p^2-q^2-r^2-s^2$	**0.0741**	0.2456	0.0175	0.0512	0.0614	(28 + 30.2 + 31.2 + 32.2)² - 28²- 30.2²- 31.2²- 32.2²		**0.0741**
(uRMP)		0.1593	0.0291	0.098	0.09		**0.0979**	0.1593	0.0291	0.0983	0.09			**0.0979**
		0.0996	0.0233	0.1	0.127		**0.0857**	0.0996	0.0233	0.0996	0.1271			**0.0857**
	D16S539	**12**						**12**				**12** **Any**		
Modified		0.2047				$p^2+p(1-p)\theta+[2p(1-p)]$	**0.3691**	0.2047				0.3691		**0.3691**
(mRMP)		0.3144					**0.5321**	0.3144				0.5321		**0.5321**
		0.2775					**0.4800**	0.2775				0.4800		**0.4800**
	D8S1179	**11**	**12**	**13**				**11**	**13**	**14**		(11 + 13 + 14)² + [2(11)(1-(11 + 13 + 14))] + [2(13)(1-(11 + 13 + 14))] + [2(14)(1-(11 + 13 + 14))]		
Forced Mod		0.0526	0.2193	0.294		(p+q+r)²+ [2p(1-(p+q+r))][2q(1-(p+q+r))][2r(1-(p+q+r)]	**0.8115**	0.0526	0.2193	0.2939				**0.8115**
(fmRMP)		0.0762	0.3296	0.166			**0.8168**	0.0762	0.3296	0.1662				**0.8168**
		0.053	0.2733	0.263			**0.8311**	0.053	0.2733	0.2627				**0.8311**

Mathematical Verification of AX RMP formulas

4. Creation of Known Mixtures for use in Setting AX Parameters

(Supporting documentation 4)

Dilution series were prepared from previously IQ-extracted buccal swabs of 12 BCI Laboratory Staff following LM-DNA Methods Revision-14. The amplification targets in these 12 single-source dilution series were 2, 1, .75, .5, .25, .15, .062, .03, and .015 ng.

A large number of known mixtures concentrated in the casework mixture target range were prepared from the same 12 extracts to assess peak height ratios at all loci and at various input levels. Mixtures were created from previously IQ-extracted buccal swabs of BCI Laboratory Staff. Three versions of each mixture were created: low-, medium-, and high-allele overlap. Each mixture set was then diluted to produce a range of total DNA targets from 2.0 to 0.125 ng.

Single-source and mixture dilutions then underwent quantitation, GlobalFiler amplification, ABI 3500 CE and Genemapper ID-X v.1.4 analysis in accordance to LM-DNA Methods Revision-23. Peak height data was imported into AX.

The 225 mixtures created for the study were designed to approximate scenarios commonly encountered in casework. Duplicates of some of the lower target mixtures were made to better capture stochastic events. All samples were amplified in duplicate.

		Total DNA Amplified (ng)					
People	**Ratios**	**2.0**	**1.0**	**0.75**	**0.5**	**0.25**	**0.125**
2	**8 to 1**	3	3	3	6	6	6
	4 to 1	3	3	3	6	6	6
	2 to 1	3	3	3	3	3	3
3	**10 to 5 to 1**	3	3	3	6	6	6
	10 to 1 to 1	3	3	3	3	3	3
	5 to 5 to 1	3	3	3	6	6	6
	5 to 1 to 1	3	3	3	6	6	6
	3 to 2 to 1	3	3	3	3	3	3
	2 to 1 to 1	3	3	3	3	3	3
	1 to 1 to 1	3	3	3	3	3	3

5. Data Analysis--Heterozygote (HT) AX plug-in.

(Supporting documentation 5)

The HT macro associated with the earlier AX version was used to examine allele drop-out at heterozygous loci in a dilution series of the 12 single source samples. The dilutions (0.75, 0.5, 0.25, 0.125ng) were compared to the 1.0 ng full profile.

