K021972

AUG 2 1 2002

# 510(k) Summary

## FastPack® Total Testosterone Immunoassay on the FastPack® Analyzer System

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

| | | | |
|---|---|---|---|
| 1. | **Submitter name, address, contact** | Qualigen, Incorporated<br>2042 Corte del Nogal<br>Carlsbad, CA 92009 | |
| | | Telephone:<br>Fax: | (760) 918-9165<br>(760) 918-9127 |
| | | Contact Person: | Dorothy Deinzer |
| | | Date Prepared: | June 14, 2002 |
| 2. | **Device name** | Proprietary name: | FastPack® Total Testosterone Immunoassay on the FastPack® Analyzer System |
| | | Common name: | Chemiluminescense assay for the determination of Total Testosterone |
| | | Classification Name: | Quantitative Determination of Total Testosterone in Human Serum |
| 3. | **Predicate device** | Diagnostic Products Corporation's Coat-A-Count Total Testosterone RIA Kit ( K964889) | |
| 4. | **Device description** | ***FastPack® Total Testosterone Immunoassay Reagents*** | |

The FastPack® Total Testosterone Immunoassay is a competitive chemiluminescense assay.

- Primary incubation: Sample, calibrator, or control (100 µL) is added to the antibody solution (100 µL) to start the sequence. The reaction time is 5 minutes at 37° C.

- Secondary incubation: The initial reaction mixture (200 µL) is transferred to the magnetic particles with bound testosterone and competition between the sample testosterone and the beads continues for an additional 2.5 minutes at 37° C.

- Removal of unbound materials: The paramagnetic particles are washed three times with wash buffer (0.2 mL/wash cycle) to remove unbound materials.

- Substrate addition and detection: Chemiluminogenic substrate [140 µL] is added to the solid phase bound complex to form a chemiluminescent glow, which is measured by the FastPack® Analyzer System at 37° C.

5. **Intended use**

The FastPack® Total Testosterone Immunoassay is a paramagnetic particle immunoassay intended for the *in vitro* quantitative determination of total testosterone in human serum. The FastPack® Total Testosterone Immunoassay is designed for use with the FastPack® Analyzer System. It is intended strictly for *in vitro* diagnostic use as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen.

6. **Comparison to Predicate Device**

The following tables compare the FastPack™ Immunoassay System for Testosterone with the DPC Coat-A-Count® Total Testosterone:

| Feature | FastPack™ System | DPC Coat-A-Count |
|---|---|---|
| Intended Use | For the *in vitro* quantitative determination of testosterone in human serum. It is intended strictly for *in vitro* diagnostic use as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen. | For the quantitative measurement of testosterone in unextracted serum or heparinized plasma. Coupled with an acid hydrolysis procedure, it is also suitable for assaying urine samples. It is intended strictly for *in vitro* diagnostic use as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen. |
| Assay Methodology: | Competitive immunoassay | Competitive immunoassay |
| Storage Condition: | 2-8 °C | 2-8 °C |

| | | |
|---|---|---|
| Data Analysis | Internal data reduction via microcomputer | Manually Graph Logit-Log |
| Temperature Control | Required | Required |
| Test Processing | Automated | Manual |
| Sample Type: | Serum | Serum, Heparinized Plasma, Acid Hydrolyzed Urine |
| Detector: | Photomultiplier Tube (PMT) | Gamma Counter |
| Label | Alkaline Phosphatase | $^{125}I$ |
| Sample Volume | 100 µL | 50 µL |
| Assay Range | 0.07 to 16 ng/mL | 4 to 1600 ng/dL |
| Instrument Required | FastPack™ Analyzer System | gamma counter vortex mixer |
| Control Levels | 2(not supplied) | 3 (not supplied) |
| Antibody | Monoclonal | Polyclonal |
| Competing component | Testosterone-3-CMO covalently coupled to paramagnetic particles | $^{125}I$ iodinated testosterone |
| Solid Phase | paramagnetic particles | Polypropylene tubes coated with antibodies to testosterone |
| Substrate | ImmuGlow™ (Indoxyl –3-phosphate and lucigenin) | None |
| Detection | Chemiluminescense | Radiometric |
| Calibration | Factory generated master curve with single-level calibration adjustment every 14 days. | Full calibration curve every test run using 6 standards. |
| Throughput | Single Sample | Batch of tubes |
| Time to Result | 12 minutes | 180 minutes |
| Reagents Supplied as | Box of 50 disposable self contained reagent packs | 100 (200 or 500) coated tubes, one (two or five) vial(s) of $^{125}I$ testosterone, 6 vials of calibrator |

