APPENDIX
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Page

FORENSIC BIOLOGY – SEXUAL OFFENSE EVIDENCE COLLECTION KIT INVENTORY		
DATE EFFECTIVE 01/06/2011	APPROVED BY Eugene Lien	PAGE 1 of 1

FB 11-035564 **Date** 6-17-2011 **Analyst** LMO

Voucher # R956175 **Subject** [redacted] kit sealed: (Y) N

kit was collected date 6/11-11 time 817-955 Am hospital Kings County

							Item number
oral swabs and smears	"no oral contact"	sealed: Y	(N)	not used	not submitted		—
number of swabs	—						
number of slides	—	**SPERM**: Y	N	not tested			
buccal specimen		sealed: (Y)	N	not used	not submitted		1A
trace evidence		sealed: Y	(N)	not used	not submitted		—
underwear		sealed: (Y)	N	not used	not submitted		1B
debris envelope		sealed: Y	(N)	not used	not submitted		—
Area(s) of body:							
Type of Debris:	hair	biological sample		unknown	other		
dried secretion		sealed: (Y)	N	not used	not submitted		1C1-1C2
location "perineum"							
number of swabs	2						
fingernail scrapings		sealed: Y	(N)	not used	not submitted		—
pulled head hairs		sealed: Y	(N)	not used	not submitted		—
pubic hair combings		sealed: (Y)	N	not used	not submitted		1D
pulled pubic hairs		sealed: Y	(N)	not used	not submitted		—
perianal and anal swabs & smears		sealed: (Y)	N	not used	not submitted		1E1-1E3
number of perianal swabs	2-1E1						
number of anal swabs	2-1E3	slide location: (perianal) / anal					
number of slides	1-1E2	**SPERM**: Y	N	not tested			
(vulvar) or penile swabs & smears		sealed: (Y)	N	not used	not submitted		1F1-1F2
number of swabs	4						
number of slides	1	**SPERM**: Y	N	not tested			
vaginal swabs and smears		sealed: (Y)	N	not used	not submitted		1G1-1G2
number of swabs	4	* note: hair-like fiber attached to one of vaginal swabs & will not be removed					
number of slides	1	**SPERM**: Y	N	not tested			
cervical swabs and smears		sealed: (Y)	N	not used	not submitted		1H1-1H2
number of swabs	4						
number of slides	1	**SPERM**: Y	N	not tested			
instruction sheet enclosed			Y (N)				
miscellaneous paperwork enclosed			Y (N)				

EXEMPLAR USED 1A ☑ First cutting sent to: 1D28 ☐ Second cutting sent to: _____ LdC

Initials: AGP Date: 6/29/11 Initials: _____ Date: _____

FORENSIC BIOLOGY – Clothing Description Worksheet		
DATE EFFECTIVE 4/26/2010	APPROVED BY Eugene Lien	PAGE 1 of 1

Case FB 11 . 03564 **Date** 6-17-11 **Analyst** UNO

Voucher R956175 **Item No.** 1B

Type of Item: T-shirt shirt pants shorts (underwear) jacket footwear other ______

Item information:

color and/or pattern: blue with navy blue trim

manufacturer: unknown size: unknown no label (label illegible)

fabric type (per label): ___ cotton ___ polyester ___ spandex ___ nylon ___ acrylic ___ wool ✓ unknown ___ other ______

fastener type(s): ___ buttons ___ zippers ___ snaps ___ hooks ___ velcro ___ laces ✓ none ___ other ______

fasteners intact: Y N (n/a) describe missing or damaged fastener(s) ______

fabric defects: Y (N) describe nature and location of defect(s)

KM Pos Control → Pos AP Pos Control → Pos

KM Neg Control → Neg AP Neg Control → Neg

KM Lot # 57 α NP Lot # 91

3% H_2O_2 Lot # 101390 Fast Blue Lot # 93

pocket contents: Y (no pockets) empty ______

stains: (Y) N describe nature and location of stain(s) two large stains fluorescent under the ALS - one on the inside crotch area + one on the inside back area. Both stains also have reddish-brown staining. Refer to diagrams

-underwear measures ~5½" x 12" (measured as "inches")

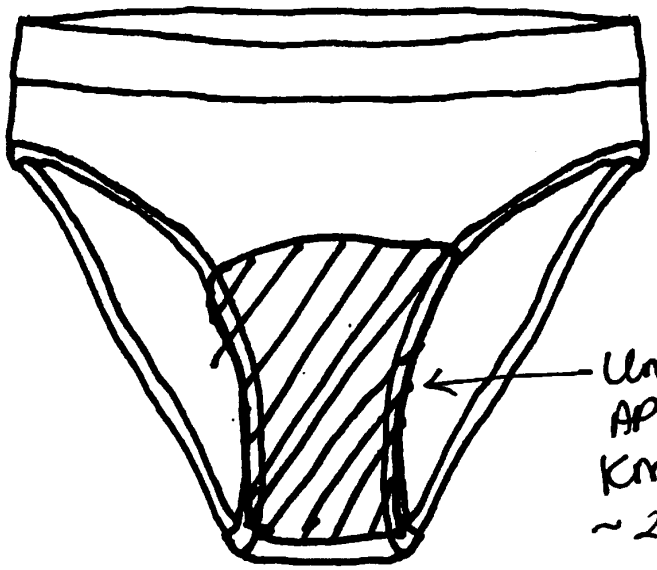
For stains that will have additional tests performed, use additional pages to document item through description, photographs and/or diagrams as needed.

Ldc

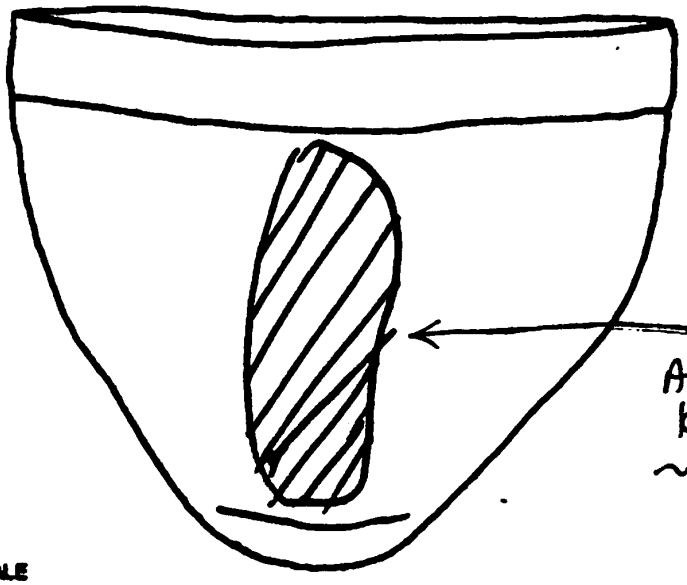
FB11-03564 dno

A2

INSIDE
FRONT



INSIDE
BACK



SKETCHES NOT TO SCALE

FBI#03564
R956175
Item 1B
Uno 6-1211

LDC

A3

FORENSIC BIOLOGY - M[redacted] EXTRACTION WORKSHEET - b[redacted]cal specimens and known bloodstains - EXEMPLARS

DATE EFFECTIVE	APPROVED BY	PAGE
10/21/2010	Eugene Lien	1 of 2

Buffer G2	1362464 75	Buffer MTL	139282150
QIAGEN Proteinase K	136264881	Buffer MW2	136258946
Sterile Water	200A	TE^{-4}	136
Ethanol (100%)	C0912022	MagAttract Suspension B	136255415
Buffer MW1	139281908		

Sample Rack Position	Tube Label	Case number-sample description	Target Date	IA
1	Neg1	extraction_negative_1_070511.0930	-	-
2	Neg2	extraction_negative_2_070511.0930	-	-
3	[redacted]	FB11-S0876 [redacted]	08/01/11	X
4	[redacted]	FB11-S0841 [redacted]	07/25/11	X
5	[redacted]	FB11-03635 [redacted]	08/23/11	LMO
6	[redacted]	FB11-00401 [redacted]	07/18/11	MWM
7	[redacted]	FB11-03745 [redacted]	07/20/11	LV
8	[redacted]	FB11-03745 [redacted]	07/20/11	LV
9	[redacted]	FB11-03717 [redacted]	07/13/11	LV
10	[redacted]	FB11-03715 [redacted]	07/10/11	LV
11	[redacted]	FB11-03715 [redacted]	07/10/11	LV
12	[redacted]	FB11-03715 [redacted]	07/10/11	LV
13	[redacted]	FB11-03665 [redacted]	07/27/11	RMM
14	[redacted]	FB11-02781 [redacted]	07/26/11	VRW
15	[redacted]	FB11_03666 [redacted]	07/27/11	RMM
16	[redacted]	FB11-03304 [redacted]	07/13/11	RMM
17	[redacted]	FB11-03564 [redacted]	07/22/11	LDC
18	[redacted]	FB11-03563 [redacted]	07/23/11	LAD
19	[redacted]	FB11-03177 [redacted]	07/13/11	RCH
20	[redacted]	FB11-03546 [redacted]	07/20/11	CMK
21	[redacted]	FB11-03775 [redacted]	07/21/11	LV
22	[redacted]	FB11-03835 [redacted]	08/23/11	REB
23	[redacted]	FB11-03816 [redacted]	08/22/11	REB
24	[redacted]	FB11-03426 [redacted]	08/07/11	REB

Performed by: QTM Date: 7/5/11 Time: 10:52 M48 robot used: #1

Extraction Set: Date: 7/5/11 Time: 09:30

Amp System (please Circle one): (Identifiler) PowerPlex Y

LDC

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A4

FORENSIC BIOLOGY - M[redacted] EXTRACTION WORKSHEET - b[redacted]cal specimens and known bloodstains - EXEMPLARS

DATE EFFECTIVE
10/21/2010

APPROVED BY
Eugene Lien

Sample Rack Position	Tube Label	Case number-sample description	Target Date	IA
25	[redacted]	FB11-03426 [redacted]	08/07/11	REB
26	[redacted]	FB11-S0846 [redacted]	07/27/11	X
27	[redacted]	FB11-S0847 [redacted]	07/27/11	X
28	[redacted]	FB11-02325 [redacted]	07/20/11	JCK
29	[redacted]	FB11-S0848 [redacted]	07/25/11	X
30	[redacted]	FB11-S0849 [redacted]	07/28/11	X
31	[redacted]	FB11-S0850 [redacted]	07/28/11	X
32	[redacted]	FB11-S0851 [redacted]	07/28/11	X
33	[redacted]	FB11-S0852 [redacted]	07/28/11	X
34	[redacted]	FB11-03577 [redacted]	08/09/11	BAN
35	[redacted]	FB11-03675 [redacted]	08/16/11	MAH
36	[redacted]	FB11-03675 [redacted]	08/16/11	MAH
37	[redacted]	FB11-03493 [redacted]	08/09/11	BAN
38	[redacted]	FB11-03677 [redacted]	08/16/11	MAH
39	[redacted]	FB11-03783 [redacted]	07/22/11	LNB
40	[redacted]	FB11-03813 [redacted]	07/22/11	JSK
41	[redacted]	FB11-S0843 [redacted]	07/27/11	X
42	[redacted]	FB11-S0842 [redacted]	07/27/11	X
43	[redacted]	FB11-S0845 [redacted]	07/27/11	X
44	[redacted]	FB11-S0844 [redacted]	07/27/11	X
45	[redacted]	FB11-03804 [redacted]	08/22/11	REB
46	[redacted]	FB11-S0857 [redacted]	07/28/11	X
47	[redacted]	FB11-S0855 [redacted]	07/28/11	X
48	[redacted]	FB11-S0853 [redacted]	07/28/11	X

