

AUG 19 1998



Smart Solutions

K982469

HiChem

DIAGNOSTICS

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS INFORMATION

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

HiChem Cholesterol Reagent is intended for the quantitative determination of total cholesterol in serum and plasma. Measurements of total cholesterol are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

The HiChem Cholesterol Reagent determines cholesterol through the enzymatic action of cholesterol esterase, cholesterol oxidase and peroxidase. The resulting increase in absorbance at approximately 500 nm is proportional to the cholesterol concentration in the sample.

The HiChem Cholesterol Reagent is an adaptation of the method first described by Allain and is intended for use with manual spectrophotometers or clinical analyzers which can automate the required manipulations.

The HiChem Cholesterol Reagent is substantially equivalent to the Beckman® SYNCHRON® Systems Cholesterol Reagent, product no. 467825, manufactured by Beckman® Instruments, Brea, CA. All three reagents support the same intended use and produce equivalent results with the same clinical purpose. In addition, they are all based on the same methodology which determines total cholesterol through the enzymatic action of cholesterol esterase and cholesterol oxidase.

The effectiveness of the manual procedure is shown by the recovery of linearity standards, the precision of control recoveries, the comparison of serum and plasma recoveries to the Beckman® Cholesterol Reagent and the validation of the chemical additives and sensitivity claims.

The recovery of total cholesterol using HiChem Cholesterol Reagent as a manual procedure is linear from 5 mg/dL to 750 mg/dL as shown by the recovery of linearity standards which span the claimed linear range. Regression statistics, comparing mean standard recoveries which range from 5 to 881 mg/dL and standard factors which range from 0 to 892, are shown below.

$$(\text{HiChem Recoveries}) = 3.7 \text{ mg/dL} + 0.975 \times (\text{Standard Factors}), \quad r^2 = 1.000, \quad \text{sy.x} = 4.11 \text{ mg/dL}, \quad \text{df} = 11$$

Precision, demonstrated by replicate assay of commercially available control sera, is shown below.

Specimen	n	mean	within-run SD	total SD
Serum control 1	29	109 mg/dL	0.85 mg/dL	0.92 mg/dL
Serum control 2	30	226 mg/dL	1.46 mg/dL	1.90 mg/dL
Serum control 2	30	501 mg/dL	3.12 mg/dL	4.47 mg/dL

Cholesterol recoveries of 113 mixed serum and plasma specimens are compared between the HiChem manual procedure and the Beckman® Cholesterol Reagent used on the Synchron CX® Systems. Least squares regression statistics are shown below.

Serum/ Plasma Comparisons:

$$(\text{HiChem Results}) = 12 \text{ mg/dL} + 0.957 \times (\text{Beckman}^\circledast \text{ Results}) \quad r^2 = 0.966 \quad \text{s(y.x)} = 8.1$$

The use of the anticoagulants EDTA, citrate, oxalate, fluoride and heparin are shown to be acceptable chemical additives by comparison of spiked and unspiked serum pools. In all cases, the biases produced by the additive were less than 2.5 mg/dL cholesterol.

The detection limit claim of 5 mg/dL is documented through the repetitive assay of a cholesterol standard. The observed detection limit, calculated as three standard deviations of a 30 replicate within run precision study, is 3.2 mg/dL and is below the claimed limit.

The effectiveness of the HiChem secondary reagent application for the Beckman® SYNCHRON CX® Systems is shown by the recovery of linearity standards, the precision of control recoveries, the recovery of serum controls over both the calibration stability and on-board stability claims, the validation of the chemical additives and sensitivity claims, and the comparison of patient specimen recoveries to the Beckman® SYNCHRON® Systems Cholesterol Reagent.

The recovery of total cholesterol using the HiChem Cholesterol Reagent on the SYNCHRON CX® Systems is linear from 5 mg/dL to 750 mg/dL as shown by the recovery of linearity standards which span the claimed linear range. Regression statistics, comparing mean standard recoveries which range from 0 to 875 mg/dL and standard factors which range from 0 to 918, are shown below.

$$(\text{HiChem Recoveries}) = -1.0 \text{ mg/dL} + 0.964 \times (\text{Standard Factors}), \quad r^2 = 0.999, \quad s_{y.x} = 8.9 \text{ mg/dL}, \quad df = 11$$

Precision, demonstrated by replicate assay of urine pools and commercially available control sera, is shown below.

Specimen	n	mean	within-run SD	total SD
Serum control 1	60	105 mg/dL	1.8 mg/dL	1.4 mg/dL
Serum control 2	60	217 mg/dL	1.2 mg/dL	2.5 mg/dL
Serum control 3	60	504 mg/dL	2.8 mg/dL	2.5 mg/dL

Cholesterol recoveries of 154 mixed serum and plasma specimens are compared between the HiChem and Beckman® CHOL Reagents on the SYNCHRON CX® Systems. Least squares regression statistics are shown below.

Serum/ Plasma Comparisons:

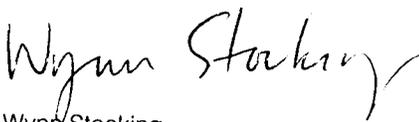
$$(\text{HiChem Results}) = -3.6 \text{ mg/dL} + 0.993 \times (\text{Beckman® Results}) \quad r^2 = 0.983 \quad s_{(y.x)} = 6.1$$

The use of the anticoagulants EDTA, citrate, oxalate, fluoride and heparin are shown to be acceptable chemical additives by comparison of spiked and unspiked serum pools. In all cases, the bias due to the addition of anticoagulants is less than 1 mg/dL cholesterol and statistically insignificant.

The detection limit claim of 5 mg/dL is documented through the repetitive assay of a cholesterol standard. The observed detection limit, calculated as three standard deviations of a 30 replicate within run precision study, is 2.7 mg/dL and is below the claimed limit.

The 14 day onboard calibration stability and the 30 day on board reagent stability claims are documented through the assay of serum controls over the claimed periods. In all cases, the changes in cholesterol recoveries over the test periods are less than 2.6% and less than the manufacturer's 3% within run precision claim for the SYNCHRON® Analyzer.

The HiChem Cholesterol Reagent is substantially equivalent to the Beckman® SYNCHRON® Systems Cholesterol Reagent, product no. 467825, manufactured by Beckman® Instruments, Brea, CA.



Wynne Stocking
Manager of Regulatory Affairs
HiChem Diagnostics



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 19 1998

Wynn Stocking
Manager, Regulatory Affairs
HiChem Diagnostics
231 North Puente Street
Brea, California 92821

Re: K982469
HiChem Cholesterol Reagent
Regulatory Class: I
Product Code: CHH
Dated: July 14, 1998
Received: July 15, 1998

Dear Mr. Stocking:

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 (Pre-market 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 pre-market 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.

Page 2

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/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

510(k) Number (if known): K982469

Device Name: HiChem Cholesterol Reagent Kit

Indications For Use:

HiChem Cholesterol Reagent is intended for the quantitative determination of total cholesterol in serum and plasma for the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

This reagent is intended to be used in a professional setting or by trained personnel and is not intended for home use.

Respectfully,

Wynd Stocking

Wynd Stocking
Regulatory Affairs Manager
HiChem Diagnostics

6 August, 1998

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

San W. Montgomery

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K982469

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)