510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k152232

B. Purpose for Submission:

New device

C. Measurand:

Cocaine and cocaine metabolites in hair

D. Type of Test:

Qualitative Enzyme Linked Immunosorbent Assay (ELISA)

E. Applicant:

Quest Diagnostics, Inc.

F. Proprietary and Established Names:

Quest Diagnostics HairCheck-DT (Cocaine)

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.3250, Cocaine and Cocaine Metabolite Test System

2. Classification:

   Class II

3. Product code:

   DIO – Enzyme Immunoassay, Cocaine and Cocaine Metabolites

4. Panel:

   Toxicology (91)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The Quest Diagnostics Hair Check-DT (Cocaine) test system utilizes an Enzyme Linked Immunosorbent Assay (ELISA) for the qualitative detection of cocaine in head hair samples through the measurement of cocaine and cocaine metabolites for concentrations at or above 300 pg/mg hair. This test system has not been evaluated for use with hair specimens from locations other than the head. It is an in vitro diagnostic device intended exclusively for in-house professional use and is not intended for sale to anyone.

   The Hair Check-DT (Cocaine) test system was evaluated in two distinct study populations; individuals known to be chronic drug abusers, and individuals proclaiming to be drug-free.

   The Quest Diagnostics Hair Check-DT (Cocaine) test system provides only a preliminary analytical test result. To confirm a presumptive screen positive result, a more specific alternate chemical method, such as gas chromatography - mass spectrometry (GC/MS) or Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS) must be used. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

3. Special conditions for use statement(s):

   The Quest Diagnostics HairCheck-DT (Cocaine) ELISA provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain confirmed analytical results a more specific alternate method such as gas chromatography/mass spectrometry (GC/MS) or Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS) must be used.

4. Special instrument requirements:

   The device is for use with an automated microplate reader capable of measuring at 450 and 620 nm.

   Confirmation testing was performed using an Agilent GC/MS system.

I. Device Description:

The assay consists of two parts; a pre-analytical hair treatment procedure (to extract cocaine from the solid hair matrix to a measurable liquid matrix), and the screening assay. The screening assay is an Enzyme-Linked ImmunoSorbent Assay (ELISA).

Kit Components
Each kit Quest Diagnostics HairCheck-DT (Cocaine) contains enough reagents to make 4,800 determinations

Reagents

- 50 x 96 well micro strip plates (12 x 8), coated with mouse anti-Cocaine monoclonal antibody.
- 2 x 4 mL of enzyme concentrate conjugate (horseradish peroxidase conjugated to cocaine) in a proprietary buffer containing stabilizing agents and thimerosal.
- 2 x 400 mL of enzyme diluent as a proprietary buffer containing stabilizing agents and thimerosal.
- 1 x 500 mL of substrate containing tetramethylbenzidine (TMB) and hydrogen peroxide in a citrate buffer containing stabilizers.
- 1 x 1000 mL of concentrated wash solution with surfactants and thimerosal as a preservative; Dilute 1:10 with deionized water prior to use.
- 1 x 500 mL of acid stop solution containing 1 N H_2SO4.

Calibrators and Controls for Screening Assay

- 100mL of 1X HairCheck-DT (Cocaine) Negative Control containing 0 pg cocaine/mg hair (No need to dilute, provided at working concentration)
- 5mL of 40X HairCheck-DT (Cocaine) Low Control containing 6,000 pg cocaine/mg hair (Dilute 1:40 with Negative Control to reach 1X Low Control working concentration of 150 pg cocaine/mg hair)
- 5mL of 40X HairCheck-DT (Cocaine) Cutoff Calibrator containing 12,000 pg cocaine/mg hair (Dilute 1:40 with Negative Control to reach 1X calibrator working concentration of 300 pg cocaine/mg hair)
- 5mL of 40X HairCheck-DT (Cocaine) High Control containing 18,000 pg cocaine/mg hair (Dilute 1:40 with Negative Control to reach 1X High Control working concentration of 450 pg cocaine/mg hair)

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Quest Diagnostics HairCheck-DT (Cocaine)

