

Company Information

Quantech Ltd.
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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: Myoglobin Immunological Test System, Class II
Trade Name: Quantech Myoglobin Assay
Common Name: Myoglobin Test Kit

Substantial Equivalence

The Quantech Myoglobin Assay is substantially equivalent to the OPUS[®] Myoglobin assay marketed by Behring Diagnostics Inc. since 1991.

Intended Use

The *Quantech Myoglobin Assay* is intended to be used as an aid in diagnosing myocardial infarction in patients exhibiting chest pain. It is intended to be used in conjunction with EKG, and physician examination, as well as possibly other biochemical blood tests to rule in or out origin of the chest pain.

Device Description

The Quantech Myoglobin Assay is based on the principle of two site, or sandwich immunoassay in combination with SPR surface mass measurement. Each test module contains a solid phase anti-myoglobin monoclonal antibody immobilized onto a gold surface. An anti-myoglobin enzyme conjugate solution and wash solution are used to enhance the specific detection of myoglobin.

The Quantech assay utilizes myoglobin-specific antibody to capture the myoglobin in the sample. This is followed by a quantitation of the surface mass increase using surface plasmon resonance (SPR), to measure the myoglobin in serum.

Comparison of Technological Characteristics

The Quantech Myoglobin Assay is similar to the Opus[®] Myoglobin assay (K915850) as follows. Both assays are in vitro immunological assays for the quantitative measurement of human myoglobin. Additionally, both assays use antibody to myoglobin 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 MYOGLOBIN Assay. Serum samples were separately spiked with myoglobin and serially diluted with corresponding unspiked serum. The average percent of expected was 107% with individuals varying from 101-115%.

Recovery - Accuracy of the Quantech MYOGLOBIN Assay was calculated from test results as the percentage of added analyte, corrected for endogenous analyte, recovered by the assay. After correcting for endogenous myoglobin content, the average recovery was 108%.

Analytical Sensitivity - Multiple duplicates of zero samples (blank) were assayed to determine the minimum quantity of myoglobin 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 myoglobin assay is 6 ng/mL.

Precision - INTRAASSAY variation was calculated by replicate evaluation of three levels of sera in one day. The mean myoglobin concentrations (with % C.V.) were 61 (11.9%), 131 (9.7%), and 378 (9.5%) ng/mL for the low, medium and high pools, respectively.

The INTERASSAY precision was determined by evaluating three pools (different from INTRAASSAY pools) in triplicate on different days. The mean myoglobin concentrations (with % C.V.) were 51 (7.1%), 110 (6.2%), and 219 (10.3%) ng/mL for the low, medium and high pools, respectively.

Interfering Substances - Physiological interference was evaluated by spiking a serum pool of myoglobin with bilirubin, triglycerides and hemoglobin at levels ten times the highest expected physiological concentration. The percent recovery of myoglobin was determined to be acceptable in all three solutions and no interference was noted by the endogenous in the Quantech Myoglobin assay.

Hook Effect - Samples well beyond the standard curve range were assayed. No high dose hook effect was observed. Therefore, the Quantech Myoglobin Assay does not give erroneously low results for grossly elevated samples up to at least 10,000 ng/ml.

Summary of Clinical Performance Data

Normal Range - Testing of apparently healthy individuals demonstrated a normal range consistent with published literature (male 19-92 ng/mL and female 12-76 ng/mL). The overall normal range observed with the Quantech MYOGLOBIN assay was **14-70 ng/mL** with 16-70 ng/mL for males and 17-55 ng/mL observed for females.

Patient Sample Correlation - Results from human samples with values distributed throughout the quantitative range of the Quantech MYOGLOBIN Assay, were compared with those obtained with a commercially available method (fluorogenic ELISA). The correlation coefficient was 0.970 (slope = 1.16, y-intercept = 7.94 ng/mL).

Conclusions Drawn From Performance Tests

The Quantech Myoglobin 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 log of the assay value is statistically similar for both devices, and in agreement with published data.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 29 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Quantech, Ltd.
. C/O Robin J. Hellen, M.S.
Hellen Professional Services
9418 Lasaine Avenue
Northridge, California 91325

Re: K981536
Quantech Myoglobin Assay
Regulatory Class: II
Product Code: DRD
Dated: April 28, 1998
Received: April 29, 1998

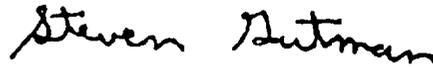
Dear Ms. Hellen:

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 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.

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 "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,



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

QUANTECH MYOGLOBIN ASSAY

Premarket Notification

PART I - 510(k) Information

III. Statement for Indications for Use

510(k) Number (if known): K981536

Device Name: Quantech Myoglobin Assay

Indications for Use:

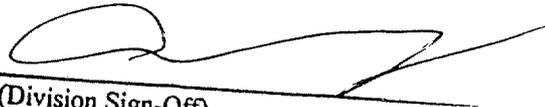
The *Quantech Myoglobin Assay* is intended to be used as an aid in diagnosing myocardial infarction in patients exhibiting chest pain. It is intended to be used in conjunction with EKG, and physician examination, as well as possibly other biochemical blood tests to rule in or out non-cardiac damaging origin of the chest pain.

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

Prescription Use:

OR

Over the Counter Use:


(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K981536