Performed by: SJM Date: 7/5/11 Time: 10:52 Tube Witnesses: Incubation VN

Extraction Set: Date: 7/5/11 Time: 09:30 Robot Set-Up VN

Amp System (please Circle one): (Identifiler) PowerPlex Y Sample in Cryobox: E884

FB11-03564 LdC

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Forensic Biology - Rotorgene Data Collection		
DATE EFFECTIVE 6/2/2010	APPROVED BY Eugene Lien	PAGE 1 of 2

Run Name: RG13Q070511.1530 **ANALYST: JLN**

Efficiency: 1.01159 **Supervisor: MA**

MA 7/06/11

Comments: threshold manually adjusted **Pass** **Fail**

Well No.	A	Tube Label	Name	Ct	Calc Conc (pg/ul)	Target	IA	Comments
A4		-	400 pg/µL	12.21	**409.77**	-	-	
A5		-	100 pg/µL	14.3	**94.59**	-	-	
A7		-	25 pg/µL	16.35	**22.59**	-	-	
A8		-	25 pg/µL	16.22	**24.85**	-	-	
B1		-	6.25 pg/µL	18.09	**6.70**	-	-	
B2		-	6.25 pg/µL	18.11	**6.60**	-	-	
B3		-	1.56 pg/µL	20.15	**1.59**	-	-	
B4		-	1.56 pg/µL	19.95	**1.83**	-	-	
B5		-	0.39 pg/µL	22.25	**0.37**	-	-	
B6		-	0.39 pg/µL	22.31	**0.35**	-	-	
B7		-	0 pg/µL		**0.00**	-	-	**pass**
B8		-	calibrator a 250 pg/µL	13.3	**190.37**	-	-	**pass**
C1		-	calibrator b 250 pg/µL	13.26	**196.52**	-	-	**pass**
C2		-	calibrator c 250 pg/µL	12.83	**265.72**	-	-	**pass**
C3		-	FB11-03712_[redacted]0.1	22.25	**0.37**	8/20/11	MA	**
C4		-	FB11-03568_[redacted]0.01	13.65	**149.23**	8/14/11	SNP	
C5		-	FB11-S0830_[redacted],0.01	13.82	**132.55**	7/23/11	X	
C6		-	FB11-02498_[redacted]0.01	14.28	**96.10**	7/22/11	AR	
C7		-	FB11-S0832_[redacted]0.01	13.63	**151.75**	7/24/11	X	
C8		-	FB10-S0956_[redacted]0.01	14.18	**103.38**	7/24/11	X	
D1		-	extraction_negative_1_070511.0930	27.81	**0.01**	-	-	
D2		-	FB11-S0876_[redacted],0.1	13.78	**136.04**	8/1/11	X	
D3		-	FB11-S0841_[redacted]0.1	13.45	**171.66**	7/25/11	X	
D4		-	FB11-03635_[redacted]0.1	13.63	**151.28**	8/23/11	LMO	
D5		-	FB11-00401_[redacted]0.1	13.31	**189.64**	7/18/11	MWM	
D6		-	FB11-03745_[redacted],0.1	10.95	**987.32**	7/20/11	LV	
D7		-	FB11-03745_[redacted]0.1	12.3	**383.46**	7/20/11	LV	
D8		-	FB11-03717_[redacted]0.1	13.16	**211.11**	7/13/11	LV	
E1		-	FB11-03715_[redacted]0.1	12.58	**315.01**	7/10/11	LV	
E2		-	FB11-03715_[redacted]0.1	13.39	**179.52**	7/10/11	LV	
E3		-	FB11-03715_[redacted],0.1	14.69	**72.31**	7/10/11	LV	
E4		-	FB11-03665_[redacted]0.1	12.39	**361.65**	7/27/11	RMM	
E5		-	FB11-02781_[redacted]0.1	14.57	**78.38**	7/26/11	VRW	
E6		-	FB11_03666_[redacted]0.1	13.18	**207.56**	7/27/11	RMM	

Comments: **RQ = Samples that require requantitation**

*** = Sample exhibits background fluorescence**

**** = Sample exhibits low background fluorescence**

Δ = Sample quantitation inhibited

A = Distribute to analyst

M = Submitted to Auto-Microcon

FB11-03564
LDC

Forensic Biology - Rotorgene Data Collection		
DATE EFFECTIVE 6/2/2010	APPROVED BY Eugene Lien	PAGE 2 OF 2

Run Name: RG13Q070511.1530 **ANALYST: JLN** 07/06/11

No.	A	Tube Label	Name	Ct	Calc Conc (pg/ul)	Target	IA	Comments
E7		-	FB11-03304[redacted]0.1	15.37	**44.87**	7/13/11	RMM	
E8		-	FB11-03564[redacted]0.1	13.49	**166.54**	7/22/11	LDC	
F1		-	FB11-03563[redacted]0.1	14.38	**89.80**	7/23/11	LAD	
F2		-	FB11-03177[redacted]0.1	13.16	**209.95**	7/13/11	RCH	
F3		-	FB11-03546[redacted]0.1	13.19	**205.56**	7/20/11	CMK	
F4		-	FB11-03775[redacted]0.1	13.31	**189.13**	7/21/11	LV	
F5		-	FB11-03835[redacted]0.1	12.52	**328.25**	8/23/11	REB	
F6		-	FB11-03816[redacted]0.1	11.25	**797.23**	8/22/11	REB	
F7		-	FB11-03426[redacted]0.1	13.32	**188.09**	8/7/11	REB	
F8		-	FB11-03426[redacted]0.1	13.23	**200.14**	8/7/11	REB	
G1		-	FB11-S0846[redacted]0.1	14.74	**69.91**	7/27/11	X	
G2		-	FB11-S0847[redacted]0.1	11.39	**724.19**	7/27/11	X	
G3		-	FB11-02325[redacted]0.1	13.15	**211.53**	7/20/11	JCK	
G4		-	FB11-S0848[redacted]0.1	11.46	**688.35**	7/25/11	X	
G5		-	FB11-S0849[redacted]0.1	12.39	**361.32**	7/28/11	X	
G6		-	FB11-S0850[redacted]0.1	11.6	**625.40**	7/28/11	X	
G7		-	FB11-S0851[redacted]0.1	13.33	**186.66**	7/28/11	X	
G8		-	FB11-S0852[redacted]0.1	13.99	**117.88**	7/28/11	X	
H1		-	FB11-03577[redacted]0.1	14.28	**96.09**	8/9/11	BAN	
H2		-	FB11-03675[redacted]0.1	13.09	**221.70**	8/16/11	MAH	
H3		-	FB11-03675[redacted]0.1	12.17	**420.15**	8/16/11	MAH	
H4		-	FB11-03493[redacted]0.1	14.94	**60.79**	8/9/11	BAN	
H5		-	FB11-03677[redacted]0.1	13.38	**180.99**	8/16/11	MAH	
H6		-	FB11-03783[redacted]0.1	13.26	**196.63**	7/22/11	LNB	
H7		-	FB11-03813[redacted]0.1	12.39	**360.27**	7/22/11	JSK	
H8		-	FB11-S0843[redacted]0.1	11.25	**802.16**	7/27/11	X	
I1		-	FB11-S0842[redacted]0.1	10.63	**1231.40**	7/27/11	X	**RQ**
I2		-	FB11-S0845[redacted]0.1	12.6	**311.24**	7/27/11	X	
I3		-	FB11-S0844[redacted]0.1	11.34	**753.32**	7/27/11	X	
I4		-	FB11-03804[redacted]0.1	14.43	**86.62**	8/22/11	REB	
I5		-	FB11-S0857[redacted]0.1	12.15	**424.90**	7/28/11	X	
I6		-	FB11-S0855[redacted]0.1	10.48	**1368.93**	7/28/11	X	**RQ**
I7		-	FB11-S0853[redacted]0.1	17.46	**10.40**	7/28/11	X	

Comments: **RQ = Samples that require requantitation**
*** = Sample exhibits background fluorescence**
**** = Sample exhibits low background fluorescence**
Δ = Sample quantitation inhibited
A = Distribute to analyst
M = Submitted to Auto-Microcon

LdC

Forensic Biology - Identifiler 28 Amplification Sheet - EXEMPLARS

DATE EFFECTIVE	APPROVED BY	PAGE
4/21/2011	Eugene Lien	1 of 1

Amp:	070611.1030
Sample #	30
TC#	7146-TC8
3130 Run:	Stripes 11-112 DA

Reviewer: MA
Analyst: SJM 7/6/11
Witness: JW

Reagent	Lot No	n=1	n=?
ID primers	1102080	2.5	83
Reaction Mixture	1911192	5.0	165
ABI Taq Gold	N170609	0.5	16.5
master mix total	---	8.0	264
Stratalinked water	119	-	-
ABI Pos Cont 100pg/µL	1101079	5 µl of 1/2 dil	

Label	Sample Description	pg/µl	dil	DNA	H2O	IA
PCS	Positive_control_070611.1030	100.00	0.50	5.0	0.0	-
ANS	Amplification_negative_070611.1030	0.00	1.00	0.0	5.0	-
ENS	extraction_negative_1_070511.0930	0.01	1.00	5.0	0.0	-
[redacted]	FB11-S0876_[redacted]	1360.40	0.2	1.8	3.2	X
[redacted]	FB11-S0841_[redacted]	1716.60	0.2	1.5	3.5	X
[redacted]	FB11-03635_[redacted]	1512.80	0.2	1.7	3.3	LMO
[redacted]	FB11-00401_[redacted]	1896.40	0.2	1.3	3.7	MWM
[redacted]	FB11-03745_[redacted]	9873.20	0.05	1.0	4.0	LV
[redacted]	FB11-03745_[redacted]	3834.60	0.05	2.6	2.4	LV
[redacted]	FB11-03717_[redacted]	2111.10	0.2	1.2	3.8	LV
[redacted]	FB11-03715_[redacted]	3150.10	0.05	3.2	1.8	LV
[redacted]	FB11-03715_[redacted]	1795.20	0.2	1.4	3.6	LV
[redacted]	FB11-03715_[redacted]	723.10	0.2	3.5	1.5	LV
[redacted]	FB11-03665_[redacted]	3616.50	0.05	2.8	2.2	RMM
[redacted]	FB11-02781_[redacted]	783.80	0.2	3.2	1.8	VRW
[redacted]	FB11_03666_[redacted]	2075.60	0.2	1.2	3.8	RMM
[redacted]	FB11-03304_[redacted]	448.70	1.00	1.1	3.9	RMM
[redacted]	FB11-03564_[redacted]	1665.40	0.2	1.5	3.5	LDC
[redacted]	FB11-03563_[redacted]	898.00	0.2	2.8	2.2	LAD
[redacted]	FB11-03177_[redacted]	2099.50	0.2	1.2	3.8	RCH
[redacted]	FB11-03546_[redacted]	2055.60	0.2	1.2	3.8	CMK
[redacted]	FB11-03775_[redacted]	1891.30	0.2	1.3	3.7	LV
[redacted]	FB11-03835_[redacted]	3282.50	0.05	3.0	2.0	REB
[redacted]	FB11-03816_[redacted]	7972.30	0.05	1.3	3.7	REB
[redacted]	FB11-03426_[redacted]	1880.90	0.2	1.3	3.7	REB
[redacted]	FB11-03426_[redacted]	2001.40	0.2	1.2	3.8	REB
[redacted]	FB11-S0846_[redacted]	699.10	0.2	3.6	1.4	X
[redacted]	FB11-S0847_[redacted]	7241.90	0.05	1.4	3.6	X
[redacted]	FB11-02325_[redacted]	2115.30	0.2	1.2	3.8	JCK
[redacted]	FB11-S0848_[redacted]	6883.50	0.05	1.5	3.5	X