In processing the dilution series data, the HT macro compares diluted samples to the known full profile. Where a locus is heterozygous, and one of the heterozygote sister alleles is at or below the established 100 RFU analytical threshold, that occurrence is counted. The RFU of the remaining sister allele is recorded and averaged for each locus. Finally, the standard deviations are calculated. The result is indicative of the RFU level below which loss of a heterozygote sister allele is possible.

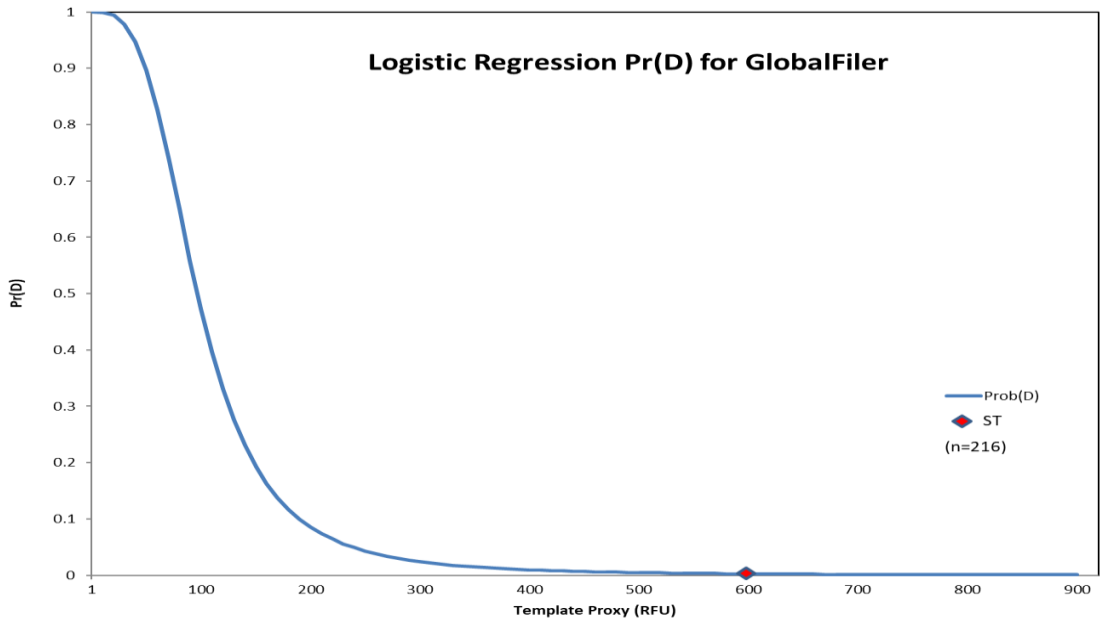
Locus	Drop-out obs	Ave RFU sister allele	Lowest sister	Highest sister	Std Dev	Avg+ 3SD
D3S1358	24	218	103	610	126	597
vWA	18	195	116	314	48	339
D16S539	11	158	103	258	59	336
CSF1PO	17	150	102	238	33	250
TPOX	12	179	106	290	69	386
AMEL	15	245	103	548	123	614
D8S1179	17	195	109	322	60	376
D21S11	30	229	106	836	167	731
D18S51	20	218	103	610	112	554
D2S441	20	183	100	303	66	380
D19S433	15	136	100	219	34	237
TH01	26	221	104	655	134	623
FGA	21	161	102	249	38	275
D22S1045	18	194	110	446	101	497
D5S818	20	213	103	404	84	465
D13S317	11	162	105	270	52	316
D7S820	21	200	102	328	71	413
SE33	32	192	104	326	65	388
D10S1248	14	275	108	**851**	237	987
D1S1656	16	203	110	440	100	504
D12S391	30	172	100	322	52	328
D2S1338	29	293	100	820	209	921
Global	437	201	100	851	118	**554**

Summary from AX Heterozygote macro. AX HT data for 12 single-source samples ranging from 0.062 to 0.015 ng. Count is the total number of dropped alleles observed in the data set.