2. Predicate 510(k) number(s):

   k023626

3. Comparison with predicate:

Item	Candidate Device Quest Diagnostics Hair Check-DT (Cocaine)	Predicate Device Quest Diagnostics HairCheck-DT (Cocaine) (k023626)
Similarities		
Intended Use	For the qualitative detection of cocaine in head hair samples through the measurement of cocaine and cocaine metabolites	Same
Methodology	ELISA	Same
Cutoff	300 pg cocaine/mg hair	Same
Specimen type	Head hair	Same
Competitive Enzyme-conjugate	HRP - Cocaine	Same
Differences		
Antibody	Mouse anti-Cocaine monoclonal antibody	Rabbit anti-Cocaine polyclonal antibody
Extraction method	Acidified Methanol (0.5% Trifluoroacetic acid)(TFA)	Methanol
Control levels	High Control: 450 pg cocaine/mg hair Low control: 150 pg cocaine/mg hair	High Control: 600 pg cocaine/mg hair Same
Calibrators	Cutoff Calibrator containing 300 pg cocaine/mg hair	Same
Sample Size	Sample Preparation modified to 10 mg of Hair used for extraction then reconstituted with 0.3 mL phosphate buffer	Sample Preparation 20 mg of Hair used for extraction then reconstituted with 0.6 mL phosphate buffer
Measurement Wavelength	Assay absorbance measured at 450 nm with a reference wavelength of 620 nm.	Assay absorbance was measured at 450 nm with a reference wavelength of 630 nm.
Kit Configuration	Kit Configuration modified to = 50 microplate kit	Kit Configuration = 5 microplate kit

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

The test consists of two parts; a pre-analytical hair treatment procedure (to extract Cocaine from the solid hair matrix to a measurable liquid matrix), and the screening assay. The screening assay is an Enzyme-Linked ImmunoSorbent Assay (ELISA).

This assay requires a sample of head hair (approximately 120 strands) that is cut as close as possible to the scalp, preferably from the back of the head at the crown. The hair sample is treated with a pre-analytical treatment to extract cocaine from the hair into a liquid sample. The liquid sample is added to a well of the microplate and enzyme conjugate is added, followed by incubation. During this phase the enzyme-labeled drug conjugate competes with drug in the liquid sample for a limited number of binding sites on the mouse antibody-coated micro wells. A wash solution is applied to remove any unbound materials. Enzyme substrate solution containing a chromogen is added. The reaction is stopped with an acid and the absorbance is read using a plate reader at 450 nm and a background reading is also taken at 620 nm. Color intensity is inversely proportional to the amount of drug present in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Reproducibility

   The reproducibility of the extraction protocol was tested using five cocaine positive donor hair specimens. Three, 10 mg aliquots of each donor sample of hair were extracted and measured in one ELISA run with %CV calculated. The results are summarized in the table below.

Hair sample	Cocaine pg/mg by GC/MS	Extraction replicate	Mean OD	CV%	ELISA Pos/Neg
1	560	3	0.811	0.6%	3/0
2	18078	3	0.025	2.3%	3/0
3	2926	3	0.116	7.8%	3/0
4	7698	3	0.059	3.5%	3/0
5	2320	3	0.231	5.2%	3/0

   Precision

   Nine aliquots were taken from the negative hair matrix pool (liquid extract of negative hair samples) and spiked with cocaine at the following levels: 0 ng/mL (0 pg/mg), 2.5 ng/mL (75 pg/mg), 5 ng/mL (150 pg/mg), 7.5 ng/mL (225 pg/mg), 10 ng/mL (300 pg/mg), 12.5 ng/mL (375 pg/mg), 15 ng/mL (450 pg/mg), and 17.5 ng/mL (525 pg/mg), 20 ng/mL (600 pg/mg) representing 0, 25, 50, 75, 100, 125, 150,

175, 200 % of the calibrator cutoff value. The aliquots were then tested in 5-replicates on each of ten different days using the Quest Diagnostics HairCheck-DT (Cocaine) ELISA. Results are summarized below.

% Relative to	0%	25%	50%	75%	100%	125%	150%	175%	200%
Target pg/mg	0	75	150	225	300	375	450	525	600
Negative Count	50	50	50	50	25	3	0	0	0
Positive Count	0	0	0	0	25	47	50	50	50
% Negative	100%	100%	100%	100%	50%	6%	0%	0%	0%
% Positive	0%	0%	0%	0%	50%	94%	100%	100%	100%

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability

Calibrator and controls are prepared from Certified Reference Material Cerilliant C-008 Cocaine 1.0 mg/mL in Acetonitrile.