* eneg run separately

LDC

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Forensic Biology - 3130xl Capillary Electrophoresis Sample Sheet

DATE EFFECTIVE	APPROVED BY	PAGE
4/21/2011	Eugene Lien	1 of 2

SAMPLE SHEET: Stripes11-112ID

ID AL: 0907017 **POP4:** 1103079

PPY AL: — **HIDI:** 10039341

LIZ 500: 1101126 **ILS 600:** —

Comments: _____ **MiniFiler AL:** —

Prepared by: JLN 7/6/11 **Run Set Up:** JLN 7/6/11

Plate set up: JLN 7/6/11 **Witness:** SBL

Buffer: 1003355 **Date:** 07/06/11

Injection Numbers: 0113 to 0118

Rerun Legend: # = bad size std, Δ = to confirm off ladder, dil = rerun at a dilution **Original run filed with:** Stripes11 112 IDA

Well	Sample	Tube Label	Case Number-Description	SYS	TYPE	IA	Comments
A1	01-	AL1	Allelic_Ladder_1	I	AL	-	
B1	02-	PCS	Positive_control_070611.1030	I	PC	-	
C1	03-	ANS	Amplification_negative_070611.1030	I	NC	-	
D1	04-	ENS	extraction_negative_1_070511.0930	I	NC	-	
E1	05-	[redacted]	FB11-S0876	I	S	X	
F1	06-	[redacted]	FB11-S0841	I	S	X	
G1	07-	[redacted]	FB11-03635	I	S	LMO	
H1	08-	[redacted]	FB11-00401	I	S	MWM	
A2	09-	[redacted]	FB11-03745	I	S	LV	
B2	10-	[redacted]	FB11-03745	I	S	LV	
C2	11-	[redacted]	FB11-03717	I	S	LV	
D2	12-	[redacted]	FB11-03715	I	S	LV	
E2	13-	[redacted]	FB11-03715	I	S	LV	
F2	14-	[redacted]	FB11-03715	I	S	LV	
G2	15-	[redacted]	FB11-03665	I	S	RMM	
H2	16-	[redacted]	FB11-02781	I	S	VRW	
A3	17-	[redacted]	Allelic_Ladder_2	I	AL	-	
B3	18-	[redacted]	FB11_03666	I	S	RMM	
C3	19-	[redacted]	FB11-03304	I	S	RMM	
D3	20-	[redacted]	FB11-03564	I	S	LDC	
E3	21-	[redacted]	FB11-03563	I	S	LAD	
F3	22-	[redacted]	FB11-03177	I	S	RCH	
G3	23-	[redacted]	FB11-03546	I	S	CMK	
H3	24-	[redacted]	FB11-03775	I	S	LV	
A4	25-	[redacted]	FB11-03835	I	S	REB	
B4	26-	[redacted]	FB11-03816	I	S	REB	
C4	27-	[redacted]	FB11-03426	I	S	REB	
D4	28-	[redacted]	FB11-03426	I	S	REB	
E4	29-	[redacted]	FB11-S0846	I	S	X	
F4	30-	[redacted]	FB11-S0847	I	S	X	
G4	31-	[redacted]	FB11-02325	I	S	JCK	
H4	32-	[redacted]	FB11-S0848	I	S	X	
A5	33-	AL3	Allelic_Ladder_3	I	AL	-	
B5	34-	PC1045	Positive_control_070611.1045	I	PC	-	
C5	35-	AN1045	Amplification_negative_070611.1045	I	NC	-	
D5	36-	EN1400	extraction_negative_1_062911.1400	I	NC	-	
E5	37-	[redacted]	FB11-03502	I	S	LNB	
F5	38-	[redacted]	FB11-03612	I	S	LNB	
G5	39-	[redacted]	FB11-03703	I	S	LNB	
H5	40-	[redacted]	FB11-03723	I	S	LNB	
A6	41-	[redacted]	FB11-03698	I	S	SSM	
B6	42-	[redacted]	FB11-03568	I	S	SNP	
C6	43-	[redacted]	FB11-03634	I	S	SNP	
D6	44-	[redacted]	FB11-03634	I	S	SNP	
E6	45-	[redacted]	FB11-00821	I	S	RDC	
F6	46-	[redacted]	FB10-08602	I	S	AGP	
G6	47-	[redacted]	FB11-03464	I	S	JSL	
H6	48-	[redacted]	FB11-S0663	I	S	X	

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LDC

Forensic Biology - 3130xl Capillary Electrophoresis Sample Sheet		
DATE EFFECTIVE 4/21/2011	APPROVED BY Eugene Lien	PAGE 2 OF 2

SAMPLE SHEET: Stripes11-112ID **Plate Set Up:** JLN

Rerun Legend: # = bad size std, Δ = to confirm off ladder, dil = rerun at a dilution

Well	Sample	Tube Label	Case Number-Description	SYS	TYPE	IA	Comments
A7	49-	AL4	Allelic_Ladder_4	I	AL	-	
B7	50-	[redacted]	FB11-03821	I	S	MA	
C7	51-	[redacted]	FB11-03821	I	S	MA	
D7	52-	[redacted]	FB11-S0826	I	S	X	
E7	53-	[redacted]	FB11-S0830	I	S	X	
F7	54-	[redacted]	FB11-S0831	I	S	X	
G7	55-	[redacted]	FB11-S0828	I	S	X	
H7	56-	[redacted]	FB11-03474	I	S	KH	
A8	57-	[redacted]	FB11-03735	I	S	KH	
B8	58-	[redacted]	FB11-03485	I	S	KAS	
C8	59-	[redacted]	FB11-03485	I	S	KAS	
D8	60-	[redacted]	FB11-03485	I	S	KAS	
E8	61-	[redacted]	FB11-03485	I	S	KAS	
F8	62-	[redacted]	FB11-03586	I	S	NNR	
G8	63-	[redacted]	FB11-03739	I	S	JSK	
H8	64-	[redacted]	FB11-03465	I	S	AMN	
A9	65-	AL5	Allelic_Ladder_5	I	AL	-	
B9	66-	PC50	Positive_control_070611.1050	I	PC	-	
C9	67-	AN50	Amplification_negative_070611.1050	I	NC	-	
D9	68-	[redacted]	FB11-02498	I	S	AR	
E9	69-	[redacted]	FB11-03540	I	S	MFK	
F9	70-	[redacted]	FB11-03550	I	S	MFK	
G9	71-	[redacted]	FB11-02709	I	S	MB	
H9	72-	[redacted]	FB11-01059	I	S	CS	
A10	73-	[redacted]	FB11-03560	I	S	VRW	
B10	74-	[redacted]	FB11-03625	I	S	VRW	
C10	75-	[redacted]	FB11-S0832	I	S	X	
D10	76-	[redacted]	FB11-S0833	I	S	X	
E10	77-	[redacted]	FB11-S0835	I	S	X	
F10	78-	[redacted]	FB10-S0956	I	S	X	
G10	79-	[redacted]	FB11-S0836	I	S	X	
H10	80-	[redacted]	FB11-S0838	I	S	X	
A11	81-	[redacted]	Allelic_Ladder_6	I	AL	-	
B11	82-	[redacted]	FB11-S0839	I	S	X	
C11	83-	[redacted]	FB11-S0837	I	S	X	
D11	84-	[redacted]	FB11-S0834	I	S	X	
E11	85-	[redacted]	FB11-03746	I	S	LV	
F11	86-	[redacted]	FB11-03746	I	S	LV	
G11	87-	[redacted]	FB11-03744	I	S	LV	
H11	88-						
A12	89-						
B12	90-						
C12	91-						
D12	92-						
E12	93-						
F12	94-						
G12	95-						
H12	96-						

FB11-03564 LdC

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A10

Forensic Biology - STR 3130xl Control Review Worksheet		
DATE EFFECTIVE 4/21/2011	APPROVED BY Eugene Lien	PAGE 1 of 1

Run Name: Stripes11-112IDA

Analyst: FR FR Date: 7/7/2011 EN Database Entry : ☑ N/A: ☐

Reviewer: BHA Date: 7/7/11 EN Database Check : ☑ N/A: ☐

Control Type	Date and time	Pass or Fail	Comment	Resolution
Allelic Ladder	n/a	Pass		
Positive Control	070611.1030	Pass		
Amplification Negative	070611.1030	Pass		
Extraction Negative 1	070511.0930	Pass		

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DATE: June 22, 2011

LABORATORY REPORT

VICTIM: [redacted]

LAB NO: FB11-03564

COMPLAINT NO: 2011-077-04384

START DATE: 6/17/2011

SUSPECT(S): [redacted] **NYSID NO(S):** [redacted] **ARREST NO(S):** [redacted]

RESULTS AND CONCLUSIONS:

Semen was found on the following item(s):

- condom from "inside garbage at 1660 Pacific St"
- underwear

Comparison could be done upon submission of a sample from a suspect and/or consensual partner. Comparison will require approximately 30 days.

Further testing could be done upon submission of additional evidence. Further analysis will require approximately 60 days.

Blood was presumptively found on the following item(s):

- underwear

No semen was found on the following item(s):

- cervical swabs and smear
- vaginal swabs and smear
- vulvar swabs and smear
- perianal swabs and smear
- anal swabs
- dried secretions swabs 1C1-1C2 from "perineum"

No amylase was found on the following items(s):

- cervical swabs and smear
- vaginal swabs and smear
- vulvar swabs and smear
- dried secretions swabs 1C1-1C2 from "perineum"

The following items were not examined:

- buccal specimen
- pubic hair combings

FB11-03564 [redacted]

EVIDENCE RECEIVED:

ITEM	VOUCHER	DATE RECEIVED	DESCRIPTION
1	R956175	6/13/2011	sexual assault kit from [redacted]
1A	"		buccal specimen
1B	"		underwear
1C1 – 1C2	"		dried secretions from "perineum"
1D	"		pubic hair combings
1E1 – 1E2	"		perianal swabs and smear
1E3	"		anal swabs
1F1 – 1F2	"		vulvar swabs and smear
1G1 – 1G2	"		vaginal swabs and smear
1H1 – 1H2	"		cervical swabs and smear
1	R956176	6/14/11	condom from "inside garbage at 1660 Pacific St"

DISPOSITION:

The following item(s) will be retained in the laboratory:

the buccal specimen from [redacted]

The remainder of the evidence will be returned to the OCME Evidence Unit.

Analyst: Mokleby
Lisa M. A. Mokleby
Criminalist II

Administrative Review Date: 6/28/11

Administrative Reviewer: SA

APPENDIX

Identification of Blood, Semen and Saliva:

The indication that human blood is present is based on a positive screening test for blood followed by the detection of human (primate) DNA. **Blood presumptively found** is based on a positive screening test for blood.

Semen has two components: the seminal plasma (which contains a protein called P30) and spermatozoa. Semen can be identified by detecting P30 and/or sperm.

The detection of an elevated level of **amylase** indicates, but does not conclusively establish, the presence of saliva. Sources of amylase may include (but are not limited to) saliva, vaginal secretions, and bacteria.

Background to DNA Testing

DNA (Deoxyribo-Nucleic Acid), the inherited genetic material found in cells, contains markers which can differ from person to person. **DNA testing** can determine these genetic markers and compare biological samples from different individuals.