6. Data Analysis--Logistic Regression Curve

(Supporting documentation 6)

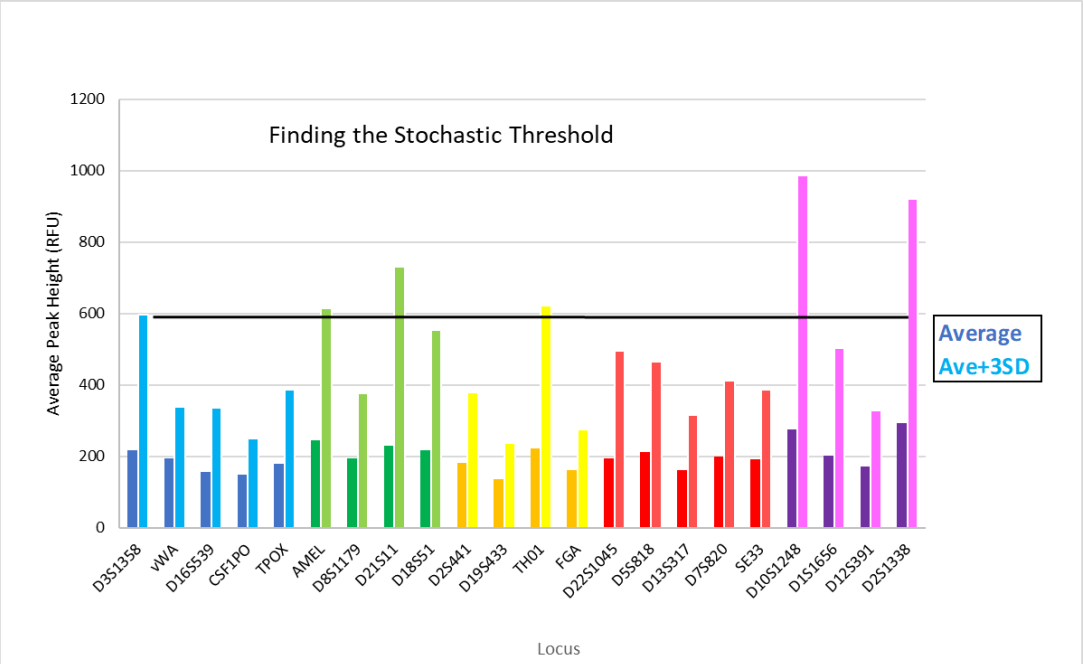
The AX software also contains a beta calculator plug-in that, using the same data, draws the logistic regression curve for the probability of allelic dropout and thus can be used to inform a decision on where to place the stochastic threshold.



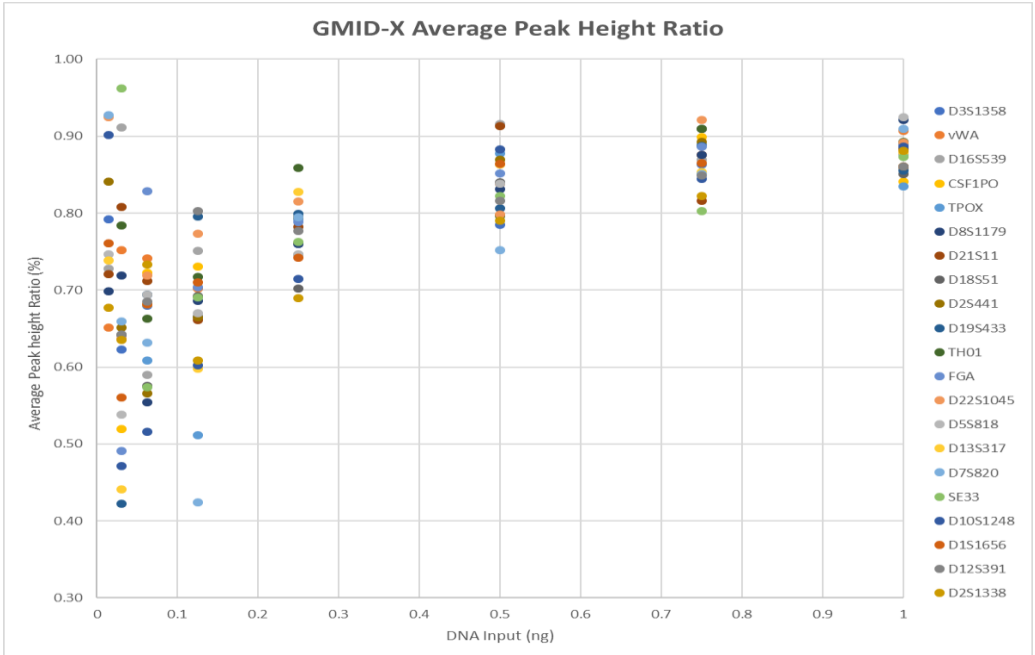
Logistic regression curve indicates the probability that one peak from a heterozygous pair will drop out or fall below the analytical threshold at various RFU levels. At 600 RFU, virtually no dropout is expected in these known mixtures. At 300, the probability of dropout is about 0.03.