Stability

Shelf-life: The accelerated and real-time stability support the shelf-life of 6 months for the reagent kit (including calibrators and controls), stored at 2-8^{o}C.

Open vial stability: The study support an open vial claim of 30 days, stored at 2-8^{o}C for all kit components, including the cutoff calibrator and controls.

Hair Specimen Stability: Established in k023626.

Shipping study:

In order to demonstrate the stability of cocaine in hair specimens during the shipping process, 56 hair samples- twenty eight (28) confirmed positive cocaine hair specimens, of which three specimens (3) have pre-shipping quantitative GC/MS results in the near cutoff positive concentration range (300 to 449 pg/mg Cocaine) and twenty eight (28) confirmed negative cocaine hair specimens, of which three (3) have pre-shipping quantitative GC/MS results in the near cutoff negative concentration range (150 to 299 pg/mg Cocaine) were shipped to eight different geographical locations and the temperatures tracked during shipping. By enclosing an electronic temperature sensor within each shipment of hair samples, we were able to retrieve a range of temperatures collected every 20 minutes during the shipping process. In order to mimic potential shipping extreme temperatures, the hair was first

cold shocked at -15°C for 15 hours and then heat shocked at +47°C for 6 hours prior to shipping.

After the boxes were returned to facility, ELISA screening and GC/MS confirmation were performed on each sample and compared to the non-shipped results for the same samples. The cocaine negative samples that were shipped maintained their negative status both for ELISA screening and GC/MS with respect to cocaine levels. One of the borderline negative samples originally screened positive prior to shipping and all three of the borderline negative samples screened positive after shipping due to variability near the cutoff of the ELISA screening method. The cocaine positive samples that were shipped maintained their positive status for both the ELISA screening and the GC/MS confirmation with respect to cocaine levels.

Summary of results for positive specimens

	Pre-Shipping		**Post-Shipping**	
	GC/MS	ELISA	GC/MS	ELISA
Positive	28	28	28	28
Negative	0	0	0	0

Summary of results for negative specimens

	Pre-Shipping		**Post-Shipping**	
	GC/MS	ELISA	GC/MS	ELISA
Positive	0	1*	0	3**
Negative	28	27	28	25

***** One of the three Near Cutoff Negative specimens (as determined by GC/MS pre-shipping) screened positive by ELISA prior to shipping.

** Three of three Near Cutoff Negative specimens (as determined by GC/MS pre-shipping) screened positive by ELISA post-shipping.

d. Detection limit:

Analytical performance of the device around the cutoff is described in Section M1.a (Precision/Reproducibility) above.

e. Analytical specificity:

Interference:

One hundred and forty three commonly used compounds, many of them prescribed medicines, and abused drugs, were tested in the study. These compounds are not pharmacologically or structurally related to Cocaine. Each compound was tested at 10,000 ng/mL (equivalent to 300,000 pg/mg of hair), in hair matrix pools at two cocaine concentrations, equivalent to 50% below (150 pg/mg) and 50% above (450 pg/mg) the Cocaine cutoff value of 300 pg/mg.

Prepared samples were run in singlet on the Quest Diagnostics Hair Cocaine ELISA. If the OD of the above cutoff pool samples spiked with compound of interest was positive (had an OD lower than or equal to the cutoff), then the tested compounded was considered to not negatively interfere. If either the below cutoff pool spiked sample or above cutoff pool spiked sample had a response that showed interference, that sample was diluted 1 :2 in corresponding below cutoff pool or above cutoff pool until no interference was observed.

The lists of compounds that do not interfere are listed in the table below and are provided in the product labeling.

Compounds That Do Not Interfere with the Assay:

(-)-11-nor-9-Carboxy-Δ9-THC	Cannabinol	Hydrochlorthiazide	Normenperidinic Acid (4-Phenylpiperidine-4-carboxylic acid hydrochloride)
(+)-11-Nor-Δ9-THC-9-carboxylic acid glucuronide	Catharanthine (Ergoloid)	Hydrocodone	Normorphine
(-) Cotinine	Chlordiazepoxide	Hydrocortisone (Cortisol)	Noroxymorphone
(-) Methamphetamine	Cimaterol	Hydromorphone	O-Desmethyl-cis-tramadol HCl
(+) Isoproterenol	Clenbuterol	Ibuprofen	Oxazepam
(+) Methamphetamine	Clonazepam	Imipramine	Oxymorphone
(+) Norpseudoephedrine	Codeine	LAMPA	PCP

