ADMIN 3.0 Axis-Shield Liquid Stable (LS) 2-Part HOMOCYSTEINE REAGENT 510(k) SUMMARY

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.

The assigned 510(k) number is: k083222

JUL 31 2009

Submission correspondent:

Dr Claire Dora
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The Technology Park
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Device Name: Axis-Shield Liquid Stable (LS) 2-Part HOMOCYSTEINE REAGENT
Classification Name: Urinary Homocystine (Nonquantitative) Test System
Trade Name: Axis-Shield Liquid Stable (LS) 2-Part HOMOCYSTEINE REAGENT
Common Name: Homocysteine Enzyme Assay
Governing Regulation: 21 CFR 862.1377
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: LPS

Legally marketed device to which equivalency is claimed:

CATCH Incorporated, Liquid Stable (LS) 2-Part Homocysteine Reagent, k062808.

Intended Use of Device:

The Liquid Stable (LS) 2-Part Homocysteine Reagent is intended for *in vitro* quantitative determination of total homocysteine in human serum and plasma. The device can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

Description of Device:

The Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent Test System includes two reagents and two calibrators.
The first reagent (Reag 1) includes Lactate dehydrogenase (LDH), Serine, nicotinamide adenine dinucleotide reduced di-sodium salt (NADH), tris [2-carboxyethyl] phosphine (TCEP) reductant, with buffers and stabilizers (Trizma Base and Trizma Hydrochloride), and preservative (Sodium Azide).
The second reagent (Reag2) includes Cystathionine beta-Synthase (CBS) and Cystathionine beta-Lyase (CBL) cycling enzymes with preservative (sodium azide).
The Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent kit will also include two calibrators; Calibrator "0" (0 µmol/L) and Calibrator "28" (28 µmol/L).

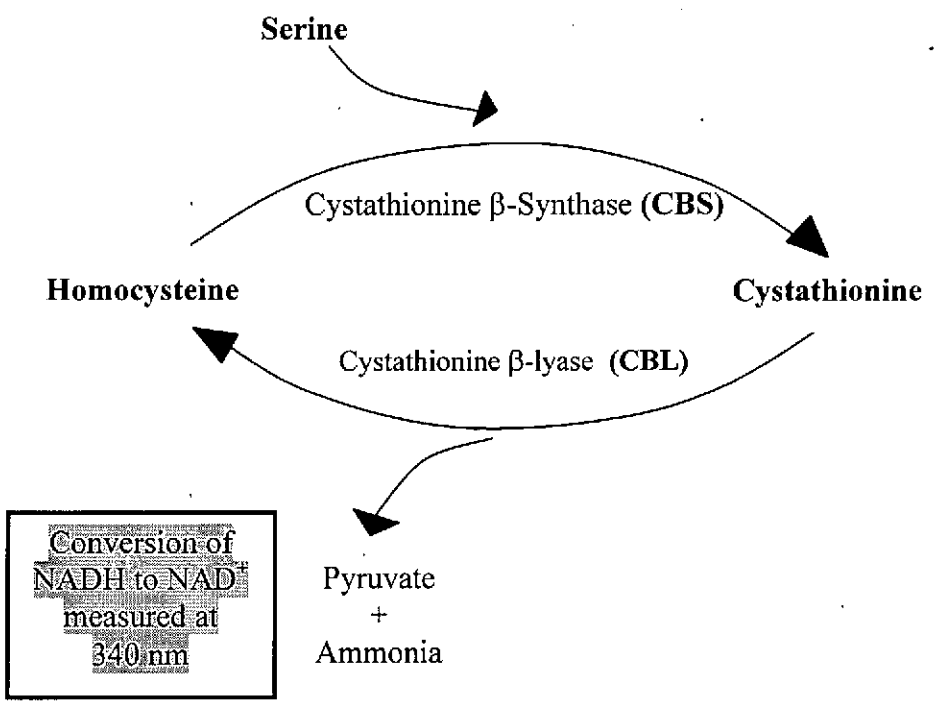
Principle of the Assay

Bound or dimerised homocysteine (oxidised form) is reduced to free homocysteine, which then reacts with serine catalysed by cystathionine beta-synthase (CBS) to form cystathionine. Cystathionine in turn is broken down by cystathionine beta-lyase (CBL) to form homocysteine, pyruvate and ammonia. Pyruvate is then converted by lactate dehydrogenase (LDH) to lactate with nicotinamide adenine dinucleotide (NADH) as coenzyme. The rate of NADH conversion to NAD^+ is directly proportional to the concentration of homocysteine (Δ A340 nm).