7. Data Analysis—peak height ratios.

(Supporting documentation 7)



Visual display of average stochastic thresholds at each locus for single-source known dilution series. The expanded data set captures a greater range of variation than previous work.

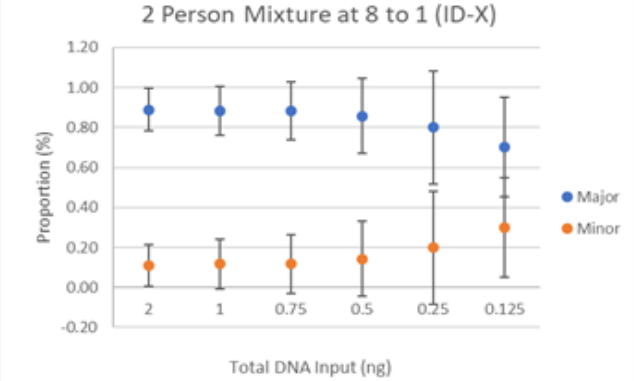


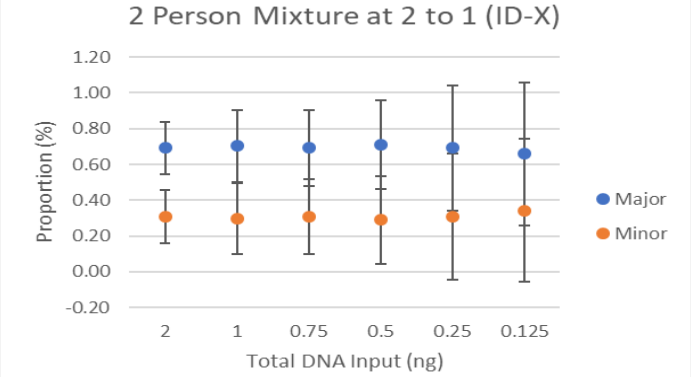
A plot of heterozygote peak height ratios shows less heterozygote peak imbalance at higher amplification targets. Contributors behave according to their own individual target.

8. Data Analysis - Overlapping peak height ranges and proportion windows

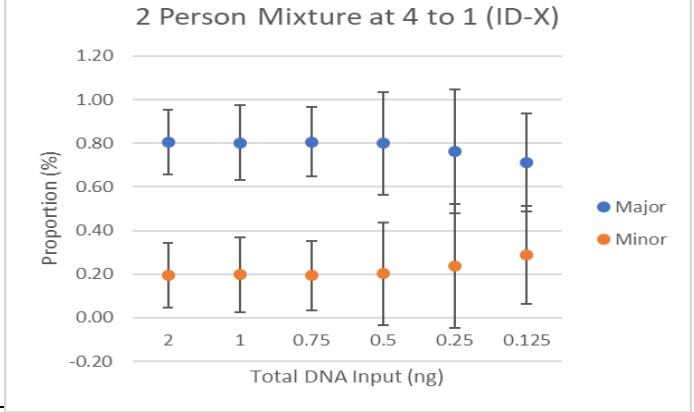
(Supporting documentation 8)