(±) Ketamine	Corticosterone	Levorphanol	Penicillin G Sodium salt
(±) MDA [(±)-3,4-Methylenedioxy amphetamine]	Cortisone	Lidocaine	Pentazocine
(±) MDEA [(±)-3,4-Methylenedioxy ethylamphetamine]	(-)-Δ8-THC	Lorazepam	Phenothiazine
(±) MDMA [(±)-3,4-Methylenedioxy methamphetamine]	(-)-Δ9-THC	LSD	Phentermine
(±) Propanolol	Desalkyl flurazepam	Meperdine	Phenylbutazone
(±)-N-Ethylamphetamine	Desipramine	Metaproterenol hemisulfate	P-Hydroxymeth amphetamine (Isodrin)
(±)-N-Propylamphetamine	Desmethyldoxepin (cis/trans)	Methedrone (Methyoxyephedrine)	Progesterone
(±)-Phenylpropanolamine (Norephedrine)	Dexamethasone	Methoxyphenamine HCl	Promethazine HCl
(±)-Methadone	Dextromethorphan	Methylergometrine maleate	Proprionyl Promazine HCl
Nandrolone (19-Nortesterone)	Diazepam	Methylphenidate	R(-) Phenylephrine
1R,2S(-)-Ephedrine	Dihydrocodeine	Monensin Sodium Salt	R(-)-Amphetamine
1S,2R(+)-Ephedrine	Dihydroergotamine Mesylate	Morphine	R(+) Methcathinone
2-Oxo-3-hydroxy-LSD (2-Oxo-3-hydroxy-lysergic acid diethylamide)	Dihydromorphine	Morphine-3-β-D-glucuronide	R,R(-)-Pseudoephedrine

Acetaminophen (4-Acetoamidophenol)	Doxepin (cis/trans)	Morphine-6-β-D-glucuronide	S(-)-Nicotine
4-MeO-PCP HCl (4-	Doxylamine succinate	Nadolol	S(+)-Amphetamine
Methoxyphencyclidine HCl)	Venlafaxine hydrochloride (Effexor)	Nalbuphine	Salbutamol (Albuterol)
6-Acetylmorphine (6-Monoacetylmorphine)	Erythromycin	Nalorphine	S, S(+) Pseudoephedrine
Acebutolol HCl	Ethylmorphine	Naltrexone	Stanozolol
p-Acetophenetidin (Phenacetine)	Fenfluramine	N-Desmethyo dramadol	Streptomycin Sulfate
Acetylsalicylic Acid	Fentanyl	Neomycin	Sufentanil
7-Aminoflunitrazepam	Flumethasone	N-Ethylcathione	Tetracycline HCl
Amoxicillin	Flunitrazepam	(±)-4-Methyl-N-ethyl-norephedrine HCl (N-Ethyl nor ephedrine)	Theophylline
Betamethasone	Flurazepam	Norbuprenorphine	cis-Tramadol
Buprenorphine	Furosamide	Norcodeine	Triazolam
Caffeine	Heroin	Nordiazepam	Trifluprom azine HCL
Cannabidiol	Normeperidine	Tylosin Tartrate	
HMMA (4-Hydroxy-3-Methoxy			

Of the 143 compounds tested, seven exhibited interference. For these compounds, and for an additional 10 dyes with the potential to interfere, the concentration of the test compound that gave a similar absorbance to the 300 pg/mg cocaine cut-off control was determined and percent cross reactivity was calculated. The results are shown below:

Compound	Positive Interference observed at or above:	Equivalent Concentration in Hair (pg/mg)
Thioridazine	2,500 ng/mL	75,000
Trifluperazine HCl	5,000 ng/mL	150,000
Chlorpromazine	10,000 ng/mL	300,000
Trimerperazine	10,000 ng/mL	300,000
Prochlorperazine dimaleate	2,500 ng/mL	75,000
Fluphenazine dihydrochloride	5,000 ng/mL	150,000
Iso-LSD	1,250 ng/mL	37,500
Basic Yellow 40	7,812.5 ng/mL	234,375
Methylene Blue	15,625 ng/mL	468,750
Basic Violet 16	31,250 ng/mL	937,500
Basic Blue 99	62,500 ng/mL	1,875,000
Basic Brown 16	62,500 ng/mL	1,875,000
Ethyl Violet	62,500 ng/mL	1,875,000
Basic Brown 17	62,500 ng/mL	1,875,000
Basic Red 51	125,000 ng/mL	3,750,000
Safranin O	125,000 ng/mL	3,750,000
Basic Yellow 87	500,000 ng/mL	15,000,000

Cross-reactivity

Cocaine, structurally-related compounds, pharmacologically-related compounds, and metabolites were tested for cross-reactivity in the assay. Eleven (11) compounds, structurally related to cocaine and known cocaine metabolites, were selected for the study (see table below for the list). The cross-reactant solutions were prepared by adding the compounds to negative hair matrix. The concentrations listed below produced a result approximately equal to the cutoff calibrator.

