JAN 27 2006

K052649

SUMMARY OF SAFETY AND EFFECTIVENESS FOR DRG SALIVARY TESTOSTERONE ELISA

Manufacturer: DRG International, Inc.
1167 U.S. Highway 22
Mountainside, NJ 07092

Contact Information: Lehnus & Associates
Gary Lehnus
150 Cherry Lane Rd.
East Stroudsburg, PA 18301
Tel: (570) 620-0198

Device Name / Classification:
The device trade name is the DRG SLV Testosterone ELISA having FDA assigned name: Testosterone test system, 21 CFR, **862.1680**, categorized as Class I "reserved" medical devices for the Clinical Chemistry and Clinical Toxicology Panel, as Product Code **CDZ**.

Test Principle
The DRG Salivary Testosterone ELISA Kit is based on the competition principle and the microplate separation. An unknown amount of free testosterone present in the sample and a fixed amount of testosterone conjugated with horseradish peroxidase compete for the binding sites of mouse monoclonal testosterone -antiserum coated onto the wells. After one hour incubation the microplate is washed to stop the competition reaction. After addition of the substrate solution the concentration of testosterone is inversely proportional to the optical density measured.

Device Intended Use:
An Enzyme Immunoassay for the *in vitro diagnostic* quantitative measurement of free active testosterone in saliva. Measurement of testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

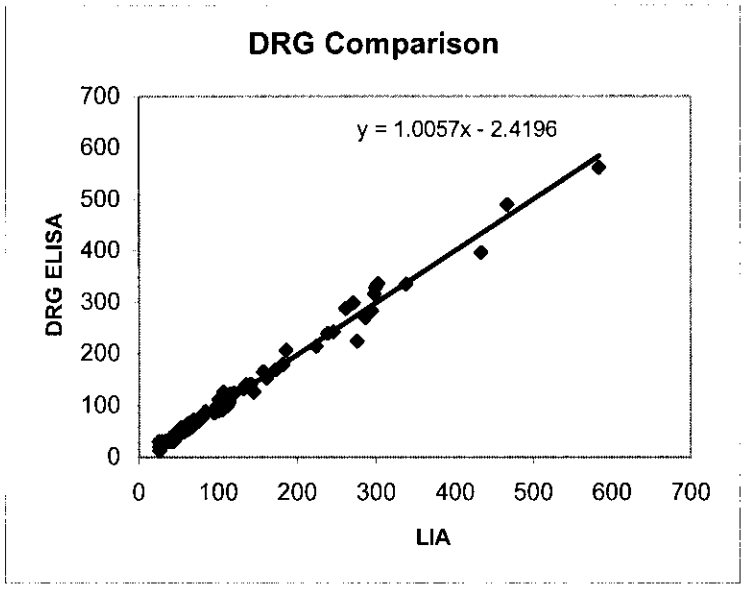
Device Performance
Normal Range Study
In order to determine the normal range of SLV Testosterone, saliva samples from 187 adult male and 188 adult female apparently healthy subjects, ages 21 to 75 years, were collected in the morning and analyzed using the DRG SLV Testosterone ELISA kit. The following range was calculated from this study.

	Men ♂			Women ♀		
Age Group Years	Range (5 - 95%)	Median	n	Range (5 - 95%)	Median	n
21 - 30	47.2 –136.2	92.8	42	7.9 – 50.4	20.8	40
31 - 40	46.8 –106.8	73.6	37	<7.0 – 44.8	17.1	40
41 - 50	36.5 –82.7	58.8	34	<7.0 – 39.4	18.3	38
51 - 60	19.1 – 89.0	44.5	36	<7.0 – 29.8	19.2	38
61 - 75	12.2 – 68.6	38.9	38	<7.0 – 29.3	16.0	32

Method comparison

A study was performed that evaluated saliva samples from 99 male and female subjects ages 20 to 70 years. The saliva samples were run in duplicate on the DRG test and a commercially available LIA method to determine the concentration of free Testosterone in the samples. A correlation of 0.904 and regression formula of y = 0.9251x - 7.4369 was obtained versus this method.

Another study was performed to further evaluate the substantial equivalence of the DRG SLV Testosterone to the LIA saliva test. The concentration of testosterone in 81 additional saliva samples collected from 40 - 65 year old men and women was determined using DRG SLV testosterone kit and the other method. From this study an R^2 = 0.9866 was obtained with the following regression.



Sensitivity

The lowest analytical detectable level of testosterone that can be distinguished from the Zero Standard is 1.857 pg/mL at the 95 % confidence limit. The lowest functional sensitivity of 7.1 pg/mL at the 95% confidence limit was obtained.