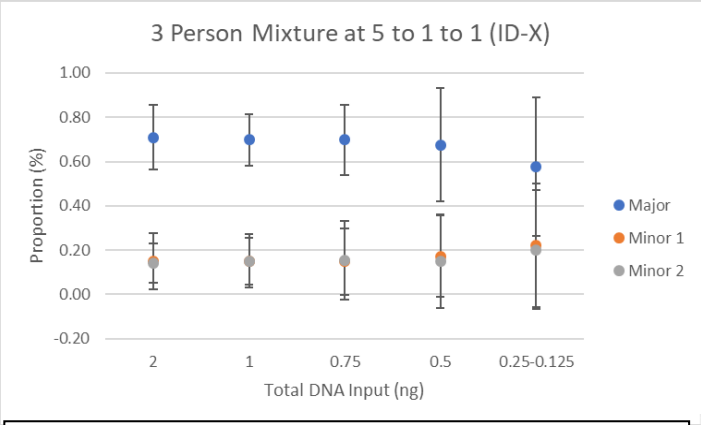
Successful deconvolution of 2-person mixtures is dependent on both the input of each contributor and the ratios of the two contributors. As shown above, heterozygote peak height imbalance becomes greater at lower DNA inputs. In the test samples, the ratios between the heterozygote peak heights of the major contributor and between the lowest peak of the major contributor and the highest peak of the minor contributor were plotted. Where the standard deviation ranges overlap, it becomes more difficult to successfully chose the correct sister alleles. RMP calculations, which permit the inclusion of multiple genotype options, permit the interpretation of some loci with overlapping contributors.

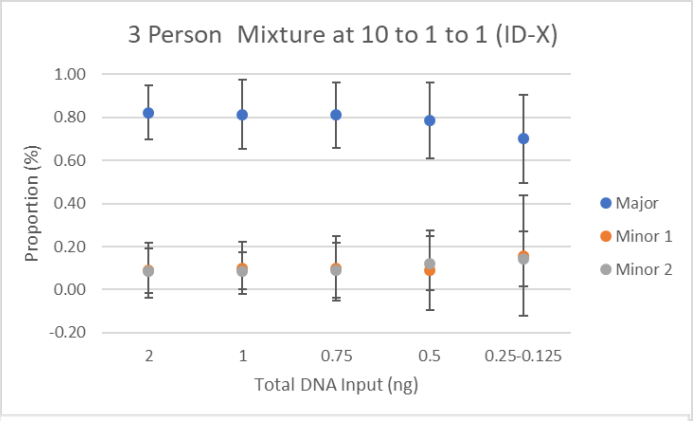




2-contributor whisker plots. Major contributors can be deconvoluted down to 0.25 ng at 8 to 1 and 0.5 ng at 4 to 1. In many cases, 2 to 1 mixtures cannot be deconvoluted based only on peak height differences.