**Performance Characteristics:**

| Feature | FastPack™ Testosterone | DPC Coat-A-count |
|---|---|---|
| ***Precision*** | Mean ng/mL<br>Between Run<br>Low 0.14 0.06 SD<br>High 7.12 10.3%C.V.<br><br>*Between Analyzer*<br>Low 0.14 0.03 SD<br><br>High 7.12 3.8%C.V. | *Intra-assay*<br><br>Reported as a graph<br>4% CV to 7.5%CV over the 1ng/mL to 16ng/mL range<br><br>*Inter-assay*<br>Level Mean ng/mL<br>Low 0.76 .09 SD |

| | | |
|---|---|---|
| | *Between Reagent Lot*<br>Low 0.14 0.01 SD<br>High 7.12 0.1%C.V. | High 6.7 6.0% C.V. |
| ***Analytical Sensitivity*** | 0.13 ng Testosterone/mL | 0.04 ng testosterone/mL<br>(4 ng testosterone/dL) |
| ***Spike Recovery*** | 94 -110% | 93 to 103% |
| ***Dilution Recovery*** | 99 – 132% | 96% to 108% |
| ***Method Comparison*** | versus DPC Coat-A-Count® Total Testosterone:<br><br>n = 144<br>Range of values (DPC): 0 to 16.9 ng Testosterone/mL<br>Range of values (Fastpack): 0 to 18.4 ng Testosterone/mL<br>y = 1.065x - 0.004<br>r = 0.930 | |
| ***Interfering Substances***<br>Bilirubin<br>Hemoglobin<br>Triglycerides | No interference up to:<br>40 mg/dL<br>1000 mg/dL<br>1000 mg/dL | No interference up to:<br>25 mg/dL<br>600 mg/dL<br>3000 mg/dL |

| **Specificity** | | | | |
|---|---|---|---|---|
| | FastPack® System | | DPC Coat-A-Count | |
| Material Tested | Test Levels ng/mL | % Cross-reactivity | Test Levels ng/mL | % Cross-reactivity |
| 5-α-DHT | 50 | 3.16 | 50 | 3.3 |
| Androstenedione | 1,000 | 1.15 | 1,000 | 0.5 |
| Androsterone | 100,000 | 0.01 | 100,000 | 0.004 |
| Estradiol | 1,000 | 0.006 | 1,000 | 0.02 |
| Danazol | 1,000 | 0.002 | 200 | 0.09 |
| Cortisol | 8,000 | 0.001 | 8,000 | 0.005 |
| DHEA | 10,000 | 0.003 | 10,000 | 0.002 |
| Oxymetholone | 100 | 0.02 | Not Reported | Not Reported |

| | | | | |
|---|---|---|---|---|
| Estrone | 500 | 0.003 | 500 | 1.01 |
| Corticosterone | 5,000 | 0.003 | 5,000 | 0.002 |
| Methyltestosterone | 100 | 0.03 | 30 | ND |
| 11-Deoxycortisol | 1,000 | ND | 1,000 | ND |
| Progesterone | 1,000 | 0.01 | 1,000 | ND |
| 19-Nor Testo | 1,000 | 2.05 | 100 | 2220 |
| 19-Nor Testo | 500 | 2.07 | 500 | 22 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 1 2002

Ms. Dorothy Deinzer
Director
Quality and Regulatory Affairs
Qualigen, Inc.
2042 Corte Del Nogal
Carlsbad, CA 92009

Re: k021972
Trade/Device Name: FastPack® Total Testosterone Immunoassay
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class I
Product Code: CDZ
Dated: June 14, 2002
Received: June 17, 2002

Dear Ms. Deinzer:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Attachment 4

# Indications for Use Statement

**510(k) Number** K021972

**Device Name** FastPack® Total Testosterone Immunoassay

**Indications for Use** The FastPack® Total Testosterone Immunoassay is a paramagnetic particle, chemiluminescence immunoassay for the *in vitro* quantitative determination of testosterone in human serum. The FastPack® Total Testosterone Immunoassay is designed for use with the FastPack® Analyzer System. It is intended strictly for *in vitro* diagnostic use as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021972

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)