Alternative forms of DNA markers are called **alleles**. Alleles are found at specific areas, or locations, of the DNA called **loci (singular, locus)**.

STR (short tandem repeat) loci contain alleles with a variable number of short repeating segments. Each STR allele can be described using a number which represents its number of repeats. A **DNA profile** is the series of numbers describing the DNA alleles found at an individual's STR DNA loci.

DNA Testing

DNA testing involves several steps, including DNA extraction, DNA quantitation, PCR/DNA amplification, and analysis of the resulting DNA alleles.

DNA extraction recovers DNA from biological samples such as blood, bone, hair, saliva, semen, and skin cells.

Differential extraction is designed to physically separate the DNA in epithelial cells from the DNA in sperm cells, in samples which potentially contain a mixture of sperm and other cell types. As a result, separate "epithelial cell," "sperm cell," and "swab (or substrate) remains" DNA fractions are generated. Incomplete separation can occur and fractions may contain both sperm DNA and epithelial cell DNA.

DNA quantitation measures the amount of DNA extracted from samples by using a technique called quantitative real time polymerase chain reaction (qRT-PCR). If sufficient DNA is detected, DNA amplification and analysis can be attempted.

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Official Website: http://www.nyc.gov/ocme

DATE: September 14, 2011

LABORATORY REPORT

VICTIM: [redacted]

LAB NO: FB11-03564

COMPLAINT NO: 2011-077-04384

START DATE: 6/22/2011

SUSPECT(S): [redacted] **NYSID NO(S):** [redacted] **ARREST NO(S):** [redacted]

ADDITIONAL REPORT

This is an additional report. For previous results, evidence received, and disposition, see report dated June 22, 2011.

RESULTS AND CONCLUSIONS:

PCR DNA testing was done, and there are results suitable for comparison.

DNA from two people was found, [redacted] and a male.

Further testing could be done upon submission of additional evidence. Further analysis will require approximately 60 days.

The DNA results in this case do not match any PCR (STR) DNA profiles in the OCME local database to date.

PCR DNA typing using the AmpFℓSTR® Identifiler® PCR Amplification Kit was done on the sample(s) listed below. A DNA profile from a male, **Male Donor A**, was determined. This DNA profile is not the same as that of [redacted] therefore, she is not the source of this DNA.

- sample 1A from condom "inside," sperm fraction

This DNA profile is expected to be found in approximately:
15 loci result (sample 1A from condom "inside," sperm fraction)
1 in greater than 6.80 trillion people

The DNA profile above is suitable for entry into the Combined DNA Index System (CODIS) and the OCME local DNA databank.

PCR DNA typing using the AmpFℓSTR® Identifiler® PCR Amplification Kit was done on the sample(s) listed below. A mixture of DNA from at least two people was found.

- sample 1A from condom "inside," epithelial fraction

The DNA profiles of the individual contributors to the mixture(s) were not determined. All of the alleles seen can be explained as a mixture of DNA from [redacted] **and Male Donor A.**

PCR DNA typing using the AmpFℓSTR® Identifiler® PCR Amplification Kit was done on the sample(s) listed below. A DNA profile was determined. Based on the random match probability for unrelated individuals, [redacted] **is the source of this DNA.**

- sample 1B from condom "outside," epithelial fraction
- sample 1B from condom "outside," swab remainder fraction

PCR DNA typing using the AmpFℓSTR® Identifiler® PCR Amplification Kit was done on the sample(s) listed below. A DNA profile was determined. This profile is the same as that of [redacted] therefore, she is the source of this DNA.

- underwear stain 1B1, substrate remainder fraction

PCR DNA typing using the AmpFℓSTR® Identifiler® PCR Amplification Kit was done on the sample(s) listed below. A DNA profile was determined. This profile is consistent with that of [redacted] therefore, she could be the source of this DNA.

- underwear stain 1B2, substrate remainder fraction

The DNA profile above is not suitable for entry into the Combined DNA Index System (CODIS) and the OCME local DNA databank.

The following sample(s) were extracted but PCR DNA typing was not performed:

- sample 1A from condom "inside," swab remainder fraction

Human DNA was found on the following sample(s); however it was insufficient for the PCR DNA testing listed in this report:

- sample 1B from condom "outside," sperm fraction
- underwear stain 1B1, epithelial fraction
- underwear stain 1B2, epithelial fraction

No human DNA suitable for STR testing was found on the following sample(s):

- underwear stain 1B1, sperm fraction
- underwear stain 1B2, sperm fraction

The following item was not examined:

- "blue denim pants"

FB11-03564 [redacted]

EVIDENCE RECEIVED:

ITEM	VOUCHER	DATE RECEIVED	DESCRIPTION
1	R956146	06/14/11	item "collected at Kings County Hospital" "blue denim pants"

DISPOSITION:

The following items will be retained in the laboratory:

DNA extracts from samples and controls tested

The remainder of the evidence will be returned to the OCME Evidence Unit.

Analyst: Lydia M. de Castro
Criminalist IV

Administrative Review Date: 9/29/14

Administrative Reviewer: AMM

APPENDIX

Identification of Blood, Semen and Saliva:

The indication that human blood is present is based on a positive screening test for blood followed by the detection of human (primate) DNA. **Blood presumptively found** is based on a positive screening test for blood.

Semen has two components: the seminal plasma (which contains a protein called P30) and spermatozoa. Semen can be identified by detecting P30 and/or sperm.

The detection of an elevated level of **amylase** indicates, but does not conclusively establish, the presence of saliva. Sources of amylase may include (but are not limited to) saliva, vaginal secretions, and bacteria.

Background to DNA Testing

DNA (Deoxyribo-Nucleic Acid), the inherited genetic material found in cells, contains markers which can differ from person to person. **DNA testing** can determine these genetic markers and compare biological samples from different individuals.

Alternative forms of DNA markers are called **alleles.** Alleles are found at specific areas, or locations, of the DNA called **loci** (singular, **locus**).

STR (short tandem repeat) loci contain alleles with a variable number of short repeating segments. Each STR allele can be described using a number which represents its number of repeats. A **DNA profile** is the series of numbers describing the DNA alleles found at an individual's STR DNA loci.

DNA Testing

DNA testing involves several steps, including DNA extraction, DNA quantitation, PCR/DNA amplification, and analysis of the resulting DNA alleles.

DNA extraction recovers DNA from biological samples such as blood, bone, hair, saliva, semen, and skin cells.

Differential extraction is designed to physically separate the DNA in epithelial cells from the DNA in sperm cells, in samples which potentially contain a mixture of sperm and other cell types. As a result, separate "epithelial cell," "sperm cell," and "swab (or substrate) remains" DNA fractions are generated. Incomplete separation can occur and fractions may contain both sperm DNA and epithelial cell DNA.

DNA quantitation measures the amount of DNA extracted from samples by using a technique called quantitative real time polymerase chain reaction (qRT-PCR). If sufficient DNA is detected, DNA amplification and analysis can be attempted.

The **PCR** (polymerase chain reaction) technique produces large amounts of DNA from small starting amounts of DNA by repeated cycles of copying the DNA loci (**DNA amplification**); after amplification the alleles present in the sample are identified.

PCR DNA testing for STRs uses the **Applied Biosystems AmpFlSTR Identifiler® PCR Amplification Kit** with 28 amplification cycles (**Identifiler® 28**) or 31 amplification cycles (**Identifiler® 31**). Each STR locus tested in the Identifiler® Kit contains between 8 and 32 identifiable alleles. The **Applied Biosystems AmpFlSTR Minifiler™ PCR Amplification Kit may also be used.** These Kits also test the Amelogenin locus, which is used to determine the sex origin of a sample.

High sensitivity PCR DNA testing uses Identifiler® 31 and replicate PCR tests when very low amounts of DNA (< 20 pg/μL) are present in a sample or when Identifiler® 28 testing does not yield an adequate DNA profile.

Y- chromosome STRs (Y-STR) are male-specific STRs, not present in females that are inherited from father to son, and should be identical for all male relatives of the paternal line. For example, brothers who share the same father will have the same Y-STR type. PCR DNA testing for Y-STRs uses the **Promega PowerPlex® Y STR Kit** with 30 cycles.

Statistics:

The rarity of a DNA profile can be expressed as an **STR population frequency estimate,** how often one would expect to see the DNA profile. STR population frequency estimates are based on the OCME STR database, the Population Data in the AmpF*l*STR® Identifiler™ PCR Amplification Kit User's Manual (2001) Population Data, Applied Biosystems, Foster City, California, the US YSTR Database, National Center for Forensic Science, Orlando, FL, the DNA View Program, Brenner, CH (1997) Symbolic Kinship program, Genetics 145:535-542, and the National Research Council (1996) The Evaluation of Forensic DNA Evidence, Natl. Acad. Press, Washington DC.

The statistical values reported reflect the approximate frequency of occurrence of a DNA profile in a population of unrelated individuals. Therefore, these are not appropriate for relatives. A profile is considered unique if it is at least as rare as 1 in greater than 6.80 trillion unrelated people.

Conclusions for DNA Typing

Is the source of: The DNA profile of an individual matches an evidentiary DNA profile and the population frequency of the evidentiary DNA profile meets the threshold of 1 in greater than 6.80 trillion, assuming the source is not an identical twin.

Could be the source of: The DNA profile of an individual is consistent with an evidentiary DNA profile, and the population frequency of the evidentiary DNA profile does not meet the threshold of 1 in greater than 6.80 trillion unrelated people.

Is a major or minor contributor to the mixture: The DNA profile of an individual matches a major or minor evidentiary DNA profile determined from a mixture, and the DNA population frequency of the determined major or the minor DNA profile meets the threshold of 1 in greater than 6.80 trillion individuals, assuming that source is not an identical twin.

Could be a major or minor contributor to the mixture: The DNA profile of an individual is consistent with a major or minor evidentiary DNA profile determined from a mixture, and the DNA population frequency of the determined major or the minor DNA profile does not meet the threshold of 1 in greater than 6.80 trillion unrelated people.

Could be a contributor to the mixture: For mixtures where individual profiles were not determined, all of the DNA alleles seen in an individual's DNA profile were also seen in the mixture for the locations where comparisons could be made.

Cannot be excluded as a contributor to the mixture: For the locations where comparisons could be made, most of the DNA alleles seen in an individual's DNA profile were also seen in the mixture. The allele(s) that were absent could be explained by any of several factors. Therefore, this person cannot be ruled out as a possible contributor to the mixture.

Excluded as a contributor to the mixture: For the locations where comparisons could be made, one or more of the DNA alleles seen in an individual's DNA profile were not seen in the mixture and this absence cannot be explained. Therefore, this person can be ruled out as a contributor.

No conclusions can be drawn: For the locations where comparisons could be made, the results do not support a positive association or an exclusion. Therefore, it cannot be determined whether a person contributed to this mixture.

Not suitable for comparison: The DNA results on the evidence are either too incomplete or too complex to be the basis for conclusions regarding the source of the DNA.

Partial Match: An association between two single-source (clean or fully deconvoluted) profiles, showing similarities but short of an exact match, that suggests that the source of a profile is potentially a relative of the source of the other, partially matching, profile. Partial matches are inadvertent, and may be found at the local, state, or national levels (through comparison at the bench, LINKAGE, or CODIS searches).

QUALITY ASSURANCE STANDARDS FOR FORENSIC DNA TESTING LABORATORIES

This document consists of definitions and standards. The standards are quality assurance measures that place specific requirements on the laboratory. Equivalent measures not outlined in this document may also meet the standard if determined sufficient through an accreditation process.