Serial dilutions of each compound were prepared and analyzed. If the OD response of the spiked sample was positive then the spiked sample was diluted further with finer dilutions until a positive result was obtained with an OD within 5% of the cutoff value (sample OD/Cutoff OD). Cross reactivity was calculated as: (Cutoff Concentration/Lowest Cross Reactant Concentration with a Positive Result) x 100.

The results are shown in the table below:

Cross reactivity of Cocaine ELISA with Structurally Similar Compounds

Compound	Cross Reactivity (%)	Tested Concentration in Negative Hair Matrix (ng/mL)	Concentration of compound (pg/mg hair) needed to produce results equivalent to 300 pg/mg of Cocaine
Anhydroecgonine	<0.1%	10,00	>300,00
Anhydroecgonine methyl ester	<0.1%	10,00	>300,00
Atropine	<0.1%	10,00	>300,00
Benzoylecgonine	143%	7	210
Cocatheylene	125%	8	240
Ecgonine	<0.1%	10,000	>300,000
Ecgonine methyl ester	<0.1%	10,000	>300,000
Meta-hydroxybenzoylecgonine	200%	5	150
Norcocaine	1%	1,000	30,000
Tropacocaine	8%	125	3,750
Cocaine	100%	10	300
Cocaine N-oxide HCl	11%	90	2,700

Cosmetic treatment

A panel of sixty (60) confirmed positive cocaine hair samples and sixty (60) screened negative cocaine hair samples were either treated with one of five (5) cosmetic hair treatments or left untreated. Cocaine positive hair is defined as a hair sample confirmed by GC/MS as having greater than 300 pg/mg cocaine. Absorbance readings after treatment were compared to absorbance readings prior to treatment, with the resulting change and direction of change noted. The resulting changes in ELISA test results are also noted, and are included in the table(s) below. (Absorbance values are normalized to the absorbance value of the cutoff calibrator absorbance value.)

ELISA Results for Cocaine Positive Hair

	Pre-Treatment		Post-Treatment		Range of % differences in raw OD from Pre-Treatment to Post - Treatment
	Number of Samples Positive by GC/MS	Number of Samples Positive by ELISA	Number of Samples Positive byGC/MS	Number of Samples Positive by ELISA	
Shampoo	12	12	12	12	-48% to + 56%
Brown Dye	12	12	12	12	-59% to + 174%
Bleach	12	12	12	12	-31% to + 278%
Perm	12	12	12	12	-60% to + 27%
Relaxer	12	12	12	12	+12% to + 197%

ELISA Results for Cocaine Negative Hair

	Pre-Treatment		Post-Treatment		Range of % differences in raw OD from Pre-Treatment to Post - Treatment
	Number of Samples Negative by GC/MS	Number of Samples Negative by ELISA	Number of Samples Negative by GC/MS	Number of Samples Negative by ELISA	
Shampoo	12	12	12	12	-8% to + 10%
Brown Dye	12	12	12	12	-13% to + 4%
Bleach	12	12	12	12	-9% to + 5%
Perm	12	12	12	12	-7% to + 6%
Relaxer	12	12	12	12	-16% to + 4%

