AUG 11 2008

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: K080634

Submitter's Name and Address

Beckman Coulter, Inc.
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Chaska, MN 55318
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Contact: Lynn Weist

Date Prepared: June 5, 2008

Device Names

Proprietary Name: sTfR, sTfR Calibrators, and sTfR QC on the Access® Immunoassay Systems

Common Name: Immunological test for soluble transferrin receptor

Classification Name: Transferrin Immunological Test

Predicate Device

Quantikine® IVD® sTfR ELISA
R & D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413

510(k) Number: K970718

Device Description

The Access sTfR reagent, calibrators, controls, and the Access Immunoassay Analyzers (Access, Access 2, Synchron LXi 725, UniCel DxC 600i, UniCel DxI 600, and UniCel DxI 800) comprise the Access Immunoassay Systems for the quantitative determination of soluble transferrin receptor in human serum and plasma.

Intended Use

The Access sTfR assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of soluble transferrin receptor (sTfR) levels in human serum and plasma (heparin) using the Access Immunoassay Systems. This assay is intended as an aid in the diagnosis of Iron Deficiency Anemia (IDA), and for the differential diagnosis of IDA and Anemia of Chronic Disease (ACD).

This assay may also be used in conjunction with a ferritin measurement to provide a calculated sTfR/log ferritin index. This index is intended as an aid in the diagnosis of IDA, and for the differential diagnosis of IDA and ACD.

The Access sTfR Calibrators are intended to calibrate the Access sTfR assay for the quantitative determination of soluble transferrin receptor levels in human serum and plasma (heparin) using the Access Immunoassay Systems.

The Access sTfR QC is intended for monitoring system performance of the Access sTfR assay.

Comparison of Technological Characteristics

Attribute	Quantikine IVD sTfR ELISA	Access sTfR
Intended Use (Assay)	For the quantitative determination of soluble transferrin receptor.	For the quantitative determination of soluble transferrin receptor. May also be used in conjunction with a ferritin measurement to provide a calculated sTfR/log ferritin index.
Assay Format	Two site, sandwich assay; Enzyme linked immunosorbent assay (ELISA)	Two site, sandwich assay; Sequential two-step immunoenzymatic chemiluminescent immunoassay

Attribute	Quantikine IVD sTfR ELISA	Access sTfR
Test System	Manual; Polystyrene microplate coated with mouse monoclonal antibody against sTfR	Automated; Paramagnetic particles coated with mouse monoclonal antibody against sTfR. Uses the same mouse monoclonal antibodies against sTfR in the capture phase and signal phase as the predicate device.
Detection System	Chromogenic reaction	Utilizes dioxetane-based chemiluminescent substrate; measures light production from a chemiluminescent reaction.
Calibrators	Calibrators are comprised of purified plasma sTfR at 6 levels (0, 3, 7, 20, 40, and 80 nmol/L)	Calibrators are comprised of natural sTfR at 6 levels (0, 3, 10, 30, 80, and 150 nmol/L) in a buffered matrix.
Controls	QCs are provided as lyophilized human sTfR at 3 levels (~7.5, ~20, ~50 nmol/L) in a buffered matrix.	QCs are human sTfR provided as a liquid at 3 levels (~10, ~25, ~90 nmol/L) in a buffered matrix.

Summary of Analytical Studies

Imprecision: Access sTfR exhibits total precision ≤ 8% at concentrations greater than 9 nmol/L, and total SD ≤ 0.72 nmol/L at concentrations ≤ 9 nmol/L. Assay precision was tested at concentrations from approximately 1 to 140 nmol/L. Within run precision ranged from 1.6 to 5.2% CV for samples > 9 nmol/L, and SD 0.04-0.22 nmol/L for samples with concentrations ≤ 9 nmol/L. Total precision ranged from 2.6 to 5.4% CV for samples > 9 nmol/L, and SD 0.08-0.38 nmol/L for samples with concentrations ≤ 9 nmol/L.

Analytical Sensitivity: The lowest detectable level of soluble transferrin receptor distinguishable from zero (Access sTfR Calibrator S0) is ≤0.05nmol/L.

Dilution Recovery (Linearity): Dilution recovery studies were performed by diluting multiple serum and plasma (heparin) samples at various levels with Access sTfR Calibrator S0 and Wash Buffer II. Sample mean recovery values for all serum and plasma samples were within the range 100±15%, with at least 92% of individual mean recovery values within the range of 100±20%.

Methods Comparison (External Site):
A comparison of sTfR values from 271 samples, ranging from approximately 10-80 nmol/L, run with both the Access sTfR assay and the R&D Systems Quantikine IVD sTfR ELISA demonstrated acceptable correlation with the following statistical data: y=0.8901X + 0.6853, r=0.96

Analytical Specificity: There was no significant interference from therapeutic drugs or similar compounds in the Access sTfR assay. In addition, there was no significant interference from potential sample contaminants (bilirubin, total protein, hemoglobin, and triglycerides) or from rheumatoid factor at concentrations up to 850 IU/mL.

Stability: sTfR reagents are stable for 28 days after opening, calibrators are stable for 90 days after opening, and controls are stable for 90 days after opening. The calibration curve is stable for 28 days.

Summary of Clinical Studies

A prospective multicenter clinical trial was conducted to test the effectiveness of Access sTfR and the sTfR/log ferritin index in differentiation of iron deficiency anemia (IDA) and anemia of chronic disease (ACD).

sTfR: Sensitivity is optimized (detection of 86% of patients with IDA or ACD + IDA with 49.1% specificity) by using a cutoff of 21nmol/L, and this is the recommended cutoff. sTfR values greater than or equal to 21 nmol/L are predictive of iron deficiency anemia.

sTfR/log ferritin index: Optimal sensitivity and specificity (detection of 80.7% of patients with IDA or ACD + IDA with 82.5 % specificity) are obtained using a cutoff of 14 (using nmol/L for sTfR in sTfR Index calculations), and this is the recommended cutoff. sTfR Index values greater than or equal to 14 are predictive of iron deficiency anemia.

Conclusion

Access sTfR, sTfR Calibrators, and sTfR QC on the Access Immunoassay Systems is substantially equivalent to R & D Systems Quantikine IVD sTfR ELISA for the measurement of soluble transferrin receptor in serum or plasma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 11 2008

Beckman Coulter, Inc.
c/o Ms Lynn Weist
Staff Regulatory Affairs Specialist
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

Re: k080634
Trade/Device Name: Access® sTfR, Access® sTfR Calibrators and Access® sTfR QC
Regulation Number: 21 CFR 866.5880
Regulation Name: Transferrin immunological test system
Regulatory Class: Class II
Product Code: DDG, JIT, JJX
Dated: July 29, 2008
Received: July 30, 2008

Dear Ms. Weist:

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). This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. 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 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K080634

Device Name: Access® sTfR, Access® sTfR Calibrators, Access® sTfR QC

Indications For Use:
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The Access sTfR QC is intended for monitoring system performance of the Access sTfR assay.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K080634