EFFECTIVE DATE:

These standards shall take effect July 1, 2009.

REFERENCES: Federal Bureau of Investigation, "Quality Assurance Standards for Forensic DNA Testing Laboratories" and "Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories," Forensic Science Communications, July 2000, Volume 2, Number 3.

1. SCOPE

The standards describe the quality assurance requirements that laboratories performing forensic DNA testing or utilizing the Combined DNA Index System (CODIS) shall follow to ensure the quality and integrity of the data generated by the laboratory. These standards also apply to vendor laboratories that perform forensic DNA testing in accordance with Standard 17. These standards do not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated.

2. DEFINITIONS

As used in these standards, the following terms shall have the meanings specified:

Accredited laboratory is a DNA laboratory that has received formal recognition that it meets or exceeds a list of standards, including the FBI Director's Quality Assurance Standards, to perform specific tests, by a nonprofit professional association of persons actively involved in forensic science that is nationally recognized within the forensic community in accordance with the provisions of the Federal DNA Identification Act (42 U.S.C. § 14132) or subsequent laws.

Accuracy is the degree of conformity of a measured quantity to its actual (true) value.

Administrative review is an evaluation of the report and supporting documentation for consistency with laboratory policies and for editorial correctness.

Analyst (or equivalent role, position, or title as designated by the Laboratory Director) is an employee that has successfully completed the laboratory's training requirements for casework sample analysis, passed a competency test, and has entered into a proficiency testing program according to these Standards. This individual conducts and/or directs the analysis of forensic samples interprets data and reaches conclusions.

Analytical documentation is the documentation of procedures, standards, controls and instruments used, observations made, results of tests performed, charts, graphs, photos and other documentation generated which are used to support the analyst's conclusions.

Analytical procedure is an orderly step-by-step process designed to ensure operational uniformity and to minimize analytical drift.

Annual is once per calendar year.

Audit is an inspection used to evaluate, confirm, or verify activity related to quality.

Biochemistry is the study of the nature of biologically important molecules in living systems, DNA replication and protein synthesis, and the quantitative and qualitative aspects of cellular metabolism.

Calibration is the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of a measurement.

Casework CODIS Administrator (or equivalent role, position, or title as designated by the Laboratory Director) is an employee of the laboratory responsible for administration and security of the laboratory's CODIS at a laboratory performing DNA analysis on forensic and casework reference samples.

Casework reference sample is biological material obtained from a known individual and collected for purposes of comparison to forensic samples.

CODIS is the Combined DNA Index System administered by the FBI. CODIS links DNA evidence obtained from crime scenes, thereby identifying serial criminals. CODIS also compares crime scene evidence to DNA profiles from offenders, thereby providing investigators with the identity of the putative perpetrator. In addition, CODIS contains profiles from missing persons, unidentified human remains and relatives of missing persons. There are three levels of CODIS: the Local DNA Index System (LDIS), used by individual laboratories; the State DNA Index System (SDIS), used at the state level to serve as a state's DNA database containing DNA profiles from LDIS laboratories; and the National DNA Index System (NDIS), managed by the FBI as the nation's DNA database containing all DNA profiles uploaded by participating states.

Competency test(s) is a written, oral and/or practical test or series of tests, designed to establish that an individual has demonstrated achievement of technical skills and met minimum standards of knowledge necessary to perform forensic DNA analysis.

Competency is the demonstration of technical skills and knowledge necessary to perform forensic DNA analysis successfully.

Contamination is the unintentional introduction of exogenous DNA into a DNA sample or PCR reaction.

Continuing education is an educational activity (such as a class, lecture series, conference, seminar, or short course) that is offered by a recognized organization or individual that brings participants up to date in their relevant area of knowledge.

Coursework is an academic class officially recognized and taught through a college or university program in which the participating student successfully completed and received one or more credit hours for the class.

Critical equipment or instruments are those requiring calibration or a performance check prior to use and periodically thereafter.

Critical reagents are determined by empirical studies or routine practice to require testing on established samples before use on evidentiary or casework reference samples.

Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on forensic and/or casework reference samples.

Differential amplification is the selection of one target region or locus over another during the polymerase chain reaction. Differential amplification can also arise between two alleles within a single locus if one of the alleles has a mutation within a PCR primer binding site causing this allele to be copied less efficiently because of the primer-template mismatch.

DNA record is a database record that includes the DNA profile as well as data required to manage and operate NDIS, i.e., the Originating Agency Identifier which serves to identify the submitting agency; the Specimen Identification Number; and DNA personnel associated with the DNA profile analyses.

DNA type **(also known as a DNA profile)** is the genetic constitution of an individual at defined locations (also known as loci) in the DNA. A DNA type derived from nuclear DNA typically consists of one or two alleles at several loci (e.g., short tandem repeat loci). The DNA type derived from mitochondrial DNA is described in relation to the revised Cambridge Reference Sequence (Nature Genetics 1999, 23, 147).

Employee is a person: (1) in the service of the applicable federal, state or local government, subject to the terms, conditions and rules of federal/state/local employment and eligible for the federal/state/local benefits of service; or (2) formerly in the service of a federal, state, or local government who returns to service in the agency on a part time or temporary basis. For purposes of a vendor laboratory, an employee is a person in the service of a vendor laboratory and subject to the applicable terms, conditions and rules of employment of the vendor laboratory.

FBI is the Federal Bureau of Investigation, the Federal agency authorized by the DNA Identification Act of 1994 to issue quality assurance standards governing forensic DNA testing laboratories and to establish and administer the National DNA Index System (NDIS).

Forensic DNA analysis is the process of identification and evaluation of biological evidence in criminal matters using DNA technologies.

Forensic sample is a biological sample originating from and associated with a crime scene. For example, a sample associated with a crime scene may include a sample that has been carried away from the crime scene.

Genetics is the study of inherited traits, genotype/phenotype relationships, and population/species differences in allele and genotype frequencies.

Guidelines are a set of general principles used to provide direction and parameters for decision making.

Integral component is that portion of an academic course that is so significant and necessary to the understanding of the subject matter as a whole, that the course would be considered incomplete without it.

Internal validation is the accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

Known samples are biological material whose identity or type is established.

Laboratory is a facility: (1) employing at least two full time employees who are qualified DNA analysts; and (2) having and maintaining the capability to perform the DNA analysis of forensic and/or casework reference samples at that facility.

Laboratory support personnel (or equivalent role, position, or title as designated by the laboratory director) are employee(s) who perform laboratory duties exclusive of analytical techniques on forensic or database samples.

Methodology is used to describe the analytical processes and procedures used to support a DNA typing technology: for example, extraction methods (manual vs. automated),

quantitation methods (slot blot, fluorometry, real time), typing test kit and platform (capillary electrophoresis, real-time gel and end-point gel systems).

Molecular biology is the study of the theories, methods, and techniques used in the study and analysis of gene structure, organization, and function.

Multi-laboratory system is used to describe an organization that has more than one laboratory performing forensic DNA analysis.

Multiplex system is a test providing for simultaneous amplification of multiple loci that is either prepared commercially or by a laboratory.

Negative amplification control is used to detect DNA contamination of the amplification reagents. This control consists of only amplification reagents without the addition of template DNA.

NIST is the National Institute of Standards and Technology.

On-site visit is a scheduled or unscheduled visit by one or more representatives of the outsourcing laboratory to the vendor laboratory work site to assess and document the vendor laboratory's ability to perform analysis on outsourced casework.

Outsourcing is the utilization of a vendor laboratory to provide DNA services in which the NDIS participating laboratory takes or retains ownership of the DNA data for entry into CODIS, when applicable. Outsourcing does not require the existence of a contractual agreement or the exchange of funds.

Ownership occurs when any of the following criteria are applicable:

(1) the originating laboratory will use any samples, extracts or any materials from the vendor laboratory for the purposes of forensic testing (i.e. a vendor laboratory prepares an extract that will be analyzed by the originating laboratory);
(2) the originating laboratory will interpret the data generated by the vendor laboratory;
(3) the originating laboratory will issue a report on the results of the analysis; or
(4) the originating laboratory will enter or search a DNA profile in CODIS from data generated by the vendor laboratory.

Performance check is a quality assurance measure to assess the functionality of laboratory instruments and equipment that affect the accuracy and/or validity of forensic sample analysis.

Platform is the type of analytical system utilized to generate DNA profiles such as capillary electrophoresis, real-time gel, and end-point gel instruments or systems.

Polymerase Chain Reaction (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles which consist of the following:

(1) denaturation of the template;
(2) annealing of primers to complementary sequences at an empirically determined temperature; and
(3) extension of the bound primers by a DNA polymerase.

Positive amplification control is an analytical control sample that is used to determine if the PCR performed properly. This control consists of the amplification reagents and a known DNA sample.

Precision characterizes the degree of mutual agreement among a series of individual measurements, values, and/or results.

Preferential amplification is the unequal sampling of the two alleles present in a heterozygous locus primarily due to stochastic (random) fluctuation arising when only a few DNA molecules are used to initiate the polymerase chain reaction.

Procedure (protocol, SOP or other equivalent) is an established practice to be followed in performing a specified task or under specific circumstances.

Proficiency testing is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as:

(1) An internal proficiency test, which is produced by the agency undergoing the test.
(2) An external proficiency test, which may be open or blind, is a test obtained from an approved proficiency test provider.

Qualified auditor is a current or previously qualified DNA analyst who has successfully completed the FBI DNA Auditor's training course.

Quality system is the organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

Quantitative PCR is a method of determining the concentration of DNA in a sample by use of the polymerase chain reaction.

Reagent blank control is an analytical control sample that contains no template DNA and is used to monitor contamination from extraction to final fragment or sequence analysis. This control is treated the same as, and parallel to, the forensic and or casework reference samples being analyzed.

Reference material (certified or standard) is a material for which values are certified by a technically valid procedure and accompanied by, or traceable to, a certificate or other documentation which is issued by a certifying body.

Reproducibility is the ability to obtain the same result when the test or experiment is repeated.

Review is an evaluation of documentation to check for consistency, accuracy, and completeness.

Second agency is an entity or organization external to and independent of the laboratory.

Semi-annual is used to describe an event that takes place two times during one calendar year, with the first event taking place in the first six months of that year and the second event taking place in the second six months of that year and where the interval between the two events is at least four months and not more than eight months.

Service is the performance of those adjustments or procedures specified which are to be performed by the user, manufacturer or other service personnel in order to ensure the intended performance of instruments and equipment.

Technical Leader (or equivalent role, position, or title as designated by the laboratory director) is an employee who is accountable for the technical operations of the laboratory and who is authorized to stop or suspend laboratory operations.

Technical review is an evaluation of reports, notes, data, and other documents to ensure there is an appropriate and sufficient basis for the scientific conclusions.

Technical reviewer is an employee who is a current or previously qualified analyst in the methodology being reviewed that performs a technical review of, and is not an author of, the applicable report or its contents.

Technician (or equivalent role, position, or title as designated by the laboratory director) is an employee who performs analytical techniques on forensic samples under the supervision of a qualified analyst. Technicians do not interpret data, reach conclusions on typing results, or prepare final reports.

Technology is used to describe the type of forensic DNA analysis performed in the laboratory, such as RFLP, STR, YSTR, or mitochondrial DNA.

Test kit is a pre-assembled set of reagents that allows the user to conduct a specific DNA extraction, quantitation or amplification.

Traceability is the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

Underlying scientific principle is a rule concerning a natural phenomenon or function that is a part of the basis used to proceed to more detailed scientific functions.

Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for forensic casework analysis and includes the following:

> (1) Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on forensic samples.
> (2) Internal validation is an accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

Vendor laboratory is a governmental or private laboratory that provides DNA analysis services to another laboratory or agency and does not take ownership of the DNA data for purposes of entry into CODIS.

Work product is the material that is generated as a function of analysis, which may include extracts, amplified product and amplification tubes or plates as defined by the laboratory.

3. QUALITY ASSURANCE PROGRAM

STANDARD 3.1 The laboratory shall establish, follow and maintain a documented quality system that is appropriate to the testing activities and is equivalent to or more stringent than what is required by these Standards.

3.1.1 The quality system shall be documented in a manual that includes or references the following elements:

3.1.1.1 Goals and objectives

3.1.1.2 Organization and management

3.1.1.3 Personnel

3.1.1.4 Facilities

3.1.1.5 Evidence control

3.1.1.6 Validation

3.1.1.7 Analytical procedures

3.1.1.8 Equipment calibration and maintenance

3.1.1.9 Reports

3.1.1.10 Review

3.1.1.11 Proficiency testing

3.1.1.12 Corrective action

3.1.1.13 Audits

3.1.1.14 Safety

3.1.1.15 Outsourcing

STANDARD 3.2 The laboratory shall maintain and follow a procedure regarding document retention that specifically addresses proficiency tests, corrective action, audits, training records, continuing education, case files and court testimony monitoring.

STANDARD 3.3 The quality system as applicable to DNA shall be reviewed annually independent of the audit required by Standard 15. The review of the quality system shall be completed under the direction of the technical leader and the approval by the technical leader shall be documented.

4. ORGANIZATION AND MANAGEMENT

STANDARD 4.1 The laboratory shall:

4.1.1 Have a managerial staff with the authority and resources needed to discharge their duties and meet the requirements of the Standards in this document.

4.1.2 Have a technical leader who is accountable for the technical operations. Multi-laboratory systems shall have at least one technical leader.

4.1.3 Have a casework CODIS administrator who is accountable for CODIS on-site at each individual laboratory facility utilizing CODIS.

4.1.4 Have at least two full time employees who are qualified DNA analysts.

4.1.5 Specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the validity of the DNA analysis.

4.1.6 Have a documented contingency plan that is approved by laboratory management if the technical leader position is vacated.

5. PERSONNEL

STANDARD 5.1 Laboratory personnel shall have the education, training and experience commensurate with the examination and testimony provided. The laboratory shall:

5.1.1 Have a written job description for personnel, that may be augmented by additional documentation, that defines responsibilities, duties and skills.

5.1.2 Have a documented training program for qualifying all analyst/technician(s).

5.1.2.1 The laboratory's training program shall include a training manual covering all DNA analytical procedures that the analyst/technician will perform. Practical exercises shall include the examination of a range of samples routinely encountered in casework.

5.1.2.2 The training program shall teach and assess the technical skills and knowledge required to perform DNA analysis.

5.1.2.2.1 The training program shall require an individual's demonstration of competency. The laboratory shall maintain documentation of the successful completion of such competency test(s).

5.1.2.2.2 When hiring experienced analyst/technician(s), the technical leader shall be responsible for assessing their previous training and ensuring it is adequate and documented. Modification to the training program may be appropriate and shall be documented by the technical leader.

5.1.2.2.3 All analyst/technician(s), regardless of previous experience, shall successfully complete a competency test(s) covering the routine DNA methodologies to be used prior to participating in independent casework analysis.

5.1.3 Have a documented program to ensure technical qualifications are maintained through participation in continuing education.

5.1.3.1 Continuing education: The technical leader, casework CODIS administrator, and analyst(s) shall stay abreast of developments within the field of DNA typing by attending seminars, courses, professional meetings or documented training sessions/classes in relevant subject areas at least once each calendar year. A minimum of eight cumulative hours of continuing education are required annually and shall be documented.

5.1.3.1.1 If continuing education is conducted internally, the title of the program, a record of the presentation, date of the training, attendance list, and the curriculum vitae of the presentor(s) shall be documented and retained by the laboratory.

5.1.3.1.2 If the continuing education is conducted externally, the laboratory shall maintain documentation of attendance through a

mechanism such as certificates, program agenda/syllabus, or travel documentation. Attendance at a regional, national or international conference shall be deemed to provide a minimum of 8 hours of continuing education.

5.1.3.1.3 Programs based on multimedia or internet delivery shall be subject to the approval of the technical leader. Participation in such programs shall be formally recorded and its completion shall be submitted to the technical leader for review and approval. The documentation shall include the time required to complete the program.

5.1.3.2 The laboratory shall have a program approved by the technical leader for the annual review of scientific literature that documents the analysts' ongoing reading of scientific literature. The laboratory shall maintain or have physical or electronic access to a collection of current books, reviewed journals, or other literature applicable to DNA analysis.

5.1.4 Maintain records on the relevant qualifications, training, skills and experience of the technical personnel.

STANDARD 5.2 The technical leader shall meet the following qualifications:

5.2.1 Minimum educational requirements: The technical leader of a laboratory shall have, at a minimum, a Master's degree in a biology-, chemistry- or forensic science- related area and successfully completed 12 semester or equivalent credit hours from a combination of undergraduate and graduate course work covering the following subject areas: biochemistry, genetics, molecular biology, and statistics or population genetics.

5.2.1.1 The 12 semester or equivalent credit hours shall include at least one graduate level course registering three (3) or more semester or equivalent credit hours.

5.2.1.2 The specific subject areas listed in 5.2.1 shall constitute an integral component of any course work used to demonstrate compliance with this Standard.

5.2.1.3 Individuals who have completed course work with titles other than those listed in 5.2.1 shall demonstrate compliance with this Standard through a combination of pertinent materials such as a transcript, syllabus, letter from the instructor or other document that supports the course content.

5.2.1.4 If the degree requirements of section 5.2.1 were waived by the American Society of Crime Laboratory Directors (ASCLD) in accordance

with criteria approved by the Director of the Federal Bureau of Investigation (FBI), such a documented waiver shall be permanent and portable.

5.2.2 Minimum experience requirements: A technical leader of a laboratory shall have three years of forensic DNA laboratory experience obtained at a laboratory where forensic DNA testing was conducted for the identification and evaluation of biological evidence in criminal matters. As of the effective date of this revision, any newly appointed technical leader shall have a minimum of three years of human DNA (current or previous) experience as a qualified analyst on forensic samples. The technical leader shall have previously completed or successfully complete the FBI sponsored auditor training within one year of appointment.

5.2.3 The technical leader shall be responsible for the following:

5.2.3.1 General duties and authority:

5.2.3.1.1 Oversee the technical operations of the laboratory.

5.2.3.1.2 Authority to initiate, suspend and resume DNA analytical operations for the laboratory or an individual.

5.2.3.2 The minimum specific responsibilities to be performed by the technical leader include the following:

5.2.3.2.1 To evaluate and document approval of all validations and methods used by the laboratory and to propose new or modified analytical procedures to be used by analysts.

5.2.3.2.2 To review the academic transcripts and training records for newly qualified analysts and approve their qualifications prior to independent casework analysis and document such review.

5.2.3.2.3 To approve the technical specifications for outsourcing agreements.

5.2.3.2.4 To review internal and external DNA Audit documents and, if applicable, approve corrective action(s), and document such review.

5.2.3.2.5 To review, on an annual basis, the procedures of the laboratory and document such review.

5.2.3.2.6 To review and approve the training, quality assurance and proficiency testing programs in the laboratory.

5.2.4. Accessibility: The technical leader shall be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. A multi-laboratory system may have one technical leader over a system of separate laboratory facilities. For multi-laboratory systems the technical leader shall conduct a site visit to each laboratory at least semi-annually.

5.2.4.1 The technical leader shall be a full time employee of the laboratory or multi-laboratory system.

5.2.4.1.1 In the event that the technical leader position of a laboratory is vacated and there is no individual in the laboratory or multi-laboratory system who meets the requirements of this standard and serve as a technical leader, the laboratory shall immediately contact the FBI and submit their contingency plan within14 days to the FBI for its approval. Work in progress by the laboratory may be completed during this 14 day period but new casework shall not be started until the plan is approved by the FBI.

5.2.5 Newly appointed technical leaders shall be responsible for the documented review of the following:

5.2.5.1 Validation studies and methodologies currently used by the laboratory; and

5.2.5.2 Educational qualifications and training records of currently qualified analysts.

STANDARD 5.3 The casework CODIS administrator shall be an employee of the laboratory and meet the following qualifications:

5.3.1 Minimum educational requirements: The casework CODIS Administrator shall meet the education requirements for an analyst as defined in Standard 5.4. A casework CODIS Administrator appointed prior to the effective date of this revision shall be deemed to have satisfied the minimum educational requirements; satisfaction of these minimum educational requirements shall be applicable to the specific laboratory the casework CODIS Administrator is employed by prior to the effective date of this revision and shall not be portable.

5.3.2 Minimum experience requirements: A casework CODIS administrator shall be or have been a current or previously qualified DNA analyst as defined in Standard 5.4 with documented mixture interpretation training. A casework CODIS administrator appointed prior to the effective date of this revision who is not or has never been a qualified analyst (with documented training in mixture interpretation) shall be deemed to have satisfied the minimum experience requirements upon completion of FBI sponsored CODIS training; satisfaction of these minimum requirements shall be applicable to the specific laboratory the

casework CODIS administrator is employed by prior to the effective date of this revision and shall not be portable.

5.3.3 Minimum CODIS training requirements. The casework CODIS Administrator shall participate in the FBI sponsored training in CODIS software within six months of assuming CODIS casework administrator duties if the Administrator had not previously attended such training. The casework CODIS Administrator shall successfully complete the FBI sponsored auditor training within one year of assuming their Administrator duties if the Administrator had not previously attended such training.

5.3.4 The casework CODIS Administrator shall be responsible for the following:

5.3.4.1 Administration of the laboratory's local CODIS network.

5.3.4.2. Scheduling and documentation of the CODIS computer training of casework analysts.

5.3.4.3 Assurance that the security of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.

5.3.4.4 Assurance that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.

5.3.4.5 Assurance that matches are dispositioned in accordance with NDIS operational procedures.

5.3.5 The casework CODIS Administrator shall be authorized to terminate an analyst's or laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified.

5.3.6 A laboratory shall not upload DNA profiles to NDIS in the event that the casework CODIS Administrator position is unoccupied.

STANDARD 5.4 The analyst shall be an employee of the laboratory and meet the following qualifications:

5.4.1 Minimum educational requirements: The analyst shall have a bachelor's (or its equivalent) or an advanced degree in a biology-, chemistry-, or forensic science-, related area and shall have successfully completed course work (graduate or undergraduate level) covering the following subject areas:

biochemistry, genetics, molecular biology; and course work and/or training in statistics and/or population genetics as it applies to forensic DNA analysis.

5.4.1.1. The specific subject areas listed in Standard 5.4.1. shall be an integral component of any coursework for compliance with this Standard.

5.4.1.2. Analysts appointed or hired after the effective date of these revisions shall have a minimum of nine cumulative semester hours or equivalent that cover the required subject areas.

5.4.1.3. Analysts who have completed course work with titles other than those listed in 5.4.1 above shall demonstrate compliance with this Standard through a combination of pertinent materials, such as a transcript, syllabus, letter from the instructor, or other document that supports the course content. The technical leader shall document approval of compliance with this Standard.