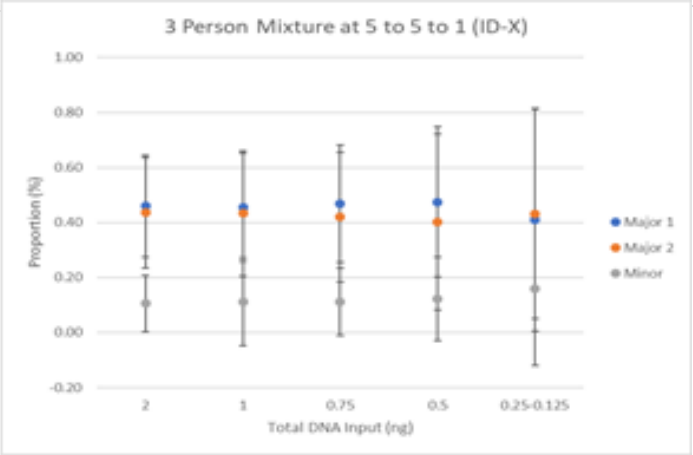


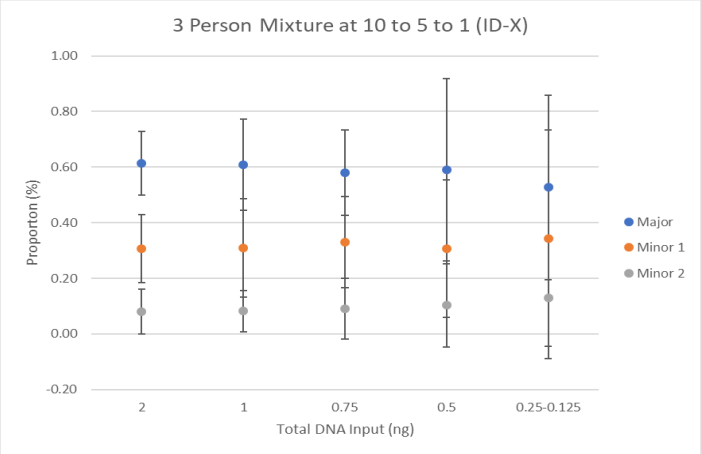




3-contributor whisker plots. Single-contributor major profiles are more likely to be deconvoluted than 2-contributor major profiles.

Deconvolution of 3-persom mixtures is limited to isolation of the major contributor or the 2-person major contributor mixture.





The first step in deconvoluting a 2- or 3-person mixture is to use heterozygous loci to estimate the proportions of each contributor. AX then presents possible allele combinations based on user-defined settings. The user then chooses the best combination of alleles based on the contributor proportions window and other factors.
There is some variability in the observed proportions in known data. An analysis of the mixture samples was used to characterize proportion variability across loci. Based on this data, two loci from the same electropherogram, for example, may exhibit proportions ranging from 80:20 down to 60:40, respectively. Therefore, a proportion window of +/-.20 or (20%) was chosen to describe the amount of contributor proportion variation that should be allowed as acceptable possible genotype combinations

9. Initial Check of AX Functionality and Reliability. **(Supporting documentation 9)**

Analysis of 2- and 3-contributor electropherograms was performed by AW and KD to confirm the utility of AX's user-determined parameters in combination with the mixture interpretation guidelines present in LM-DNA Methods Revision-24. Both arrived at the same overall conclusions for the profiles, however there were some differences in the loci chosen for interpretation or in the reasons for not interpreting a locus.

To improve consistency, an illustrated interpretation reference guide was created during a review of these differences.

(Supporting documentation Appendix B)

10. Verification of system using additional electropherograms **(Supporting documentation 10)**

Electropherograms from 36 2-person mixtures and 14 3-person mixtures which were not part of the data set used for this study were analyzed using AX. For the profiles that could be deconvoluted, the proper genotypes were selected by both AW and KD.

11. Conclusions

The use of AX permitted the interpretation of electropherograms that normally would not be interpretable and permitted the calculation of more powerful statistics. This benefit was achieved through being able to consider number of contributors (mRMP) and peak height differences (rRMP) in selecting which genotypes to include in the calculations.

The AX software calculation functions have been shown to produce results identical to those obtained from Popstats. Where additional AX functions are not supported in Popstats, manual calculations were used to confirm that AX was following the expected process. When used together with laboratory profile interpretation guidelines, AX has been shown to improve our ability to interpret 2-and 3-person mixtures and is sufficient to be used in casework.

Additional Validation A performance check and functional testing will be required for the Richfield lab, where the same network version of AX will be accessed. A function test and performance check will be required for any minor software upgrades.

Limitations The use of AX is limited to 1-,2-, and 3-person mixtures. AX is a calculation aid and so the user is responsible for using it within the interpretation parameters established in the methods manual.

Reference and Reading Materials

1. BCI GlobalFiler Internal Validation Study (2015)
2. BCI DNA Methods Manual LM-DNA Methods Revision-24
3. Interpretation Guidelines for Autosomal STR Typing by Forensic DNA Testing Laboratories (2017).
4. Validation Guidelines for DNA Analysis Methods (2012)
5. ArmedXpert™ User Manual Software version 3.0.x Rev. 471.
6. Quality Assurance Standards (QAS) Standards for Forensic DNA Testing Laboratories (2020)
7. Mathematics in DNA Data Analysis: An Excel 2003 VBA Application. Overson (2007)
8. Estimating the probability of allelic drop-out of STR alleles in forensic genetics. Tvedebrink, et. al. Forensic Science International: genetics 3 (2009) 222-226.
9. ANSI/ASB Standard 020 First Edition 2018

Appendix A Application of AX--Statistical benefits of the RMP

(Supporting documentation Appendix A)

Below is an example of a single source casework-like sample where additional loci are used to calculate an RMP in ArmedXpert™ compared to Popstats. Twenty loci are used instead of ten because of the software's ability to account for allelic drop-out using a modified RMP approach. It considers both the homozygote and heterozygote genotypes for the "dropped" allele.