Positive Specimens Individual Results

Treatment	ID	GC/MS Pre-Cosmetic Treatment pg/mg	ELISA Pre-Treat Raw OD	ELISA Pre-Treat P/N	ELISA Post-Treat Raw OD	ELISA Post-Treat P/N
		Cocaine				
Shampoo	P1	809	0.772	POS	0.976	POS
	P2	1391	0.505	POS	0.504	POS
	P3	4209	0.164	POS	0.165	POS
	P4	5927	0.089	POS	0.115	POS
	P5	804	0.664	POS	0.849	POS
	P6	929	0.475	POS	0.739	POS
Shampoo	P7	793	0.817	POS	0.698	POS
	P8	984	0.275	POS	0.316	POS
	P9	1336	0.417	POS	0.222	POS
	P10	1471	0.617	POS	0.322	POS
	P11	2064	0.229	POS	0.143	POS
	P12	812	0.437	POS	0.3	POS
Brown Dye	P13	951	0.722	POS	0.623	POS
	P14	968	0.739	POS	0.544	POS
	P15	1553	0.429	POS	0.368	POS
	P16	1596	0.366	POS	0.414	POS
	P17	3536	0.199	POS	0.082	POS
	P18	1306	0.166	POS	0.455	POS
	P19	1480	0.57	POS	0.389	POS
	P20	1852	0.322	POS	0.259	POS
	P21	919	0.499	POS	0.467	POS
	P22	968	0.125	POS	0.262	POS
	P23	4375	0.159	POS	0.166	POS
	P24	6948	0.047	POS	0.043	POS
Bleach Blonde	P25	810	0.516	POS	0.899	POS
	P26	1315	0.264	POS	0.379	POS
	P27	3605	0.118	POS	0.16	POS
	P28	5158	0.043	POS	0.06	POS
	P29	5796	0.063	POS	0.096	POS

	P30	6812	0.073	POS	0.067	POS
	P31	22770	0.034	POS	0.028	POS
	P32	39769	0.016	POS	0.016	POS
	P33	750	0.389	POS	0.627	POS
	P34	6920	0.049	POS	0.185	POS
	P35	1440	0.315	POS	0.511	POS
	P36	1607	0.345	POS	0.239	POS
Perm	P37	1662	0.181	POS	0.23	POS
	P38	1779	0.249	POS	0.365	POS
	P39	2298	0.112	POS	0.123	POS
	P40	3497	0.1	POS	0.088	POS
	P41	4142	0.054	POS	0.087	POS
	P42	4522	0.11	POS	0.107	POS
	P43	5461	0.098	POS	0.104	POS
	P44	5698	0.093	POS	0.112	POS
	P45	5993	0.034	POS	0.039	POS
	P46	6376	0.072	POS	0.081	POS
	P47	6786	0.082	POS	0.102	POS
	P48	8315	0.219	POS	0.087	POS
Relaxer	P49	9203	0.049	POS	0.067	POS
	P50	20000	0.021	POS	0.026	POS
	P51	856	0.619	POS	0.833	POS
	P52	1455	0.189	POS	0.509	POS
	P53	1555	0.354	POS	0.409	POS
	P54	1597	0.065	POS	0.107	POS
	P55	2039	0.245	POS	0.294	POS
	P56	3462	0.109	POS	0.122	POS
	P57	4491	0.129	POS	0.187	POS
	P58	8147	0.024	POS	0.043	POS
	P59	11024	0.03	POS	0.089	POS
	P60	20000	0.015	POS	0.031	POS

Negative Specimens Individual Results

Treatment	ID	GC/MS Pre-Cosmetic Treatment pg/mg	ELISA Pre-Treat Raw OD	ELISA Pre-Treat P/N	ELISA Post-Treat Raw OD	ELISA Post-Treat P/N
		Cocaine				
Shampoo	N1	0	2.65	NEG	2.698	NEG
	N2	0	2.785	NEG	2.559	NEG
	N3	0	2.828	NEG	2.928	NEG
	N4	0	2.767	NEG	2.85	NEG
	N5	0	2.795	NEG	2.767	NEG
	N6	0	2.553	NEG	2.802	NEG
Shampoo	N7	0	2.5	NEG	2.64	NEG
	N8	0	2.837	NEG	2.763	NEG
	N9	0	2.562	NEG	2.406	NEG
	N10	0	2.572	NEG	2.663	NEG
	N11	0	2.648	NEG	2.705	NEG
	N12	0	2.679	NEG	2.647	NEG
Brown Dye	N13	0	2.703	NEG	2.471	NEG
	N14	0	2.756	NEG	2.583	NEG
	N15	0	2.41	NEG	2.5	NEG
	N16	0	2.618	NEG	2.326	NEG
	N17	0	2.678	NEG	2.57	NEG
	N18	0	2.559	NEG	2.375	NEG
	N19	0	2.81	NEG	2.455	NEG
	N20	0	2.94	NEG	2.468	NEG
	N21	0	2.731	NEG	2.605	NEG
	N22	0	2.765	NEG	2.427	NEG
	N23	0	2.772	NEG	2.515	NEG
	N24	0	2.528	NEG	2.526	NEG
Bleach Blonde	N25	0	2.72	NEG	2.484	NEG
	N26	0	2.487	NEG	2.611	NEG
	N27	0	2.568	NEG	2.512	NEG
	N28	0	2.754	NEG	2.711	NEG