Specificity

The following materials have been evaluated for cross reactivity. The percentage indicates cross reactivity at 50% displacement compared to Testosterone.

Steroid	% Cross Reaction
Testosterone	100%
5α-Dihydrotestosterone	0.80%
Androstenedione	0.90%
11ß-hydroxysterone	3.30%
17α-methyltestosterone	0.10%
19-Nortestosterone	3.30%
Epitestosterone	0.10%
Estradiol	0.10%
Progesterone	< 0,10%
Cortisol	< 0,10%
Estrone	< 0,10%
Danazol	< 0,10%

Reproducibility

Intra-Assay

The intra-assay variation was determined by 20 replicate measurements of 5 saliva samples within one run. The within-assay variability is shown below:

Mean (pg/ml)	144.00	256.15	81.30	35.35	12.94
SD	8.974	17.587	5.545	2.498	1.787
CV (%)	6.23	6.87	6.82	7.07	13.81
n =	20	20	20	20	20

Inter-Assay

The inter-assay (between-run) variation was determined by duplicate measurements of 5 saliva samples over 10 days.

Mean (pg/mL)	823.08	87.57	118.82	112.13	33.61
SD	45.314	6.864	8.864	8.628	3.232
CV (%)	5.51	7.84	7.46	7.69	9.62
n =	20	20	20	20	20

Inter-Lot

The Inter-Lot (between-lot) variation was determined by triplicate measurements of five saliva samples in three different kit lots. The between lot variability is shown below:

	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Mean (pg/ml)	64.5	352.89	517.65	44.00	116.54
SD (pg/ml)	3.77	13.44	15.01	1.53	5.00
CV (%)	5.85	3.81	2.90	3.47	4.29
n =	9	9	9	9	9

Recovery

Recovery of the DRG ELISA was determined by adding increasing amounts of the analyte to six different saliva samples containing different amounts of endogenous analyte. Each sample (native and spiked) was assayed and analyte concentrations of the samples were calculated from the standard curve. The percentage recoveries were determined by comparing expected and measured values of the samples

Sample	Measured (pg/ml)	Expected (pg/ml)	Recovery (%)
1	8.39	-	-
	2396.90	2508.39	95.56
	517.17	508.39	101.73
	271.10	258.39	104.92
	55.95	58.39	95.82
2	46.23	-	-
	2474.70	2546.23	97.19
	564.37	546.23	103.32
	308.97	296.23	104.30
	88.87	96.23	92.35
3	122.09	-	-
	2602.41	2622.09	99.25
	591.16	622.09	95.03

	352.56	372.09	94.75
	166.40	172.09	96.69
4	210.00	-	-
	2650.00	2710.00	97.8
	700.00	710.00	98.6
	240.00	240.00	100.0
5	1250.00	-	-
	3700.00	3750.00	98.7
	1680.00	1750.00	96.0
	1250.00	1280.00	97.7
6	2090.00	-	-
	4550.00	4590.00	99.1
	2650.00	2590.00	102.3
	2130.00	2120.00	100.5

Linearity

Six saliva samples containing different amounts of analyte were serially diluted with zero standard and assayed with the DRG ELISA. Three native samples were serially diluted, and 3 samples were spiked with testosterone and then serially diluted up to 1:128. The percentage recovery was calculated by comparing the expected and measured values for testosterone. An assay linearity of 7.1 – 4500 pg/mL has been identified as the usable range. Samples above this range must be diluted and re-run.

	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Concentration (pg/ml)	4312.00	1838.00	440.00	8000.0	4500.0	5500.0
Average % Recovery	97.5	99.6	98.9	100.3	100.8	100.7
Range of Recovery % from	96.3	98.4	93.6	93.6	93.7	94.1
to	98.7	101.0	106.7	106.7	107.0	107.8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DRG International, Inc.
c/o Mr. Gary Lehnus
Lehnus & Associates
150 Cherry Land Rd.
East Stroudsburg, PA 18301

JAN 27 2006

Re: k052649
Trade/Device Name: DRG SLV Testosterone ELISA Test
Regulation Number: 21 CFR§ 862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class I
Product Code: CDZ
Dated: December 27, 2005
Received: January 9, 2006

Dear: Mr. Lehnus

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052649

Device Name: DRG SLV Testosterone ELISA Test

Indications For Use:

An enzyme immunoassay for the *in vitro diagnostic* quantitative measurement of free active testosterone in saliva.

Measurement of testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OIVD)

Ann Chappie
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K052649