Locus	LGS 3	Genotype	Popstats Calculation	Frequency	Genotype	ArmedXpert Calculation	Frequency
D3S1358	16,18	16,18	2pq	0.0363	16,18	2pq	0.0363
vWA	17				17,Any	$2p(1-p)+p^2(1-p)\theta$	0.4172
D16S539	11				11,Any	$2p(1-p)+p^2(1-p)\theta$	0.5320
CSF1PO	10				10,Any	$2p(1-p)+p^2(1-p)\theta$	0.4394
TPOX	12				12,Any	$2p(1-p)+p^2(1-p)\theta$	0.0524
AMEL	X						
D8S1179	12				12,Any	$2p(1-p)+p^2(1-p)\theta$	0.2444
D21S11	30.2,31.2	30.2,31.2	2pq	0.0018	30.2,31.2	2pq	0.0018
D18S51	13				13,Any	$2p(1-p)+p^2(1-p)\theta$	0.0805
DYS391	ND						
D2S441	10,14	10,14	2pq	0.0454	10,14	2pq	0.0454
D19S433	14,15	14,15	2pq	0.0338	14,15	2pq	0.0338
TH01	6,9.3	6,9.3	2pq	0.0254	6,9.3	2pq	0.0254
FGA	20,21	20,21	2pq	0.0133	20,21	2pq	0.0133
D22S1045	15				15,Any	$2p(1-p)+p^2(1-p)\theta$	0.0651
D5S818	12				12,Any	$2p(1-p)+p^2(1-p)\theta$	0.6034
D13S317	8,13	8,13	2pq	0.0078	8,13	2pq	0.0078
D7S820	8				8,Any	$2p(1-p)+p^2(1-p)\theta$	0.4059
SE33	ND						
D10S1248	13,16	13,16	2pq	0.0410	13,16	2pq	0.0410
D1S1656	11,15.3	11,15.3	2pq	0.0026	11,15.3	2pq	0.0026
D12S391	19,21	19,21	2pq	0.0190	19,21	2pq	0.0009
D2S1338	24				24,Any	$2p(1-p)+p^2(1-p)\theta$	0.1604
Total (African-American Population)				1.8420E+18			1.4489E+26

Single source casework-like sample where additional loci can be used to calculate an RMP in AX compared to Popstats. The modified random match probability (mRMP) is used to account for dropped alleles (referred to as "Allele, Any") and incorporated into the overall probability. African-American population frequencies are used as an example.

Locus	KBS/AS Tube 50	Considered Genotypes	Popstats Calculation	Frequency	Considered Genotype	ArmedXpert Calculation	Frequency
D3S1358	14,15,17	All homs, all hets	$(p^2+p(1-p)\theta)+2pq+(q^2+q(1-q)\theta)+2pr+(r^2+r(1-r)\theta)+2qr$	0.3781	All homs, all hets	$(p^2+p(1-p)\theta)+2pq+(q^2+q(1-q)\theta)+2pr+(r^2+r(1-r)\theta)+2qr$	0.3781
vWA	15,16,17,18	All homs, all hets	$(p^2+p(1-p)\theta)+2pq+(q^2+q(1-q)\theta)+2pr+(r^2+r(1-r)\theta)+2qr+(s^2+s(1-s)\theta)+2ps+2qs+2rs$	0.6888	Hets. Only	2pq+2pr+2ps+2qr+2qs+2rs	0.5055
D16S539	8,9,12,14	All homs, all hets	$(p^2+p(1-p)\theta)+2pq+(q^2+q(1-q)\theta)+2pr+(r^2+r(1-r)\theta)+2qr+(s^2+s(1-s)\theta)+2ps+2qs+2rs$	0.2013	Hets. Only	2pq+2pr+2ps+2qr+2qs+2rs	0.1206
CSF1PO	10,11,12,13	All homs, all hets	$(p^2+p(1-p)\theta)+2pq+(q^2+q(1-q)\theta)+2pr+(r^2+r(1-r)\theta)+2qr+(s^2+s(1-s)\theta)+2ps+2qs+2rs$	0.7129	Hets. Only	2pq+2pr+2ps+2qr+2qs+2rs	0.4930
TPOX	8,10,11	All homs, all hets	$(p^2+p(1-p)\theta)+2pq+(q^2+q(1-q)\theta)+2pr+(r^2+r(1-r)\theta)+2qr$	0.4537	All homs, all hets	$(p^2+p(1-p)\theta)+2pq+(q^2+q(1-q)\theta)+2pr+(r^2+r(1-r)\theta)+2qr$	0.4537
Total (African-American Population)				58.99			193.96