	N29	0	2.853	NEG	2.875	NEG
	N30	0	2.744	NEG	2.862	NEG
	N31	0	2.712	NEG	2.644	NEG
	N32	0	2.911	NEG	2.785	NEG
	N33	0	2.472	NEG	2.579	NEG
	N34	0	2.737	NEG	2.718	NEG
	N35	0	2.674	NEG	2.654	NEG
	N36	0	2.709	NEG	2.775	NEG
Perm	N37	0	2.469	NEG	2.327	NEG
	N38	0	2.486	NEG	2.4	NEG
	N39	0	2.445	NEG	2.504	NEG
	N40	0	2.439	NEG	2.56	NEG
	N41	0	2.436	NEG	2.271	NEG
	N42	0	2.574	NEG	2.519	NEG
	N43	0	2.578	NEG	2.573	NEG
	N44	0	2.672	NEG	2.52	NEG
	N45	0	2.574	NEG	2.496	NEG
	N46	0	2.452	NEG	2.303	NEG
	N47	0	2.578	NEG	2.531	NEG
	N48	0	2.446	NEG	2.589	NEG
Relaxer	N49	0	2.481	NEG	2.393	NEG
	N50	0	2.338	NEG	2.251	NEG
	N51	0	2.543	NEG	2.3	NEG
	N52	0	2.381	NEG	2.355	NEG
	N53	0	2.576	NEG	2.161	NEG
	N54	0	2.583	NEG	2.281	NEG
	N55	0	2.528	NEG	2.323	NEG
	N56	0	2.294	NEG	2.139	NEG
	N57	0	2.223	NEG	2.317	NEG
	N58	0	2.365	NEG	2.248	NEG
	N59	0	2.475	NEG	2.228	NEG
	N60	0	2.359	NEG	2.396	NEG

This study agrees with the extensive published literature that use of various cosmetic hair treatments can potentially reduce the amount of drugs and drug metabolites detected in hair specimens. It is possible that a cosmetic hair treatment could cause a negative hair sample to read positive or a positive hair sample to read negative. These effects are dependent upon the nature of the hair specimen and the treatment used and independent

of the method of analysis.

f. Assay cut-off:

The Assay cut-off is 300 pg cocaine/mg hair. Analytical performance of the device around the claimed cutoff is described in the precision section M.1a above.

2. Comparison studies:

a. Method comparison with predicate device:
A total of 100 donor head hair specimens were analyzed in singlet using the candidate assay and GC/MS. The results are summarized below:

Concordance Table

Candidate Device Result	Negative (Less thanhalf the cutoff concentration) by confirmatory analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration) by confirmatory analysis	Near Cutoff Positive (Between the cutoff and50% above the cutoff concentration) by confirmatory analysis	High Positive (greater than 50% above the cutoff concentration) by confirmatory analysis
[Conc] by GCMS	<150 pg/mg	150-299 pg/mg	300-450 pg/mg	>450 pg/mg
Negative	44	2	0	0
Positive	1	3	5	45

Summary and Justification of Discordant Results between ELISA and GC/MS

Reference number	Specimen	Device Result	Confirmation results by GC/MS			
			BE	COC	CE	NOR
1	313707BH	Pos	0	0	0	0
2	840072CH	Pos	0	155	0	0
3	769009BH	Pos	0	190	0	0
4	757751BH	Pos	80	272	0	0

(1) This sample was dyed a bright pink color. An investigation of this issue concluded that dyes within the bright pink color interfere with the immunoassay, producing false positive results. This dyes tested are included in the Interference section above.

(2) This specimen confirmed negative by GC-MS with a quantitative value of 155 pg cocaine/mg hair

(3) This specimen confirmed negative by GC-MS with a quantitative value of 190 pg cocaine/mg hair

(4) This specimen confirmed negative by GC-MS with a quantitative value of 272 pg cocaine/mg hair, but also contained 80 pg/mg of benzoylecgonine

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.