5.4.2 Minimum experience requirements: The analyst shall have six (6) months of forensic human DNA laboratory experience. If prior forensic human DNA laboratory experience is accepted by a laboratory, the prior experience shall be documented and augmented by additional training, as needed, in the analytical methodologies, platforms and interpretations of human DNA results used by the laboratory.

5.4.2.1 The analyst shall complete the analysis of a range of samples routinely encountered in forensic casework prior to independent work using DNA technology.

5.4.2.2 The analyst shall successfully complete a competency test before beginning independent DNA analysis.

STANDARD 5.5 The technician shall meet the following qualifications:

5.5.1 Documented training specific to their job function(s).

5.5.2 Successful completion of a competency test before participating in DNA analysis on evidence.

STANDARD 5.6 Laboratory technical support personnel shall have documented training specific to their job function(s).

6. FACILITIES

STANDARD 6.1 The laboratory shall have a facility that is designed to ensure the integrity of the analyses and the evidence.

6.1.1 Access to the laboratory shall be controlled and limited in a manner to prevent access by unauthorized personnel. All exterior entrance/exit points require security control. The distribution of all keys, combinations, etc., shall be documented and limited to the personnel designated by laboratory management.

6.1.2 Except as provided in 6.1.4., techniques performed prior to PCR amplification such as evidence examinations, DNA extractions, and PCR setup shall be conducted at separate times or in separate spaces from each other. Standard 6.1.4 is applicable if robotic workstations are used by the laboratory.

6.1.3 Except as provided in 6.1.4., amplified DNA product, including real time PCR, shall be generated, processed and maintained in a room(s) separate from the evidence examination, DNA extractions and PCR setup areas. The doors between rooms containing amplified DNA and other areas shall remain closed.

6.1.4 A robotic workstation may be used to carry out DNA extraction, quantitation, PCR setup, and/or amplification in a single room, provided that the analytical process has been validated in accordance with Standard 8. If the robot performs analysis through amplification, the robot shall be housed in a separate room from that used for initial evidence examinations.

6.1.5 The laboratory shall have and follow written procedures for cleaning and decontaminating facilities and equipment.

7. EVIDENCE CONTROL

STANDARD 7.1 The laboratory shall have and follow a documented evidence control system to ensure the integrity of physical evidence.

7.1.1 Evidence shall be marked with a unique identifier on the evidence package. The laboratory shall clearly define what constitutes evidence and what constitutes work product. The laboratory shall have and follow a method to distinguish each sample throughout processing (such as plate or rack mapping) that may not require the assignment of unique identifiers or individual evidence seals for each specimen.

7.1.2 Chain of custody for all evidence shall be documented and maintained in hard or electronic format. The chain of custody shall include the signature, initials or electronic equivalent of each individual receiving or transferring the evidence, the corresponding date for each transfer, and the evidentiary item(s) transferred.

7.1.3 The laboratory shall have and follow documented procedures designed to minimize loss, contamination, and/or deleterious change of evidence and work product in progress.

7.1.4 The laboratory shall have secure, controlled access areas for evidence storage and work product in progress.

STANDARD 7.2 Where possible, the laboratory shall retain or return a portion of the evidence sample or extract.

STANDARD 7.3 The laboratory shall have and follow a documented policy for the disposition of evidence that includes a policy on sample consumption.

8. VALIDATION

STANDARD 8.1 The laboratory shall use validated methodologies for DNA analyses. There are two types of validations: developmental and internal.

STANDARD 8.2 Developmental validation shall precede the use of a novel methodology for forensic DNA analysis.

8.2.1 Developmental validation studies shall include, where applicable, characterization of the genetic marker, species specificity, sensitivity studies, stability studies, reproducibility, case-type samples, population studies, mixture studies, precision and accuracy studies, and PCR-based studies. PCR-based studies include reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, assessment of appropriate controls, and product detection studies. All validation studies shall be documented.

8.2.2 Peer-reviewed publication of the underlying scientific principle(s) of a technology shall be required.

STANDARD 8.3 Except as provided in Standard 8.3.1.1, internal validation of all manual and robotic methods shall be conducted by each laboratory and reviewed and approved by the laboratory's technical leader prior to using a procedure for forensic applications.

8.3.1 Internal validation studies conducted after the date of this revision shall include as applicable: known and non-probative evidence samples or mock evidence samples, reproducibility and precision, sensitivity and stochastic studies, mixture studies, and contamination assessment. Internal validation studies shall be documented and summarized. The technical leader shall approve the internal validation studies.

8.3.1.1 Internal validation data may be shared by all locations in a multi-laboratory system. Each laboratory in a multi-laboratory system shall complete, document and maintain applicable precision, sensitivity, and contamination assessment studies. The summary of the validation data shall be available at each site.

8.3.2 Internal validation shall define quality assurance parameters and interpretation guidelines, including as applicable, guidelines for mixture interpretation.

8.3.3 A complete change of detection platform or test kit (or laboratory assembled equivalent) shall require internal validation studies.

STANDARD 8.4 Before the introduction of a methodology into the laboratory, the analyst or examination team shall successfully complete a competency test to the extent of his/her/their participation in casework analyses.

STANDARD 8.5 The performance of a modified procedure shall be evaluated by comparison with the original procedure using similar DNA samples.

STANDARD 8.6 Each additional critical instrument shall require a performance check. Modifications to an instrument, such as a detection platform, that do not affect the analytical portion of the instrument shall require a performance check.

STANDARD 8.7 Modifications to software, such as an upgrade, shall require a performance check prior to implementation. New software or significant software changes that may impact interpretation or the analytical process shall require a validation prior to implementation.

9. ANALYTICAL PROCEDURES

STANDARD 9.1 The laboratory shall have and follow written analytical procedures approved by the technical leader. The standard operating procedures are to be reviewed annually by the technical leader independent of the audit required by Standard 15 and this review shall be documented.

9.1.1 The laboratory shall have and follow a standard operating procedure for each analytical method used by the laboratory. The procedures shall specify reagents, sample preparation, extraction methods (to include differential extraction of nuclear DNA samples with adequate amount of sperm), equipment, and controls which are standard for DNA analysis and data interpretation.

STANDARD 9.2 The laboratory shall use reagents that are suitable for the methods employed.

9.2.1 The laboratory shall have written procedures for documenting commercial reagents and for the formulation of in-house reagents.

9.2.2 Commercial reagents shall be labeled with the identity of the reagent and the expiration date as provided by the manufacturer or as determined by the laboratory.

9.2.3 In-house reagents shall be labeled with the identity of the reagent, the date of preparation and/or expiration, and the identity of the individual preparing the reagent.

STANDARD 9.3 The laboratory shall identify critical reagents and evaluate them prior to use in casework. These critical reagents shall include but are not limited to the following:

9.3.1 Test kits or systems for performing quantitative PCR and genetic typing

9.3.2 Thermostable DNA polymerase, primer sets and allelic ladders used for genetic analysis that are not tested as test kit components under Standard 9.3.1.

STANDARD 9.4 The laboratory shall quantify the amount of human DNA in forensic samples prior to nuclear DNA amplification. Quantitation of human DNA is not required for casework reference samples if the laboratory has a validated system that has been demonstrated to reproducibly and reliably yield successful DNA amplification and typing without prior quantitation.

STANDARD 9.5 The laboratory shall monitor the analytical procedures using the following controls and standards.

9.5.1 Where quantitation is used, quantitation standards shall be used.

9.5.2 Positive and negative amplification controls associated with samples being typed shall be amplified concurrently with the samples at all loci and with the same primers as the forensic samples. All samples typed shall also have the corresponding amplification controls typed.

9.5.3 Reagent blank controls associated with each extraction set being analyzed shall be:

9.5.3.1 Extracted concurrently;

9.5.3.2 Amplified utilizing the same primers, instrument model and concentration conditions as required by the sample(s) containing the least amount of DNA; and

9.5.3.3 Typed utilizing the same instrument model, injection conditions and most sensitive volume conditions of the extraction set.

9.5.4 Allelic ladders and internal size makers for variable number tandem repeat sequence PCR based systems.

9.5.5 The laboratory shall check its DNA procedures annually or whenever substantial changes are made to a procedure against an appropriate and available NIST standard reference material or standard traceable to a NIST standard.

STANDARD 9.6 The laboratory shall have and follow written guidelines for the interpretation of data.

9.6.1 The laboratory shall verify that all control results meet the laboratory's interpretation guidelines for all reported results.

9.6.2 For a given population(s), the statistical interpretation of autosomal loci shall be made following the recommendations 4.1, 4.2 or 4.3 as deemed applicable of the National Research Council report entitled "The Evaluation of Forensic DNA Evidence" (1996) and/or court directed method. These calculations shall be derived from a documented population database appropriate for the calculation.

9.6.3 A laboratory performing genetic analyses not addressed by Standard 9.6.2, such as Y-chromosome or mtDNA typing shall have and follow documented statistical interpretation guidelines specific for such testing.

9.6.4 Laboratories analyzing forensic samples shall have and follow a documented procedure for mixture interpretation that addresses major and minor contributors, inclusions and exclusions, and policies for the reporting of results and statistics.

STANDARD 9.7 The laboratory shall have and follow a documented policy for the detection and control of contamination.

10. EQUIPMENT CALIBRATION AND MAINTENANCE

STANDARD 10.1 The laboratory shall use equipment suitable for the methods employed.

STANDARD 10.2 The laboratory shall have and follow a documented program for conducting performance checks and calibration of instruments and equipment.

10.2.1 At a minimum, the following critical instruments or equipment shall require annual performance checks:

10.2.1.1 Thermometer traceable to national or international standard(s) that is used for conducting performance checks.

10.2.1.2 Balance/scale

10.2.1.3 Thermal Cycler temperature verification system

10.2.1.4 Thermal Cycler including quantitative-PCR

10.2.1.5 Electrophoresis detection systems

10.2.1.6 Robotic systems

10.2.1.7 Genetic Analyzers

10.2.1.8 Mechanical pipettes.

STANDARD 10.3 The laboratory shall have a schedule and follow a documented program to ensure that instruments and equipment are properly maintained. The laboratory shall retain documentation of maintenance, service or calibration.

STANDARD 10.4 New critical instruments and equipment, or critical instruments and equipment that have undergone repair, service or calibration, shall undergo a performance check before use in casework analysis.

10.4.1 At a minimum, the following critical equipment shall undergo a performance check following repair, service or calibration:

10.4.1.1 Electrophoresis detection systems

10.4.1.2 Robotic systems

10.4.1.3 Genetic Analyzers

10.4.1.4 Thermal cycler including quantitative-PCR

11. REPORTS

STANDARD 11.1 The laboratory shall have and follow written procedures for taking and maintaining casework notes to support the conclusions drawn in laboratory reports. The laboratory shall maintain all analytical documentation generated by analysts related to case analyses. The laboratory shall retain, in hard or electronic format, sufficient documentation for each technical analysis to support the report conclusions such that another qualified individual could evaluate and interpret the data.

STANDARD 11.2 Casework reports shall include the following elements:

11.2.1 Case identifier;

11.2.2 Description of evidence examined;

11.2.3 A description of the technology;

11.2.4 Locus or amplification system;

11.2.5 Results and/or conclusions;

11.2.6 A quantitative or qualitative interpretative statement;

11.2.7 Date issued;

11.2.8 Disposition of evidence; and

11.2.9 A signature and title, or equivalent identification, of the person accepting responsibility for the content of the report.

STANDARD 11.3 Except as otherwise provided by state or federal law, reports, case files, DNA records and databases shall be confidential.

11.3.1 The laboratory shall have and follow written procedures to ensure the privacy of the reports, case files, DNA records and databases.

