DEC 21 1999

K990258

Company Information

Quantech Ltd.
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(651) 647-6370
Thomas Witty, Ph.D. - Vice President, Research and Development

Contact Information

Robin J. Hellen, M.S.
Hellen Professional Services
(818) 709-5646

Product Name

Classification Name:	Human Chorionic Gonadotropin (hCG) Test Systems, Class II
Trade Name:	Quantech Total β-hCG Assay
Common Name:	β-hCG Test Kit

CLIA Categorization

We believe the Quantech Total β-hCG Assay to be moderately categorized based on previous classification of analogous tests.

Substantial Equivalence

The Quantech Total β-CG Assay is substantially equivalent to the AxSYM® Total β-hCG assay marketed by Abbott Laboratories since 1998.

Intended Use

The *Quantech Total β-hCG Assay* is intended to be used with EDTA stabilized plasma as aid in the early detection of pregnancy.

Device Description

The Quantech Total β-hCG assay is based on the principle of two site, or sandwich immunoassay in combination with surface plasmon resonance (SPR) surface mass measurement. Each test module contains a solid phase anti-β-hCG monoclonal antibody immobilized onto a gold surface. An anti-hCG polyclonal antibody, used to enhance the specific detection by SPR is introduced sequentially.

Comparison of Technological Characteristics

The Quantech Total β-hCG Assay is similar to the AxSYM® Total β-hCG assay as follows. Both assays are in vitro "sandwich" immunometric assays for the quantitative measurement of total β-hCG. Additionally, both assays use antibody to β-hCG coated on a solid support, and both instruments utilize a microprocessor for instrument control, data acquisition, and data reduction.

Summary of Non-Clinical Performance Data

Dilution Linearity/Parallelism - The parallelism study was conducted to evaluate the linearity of the Quantech Total β-hCG Assay. Plasma samples were separately spiked with hCG and serially diluted with corresponding unspiked serum. The average percent of expected was 101%.

Recovery - Accuracy of the Quantech Total β-hCG Assay was calculated from test results as the percentage of added analyte, corrected for endogenous analyte, recovered by the assay. After correcting for endogenous β-hCG content, the average recovery was 104%.

Analytical Sensitivity - Multiple replicates of zero samples (male plasma) were assayed to determine the minimum quantity of β-hCG detectable by the Quantech Assay. The average SPR signal shift plus two standard deviations (2 S.D.) was calculated and translated into a dose. The calculated analytical sensitivity of the Quantech Total β-hCG assay is 8.8 mIU/mL.

Precision - The INTRAASSAY precision was determined by evaluating three pools using 10 different biosensors in one day. The mean B-hCG concentrations (with % C. V.) were 38.7 (15.8%), 132 (12.8%), and 617 (4.5%) mIU/mL for the low, medium and high pools, respectively.

The INTERASSAY precision was determined by evaluating three pools in triplicate on different days. The mean β-hCG concentrations (with % C.V.) were 41.3 (13.0%), 156 (11.4%), and 746 (7.0%) mIU/mL for the low, medium and high pools, respectively.

TOTAL IMPRECISION was determined from the interassay data, and is a combination of results from multiple runs on multiple days. The mean β-hCG concentrations (with % C.V.) were 41.3 (18.5%), 156 (14.8%), and 746 (9.4%) mIU/mL for the low, medium and high pools, respectively.

Summary of Non-Clinical Performance Data (Cont.)

Interfering Substances - Physiological interference was evaluated by spiking a plasma pool of hCG with hemoglobin, bilirubin and triglycerides at levels at least ten times the highest expected physiological concentration. The percent recovery of β-hCG was determined to be acceptable in all three solutions based on the overlapping expected ranges before and after spiking and no interference was noted by the endogenous substances in the Quantech Total β-hCG Assay.

Hook Effect - Samples well beyond the standard curve range were assayed. No high dose hook effect was observed. Therefore, the Quantech Total β-hCG Assay does not give erroneously low results for greatly elevated samples up to at least 100,000 mIU/mL.

Summary of Clinical Performance Data

Normal Range - Testing of apparently healthy, non-pregnant individuals demonstrated that the Quantech Total β-hCG Assay and the predicate device perform similarly at and below the clinically accepted cut-off of 25 mIU/mL hCG. Both methods are also compatible with published expected values. The mean of the normals was below the detection limit of both assays.

The Quantech device demonstrates no false positive results with these apparently healthy individuals and is in 100% agreement with the predicate device.

Patient Sample Correlation - Results from human samples with values distributed throughout the quantitative range of the Quantech Total β-hCG Assay, were compared with those obtained with a commercially available method (fluorogenic ELISA). The correlation coefficient was 0.98 (slope = 0.86, y-intercept = 7.2 mIU/mL).

Conclusions Drawn From Performance Tests

The Quantech Total β-hCG Assay provides results which are internally accurate, unaffected by ordinary variation of sample matrix and equivalent to the results obtained using the approved device in a valid laboratory setting.

Additionally, both clinically-based studies (normal range, patient correlation) demonstrated essential equivalence between the two devices as measured by their correlation and the degree to which assay results are linearly related to one another over a broad range of values. Likewise, the normal range evaluation provided empirical evidence that the assay value is similar for both devices, and in agreement with published data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 1999

BioCheck, Inc.
c/o Ms. Robin J. Hellen, M.S.
Hellen Professional Services
9418 Lasaine Avenue
Northridge, California 91325

Re: K990258
Trade Name: Quantech Total β-hCG Assay
Regulatory Class: II
Product Code: NAL
Dated: November 18, 1999
Received: November 19, 1999

Dear Ms. Hellen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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

Statement for Indications for Use

510(k) Number (if known): K990258

Device Name: *Quantech Total β-hCG Assay*

Indications for Use:

The Quantech Total β-hCG Assay is intended to be used for the quantitative determination of human chorionic gonadotropin in EDTA-stabilized plasma, for the early detection of pregnancy.

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Joan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990258

Prescription Use: ✓ **OR** **Over the Counter Use:** _____