Reduction: Dimerised homocysteine, mixed disulfide, and protein-bound forms of HCY in the sample are reduced to form free HCY by the use of tris [2-carboxyethyl] phosphine (TCEP).

	TCEP	
HCY-SS-HCY (dimerised homocysteine)	----------→	
R1-SS-HCY (R1 = thiol residue)	----------→	Homocysteine (HCY)
Protein-SS-HCY	----------→	

Enzymatic Conversion: Free HCY is converted to cystathionine by the use of cystathionine beta-synthase and excess serine. The cystathionine is then broken down to homocysteine, pyruvate and ammonia. Pyruvate is converted to lactate via lactate dehydrogenase with NADH as coenzyme. The rate of NADH conversion to NAD+ (Δ A340 nm) is directly proportional to the concentration of homocysteine.



Comparison of Technological Characteristics:

The Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent and CATCH Incorporated Liquid Stable (LS) 2-Part Homocysteine Reagent are both two reagent clinical chemistry enzymatic assays for the quantitative determination of total homocysteine in human serum and plasma. The reagent and calibrator formulations and the assay methodology of the Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent assay are essentially equivalent to the CATCH Incorporated Liquid Stable (LS) 2-Part Homocysteine Reagent assay. The difference between the assays is the concentration of Cystathionine beta–Synthase in Reagent 2. The Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent assay contains 0.748 KU/L Cystathionine beta–Synthase, whereas the CATCH Incorporated Liquid Stable (LS) 2-Part Homocysteine Reagent contains >20 KU/L Cystathionine beta–Synthase.

Summary of Non-Clinical Performance:

The Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent assay is substantially equivalent to CATCH Incorporated Liquid Stable (LS) 2-Part Homocysteine Reagent assay in terms of precision, limit of detection (sensitivity) and specificity (interferences) as demonstrated in non-clinical performance data in this 510(k) submission.

Summary of Clinical Performance:

The Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent assay demonstrated substantially equivalent performance to the CATCH Incorporated Liquid Stable (LS) 2-Part Homocysteine Reagent assay indicated by a method comparison study.

Passing-Bablok linear regression method comparison was performed on 94 plasma specimens in the range of 6.5 to 49.0 µmol/L homocysteine. The Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent assay versus the CATCH Incorporated Liquid Stable (LS) 2-Part Homocysteine Reagent gave a slope of 0.991 (95% Confidence interval 0.980 to 1.001) and an intercept of 0.165 (95% Confidence interval 0.031 to 0.290). The Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent assay versus CATCH Incorporated Liquid Stable (LS) 2-Part Homocysteine Reagent gave an r value of 1.00 (95% Confidence interval 1.00 to 1.00). The average percent bias exhibited by Axis-Shield Liquid Stable 2-Part Homocysteine Reagent versus CATCH Incorporated Liquid Stable 2-Part Homocysteine Reagent in this study was 0.01% (95% Confidence interval of the average percent bias is -0.10 to 0.07%).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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Axis-Shield Diagnostics Ltd.
c/o Dr. Claire Dora
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Dundee, Scotland
United Kingdom DD2 1XA

JUL 31 2009

Re: k083222
Trade/Device Name: Axis-Shield Liquid Stable (LS) 2-Part HOMOCYSTEINE REAGENT
Regulation Number: 21 CFR § 862.1377
Regulation Name: Urinary Homocysteine (Nonquantitative) Test System
Regulatory Class: Class II
Product Code: LPS, JIT
Dated: June 11, 2009
Received: June 16, 2009

Dear Dr. Claire Dora:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k083222

Device Name: Axis-Shield Liquid Stable (LS) 2-Part HOMOCYSTEINE REAGENT

For *in vitro* diagnostic use.

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The Liquid Stable (LS) 2-Part Homocysteine Reagent is intended for *in vitro* quantitative determination of total homocysteine in human serum and plasma. The device can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k083222