11.3.2 The laboratory shall have and follow written procedures for the release of reports, case files, DNA records and databases in accordance with applicable state or federal law.

11.3.3 Personally identifiable information shall only be released in accordance with applicable state and federal law.

12. REVIEW

STANDARD 12.1 The laboratory shall conduct and document administrative and technical reviews of all case files and reports to ensure conclusions and supporting data are reasonable and within the constraints of scientific knowledge. The review of data generated external to the laboratory is governed by Standard 17.

12.1.1 An individual conducting technical reviews shall be or have been an analyst qualified in the methodology being reviewed.

STANDARD 12.2 Completion of the technical review shall be documented and the technical review of forensic casework shall include the following elements:

12.2.1 A review of all case notes, all worksheets, and the electronic data (or printed electropherograms or images) supporting the conclusions.

12.2.2 A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images).

12.2.3 A review of all profiles to verify correct inclusions and exclusions (if applicable) as well as a review of any inconclusive result for compliance with laboratory guidelines.

12.2.4 A review of all controls, internal lane standards and allelic ladders to verify that the expected results were obtained.

12.2.5 A review of statistical analysis, if applicable.

12.2.6 A review of the final report's content to verify that the results/conclusions are supported by the data. The report shall address each tested item or its probative fraction.

12.2.7 Verification that all profiles entered into CODIS are eligible, have the correct DNA types and correct specimen category

12.2.7.1 Prior to upload to or search of SDIS, verification of the following criteria for DNA profiles: eligibility for CODIS, correct DNA types, and appropriate specimen category.

12.2.7.2 For entry into a searchable category at SDIS, verification of the following criteria for DNA profiles by two concordant assessments by a qualified analyst or technical reviewer: eligibility for CODIS; correct DNA types; and appropriate specimen category.

STANDARD 12.3 The administrative review shall include the following elements, any or all of which may be included within the technical review:

12.3.1 A review of the case file and final report for clerical errors and that information specified in Standard 11.2 is present and accurate.

12.3.2 A review of chain of custody and disposition of evidence.

12.3.3 A procedure to document the completion of the administrative review.

STANDARD 12.4 The laboratory shall document the elements of a technical and administrative review. Case files shall be reviewed and documented according to the laboratory's procedure.

STANDARD 12.5 The laboratory shall have and follow a documented procedure to address unresolved discrepant conclusions between analysts and reviewer(s).

STANDARD 12.6 The laboratory shall have and follow a documented procedure for the verification and resolution of database matches.

STANDARD 12.7 The laboratory shall have and follow a program that documents the annual monitoring of the testimony of each analyst.

13. PROFICIENCY TESTING

STANDARD 13.1 Analysts, technical reviewers, technicians, and other personnel designated by the technical leader, shall undergo semi-annual external proficiency testing in each technology performed to the full extent in which they participate in casework. Semi-annual is used to describe an event that takes place two times during one calendar year, with the first event taking place in the first six months of that year and the second event taking place in the second six months of that year and where the interval between the two events is at least four months and not more than eight months. Such external proficiency testing shall be an open proficiency testing program and shall be submitted to the proficiency testing provider in order to be included in the provider's published external summary report.

13.1.1 Individuals routinely utilizing both manual and automated methods shall be proficiency tested in each at least once per year to the full extent in which they participate in casework.

13.1.2 Newly qualified individuals shall enter the external proficiency testing program within six months of the date of their qualification.

13.1.3 For purposes of tracking compliance with the semi-annual proficiency testing requirement, the laboratory shall define, document and consistently use the date that the proficiency test is performed as the received date, assigned date, submitted date, or the due date.

13.1.4 Except as provided in Standard 13.1.4.1, each analyst shall be assigned and complete his/her own external proficiency test.

13.1.4.1 Laboratories that use a team approach to casework examination may do so on external proficiency tests. However, all analysts, technicians, and technical reviewers shall be proficiency tested at least once per year in each of the DNA technologies, including test kits for DNA typing, and each platform in which they perform forensic DNA analysis.

13.1.5 Typing of all CODIS core loci or CODIS core sequence ranges shall be attempted for each technology performed.

13.1.6 The laboratory shall maintain the following records for proficiency tests:

13.1.6.1 The test set identifier,
13.1.6.2 Identity of the analyst, and other participants, if applicable,
13.1.6.3 Date of analysis and completion,
13.1.6.4 Copies of all data and notes supporting the conclusions,
13.1.6.5 The proficiency test results,
13.1.6.6 Any discrepancies noted, and
13.1.6.7 Corrective actions taken.

13.1.7 The laboratory shall include, at a minimum, the following criteria for evaluating proficiency test results:

13.1.7.1 Inclusions and exclusions as well as all reported genotypes and/or phenotypes are correct or incorrect according to consensus results or are within the laboratory's interpretation guidelines.

13.1.7.2 All results reported as inconclusive or not interpretable are consistent with written laboratory guidelines.

13.1.7.2.1 The technical leader shall review any inconclusive result for compliance with laboratory guidelines.

13.1.7.3 All discrepancies/errors and subsequent corrective actions shall be documented.

13.1.7.4 All final reports are graded as satisfactory or unsatisfactory.

13.1.7.4.1 A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data.

13.1.7.4.1.1 Administrative errors and corrective actions, as applicable, shall be documented.

13.1.8 All proficiency test participants shall be informed of his/her final test results and this notification shall be documented.

13.1.9 The technical leader shall be informed of the results of all participants and this notification shall be documented. The technical leader shall inform the casework CODIS administrator of all non-administrative discrepancies that affect the typing results and/or conclusions at the time of discovery.

STANDARD 13.2 The laboratory shall use an external proficiency test provider that is in compliance with the current proficiency testing manufacturing guidelines established by the American Society of Crime Laboratory Directors/ Laboratory Accreditation Board or be in compliance with the current International Organization for Standardization.

14. CORRECTIVE ACTION

STANDARD 14.1 The laboratory shall establish and follow a corrective action plan to address when discrepancies are detected in proficiency tests and casework analysis. A laboratory corrective action plan shall define what level/type of discrepancies are applicable to this practice and identify (when possible) the cause, effect of the discrepancy, corrective actions taken and preventative measures taken (where applicable) to minimize its reoccurrence. Documentation of all corrective actions shall be maintained in accordance with Standard 3.2.

STANDARD 14.2 Corrective actions shall not be implemented without the documented approval of the technical leader.

15. AUDITS

STANDARD 15.1 The laboratory shall be audited annually in accordance with these standards. The annual audits shall occur every calendar year and shall be at least 6 months and no more than 18 months apart.

STANDARD 15.2 At least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) and having at least one team member who is or has been previously qualified in the laboratory's current DNA technologies and platform.

> 15.2.1 Each analyst, casework CODIS administrator and technical leader shall have his/her education, experience and training qualifications evaluated and approved during two successive, separate external audits conducted after July 1, 2004. Approval of an individual's education, experience and training qualifications shall be documented in the audit document.
>
> 15.2.2 Each validation study shall be evaluated and approved during one external audit. Approved validation studies shall be documented in the audit document.

STANDARD 15.3. For internal audits, the auditor or audit team shall have the following expertise: currently qualified auditor and currently or previously qualified as an analyst in the laboratory's current DNA technologies and platform.

STANDARD 15.4 Internal and external audits shall be conducted utilizing the FBI DNA Quality Assurance Standards Audit Document.

STANDARD 15.5 Internal and external DNA Audit documents and, if applicable, corrective action(s) shall be submitted to the technical leader for review to ensure that findings, if any, were appropriately addressed.

> 15.5.1 For NDIS participating laboratories, all external audit documentation and laboratory responses shall be provided to the FBI within 30 days of laboratory receipt of the audit documents or report.

STANDARD 15.6 Internal and external audit documentation shall be retained and available for inspection during subsequent audits.

16. SAFETY

STANDARD 16.1 The laboratory shall have and follow a documented environmental health and safety program. This program shall include the following:

16.1.1 A blood borne pathogen and chemical hygiene plan

16.1.2 Documented training on the blood borne pathogen and chemical hygiene plan.

STANDARD 16.2 The laboratory's environmental health and safety program shall be reviewed once each calendar year and such review shall be documented.

STANDARD 17. OUTSOURCING

STANDARD 17.1 A vendor laboratory performing forensic DNA analysis shall comply with these Standards and the accreditation requirements of federal law.

17.1.1 An NDIS participating laboratory that outsources DNA sample(s) to a vendor laboratory to generate DNA data that will be entered into CODIS shall require the vendor laboratory to provide documentation of compliance with these Standards and the accreditation requirements of federal law. The NDIS participating laboratory shall maintain such documentation.

STANDARD 17.2 Except as provided in Standard 17.2.1, an NDIS participating laboratory's technical leader shall document approval of the technical specifications of the outsourcing agreement with a vendor laboratory before it is awarded. Such documentation shall be maintained by the NDIS participating laboratory.

17.2.1 A vendor laboratory that is performing forensic DNA analysis for a law enforcement agency or other entity and generating DNA data that may be entered into or searched in CODIS shall not initiate analysis for a specific case or set of cases until documented approval has been obtained from the appropriate NDIS participating laboratory's technical leader of acceptance of ownership of the DNA data.

STANDARD 17.3 An NDIS participating laboratory shall not upload or accept DNA data for upload to or search in CODIS from any vendor laboratory or agency without the documented prior approval of the technical specifications of the outsourcing agreement and/or documented approval of acceptance of ownership of the DNA data by the NDIS participating laboratory's technical leader.

STANDARD 17.4 An NDIS participating laboratory shall have and follow a procedure to verify the integrity of the DNA data received through the performance of the technical review of DNA data from a vendor laboratory.

STANDARD 17.5 Prior to the upload or search of DNA data to SDIS, the technical review of a vendor laboratory's DNA data shall be performed by an analyst or technical reviewer employed by the NDIS participating laboratory who is qualified or previously qualified in the technology, platform and typing amplification test kit used to generate the data and participates in the laboratory's proficiency testing program.

17.5.1 The technical review shall include the following elements:

17.5.1.1 A review of all DNA types to verify that they are supported by the raw and/or analyzed data (electropherograms or images).

17.5.1.2 A review of all associated controls, internal lane standards and allelic ladders to verify that the expected results were obtained.

17.5.1.3 A review of the final report (if provided) to verify that the results/conclusions are supported by the data. The report shall address each tested items (or its probative fractions) submitted to the vendor laboratory.

17.5.1.4 Verification of the DNA types, eligibility, and the correct specimen category for entry into CODIS.

STANDARD 17.6 An NDIS participating laboratory or multi-laboratory system outsourcing DNA sample(s) to a vendor laboratory or accepting ownership of DNA data from a vendor laboratory shall have and follow a procedure to perform an on-site visit(s) of the vendor laboratory. This procedure shall include, at a minimum, the following elements:

17.6.1 A documented initial on-site visit prior to the vendor laboratory's beginning of casework analysis for the laboratory.

17.6.1.1 The on-site visit shall be performed by the technical leader, or a designated employee of the NDIS participating laboratory who is a qualified or previously qualified DNA analyst in the technology, platform and typing amplification test kit, used to generate the DNA data.

17.6.2 If the outsourcing agreement extends beyond one year, an annual on-site visit shall be required. Each annual on-site visit shall occur every calendar year and shall be at least 6 months and no more than 18 months apart.

17.6.2.1 An NDIS participating laboratory may accept an on-site visit conducted by another NDIS participating laboratory using the same technology, platform and typing amplification test kit, for the generation of the DNA data and shall document the review and approval of such on-site visit.