Partial calculation comparison of the blue channel in a GlobalFiler® mixture profile for a 2-person mixture in Popstats and ArmedXpert™. The unrestricted random match probability (uRMP) approach and the assumption regarding the number of contributors limits the considered genotypes and allows for greater overall discrimination power. Further genotypic limitations could be considered depending upon the heights of the alleles observed at a given locus.

Appendix B AX Interpretation Guidelines

See (Supporting documentation Appendix B)

Appendix C Equipment, data and software used

Equipment, data and software used
GeneMapper® ID-X v1.4X
3500xl Genetic Analyzer
HT plug-in from ArmedXpert™
CODIS 8.0 Popstats
National Institute of Standards and Technology (NIST) Revised 1036 US Population Dataset
ArmedXpert™ v3.0.8.21, v3.0.8.27
Beta Calculator plug-in from ArmedXpert™

Appendix D FBI QAS 2020 reference

Definitions:

Functional testing is a process to confirm that a software performs the tasks as expected.

Reliability testing is the process of testing a software program beyond its functional aspects to ensure it works appropriately in the laboratory environment. This may include testing multi-user or multi-site scenarios, direct-access and network/server-access scenarios, and interaction with other software programs.

Sensitivity studies (for the purposes of Standard 8.8) are used to assess the ability of the system to reliably determine the presence of a contributor's DNA over a broad variety of evidentiary typing results (to include mixtures and low-level DNA quantities).

Specificity studies (for the purposes of Standard 8.8) are used to evaluate the ability of the system to provide reliable results over a broad variety of evidentiary typing results (to include mixtures and low-level DNA quantities).

8.8 Is new software or new modules of existing software and modifications to software evaluated to assess the suitability of the software for its intended use in the laboratory and to determine the necessity of validation studies or software testing? yes
a. Is the evaluation documented and does it include the determination of which studies will and will not be conducted? yes

8.8.2 Is new software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations subject to internal validation specific to the laboratory's intended use prior to implementation in forensic DNA analysis?

8.8.2.1 Do the internal software validation studies for new software or new modules of existing software used as a component of instrumentation include:
a. Functional testing? Section 9.
b. Reliability testing? Section 9.

8.8.2.2 Do the internal software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data include:

a. Functional testing? b. Reliability testing? Section 9.
c. Precision and accuracy studies (as applicable)? n/a
d. Sensitivity studies (as applicable) Section 4.
e. Specificity studies (as applicable)? n/a

8.8.2.3 Do the internal software validation studies for new software or new modules of existing software for statistical calculations include:
a. Functional testing? Section 9
b. Reliability testing? Section 9
c. Precision and accuracy studies (as applicable)? N/A

8.8.2.4 Does software that does not impact the analytical process, interpretation, or statistical calculations undergo, at a minimum, a functional test? N/A

8.8.4 For multi-laboratory systems:
a. Are the summaries of shared software validation and software testing data available at each site? DNAShare-network drive
b. Has each laboratory in a multi-laboratory system completed, documented, and maintained applicable site-specific reliability testing? DNAShare-network drive

8.8.5 Is all software validation and testing documented and reviewed and approved by the technical leader prior to implementation? Memorandum from DNA TL Lewis Maddox

8.9 Are developmental validation studies, internal validation studies, modified procedure evaluations, and software testing, including the documented approval of the technical leader, available for review? Yes, located on the DNAShare network drive