K093908

Summary of Safety and Effectiveness Information
CCPoint® kit

DEC 1 2010

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Date of preparation: November 30, 2010

II. Device/Trade name: CCPoint®
Common name: Anti-CCP test
Governing regulation: 866.5775
Device classification: Class II
Classification panel: Immunology
Product code: NHX

III. Description of Device: The Euro-Diagnostica CCPoint® test is a visually read, qualitative rapid lateral flow test for the detection of IgG antibodies to Cyclic Citrullinated Peptides (CCP) in human serum or plasma. The results of the test are to be used as an aid to the diagnosis of Rheumatoid Arthritis (RA), in conjunction with other laboratory and clinical findings. For use by trained laboratory professionals. For in vitro diagnostic use.

The CCPoint® test is a colloidal gold based lateral flow immunoassay. Reactive cyclic citrullinated peptides are immobilised as a discrete line on a porous membrane located in the test zone.
The detection reagent, consisting of colloidal gold particles conjugated to anti-human IgG, is deposited within the device onto the conjugate pad.
In the assay procedure, a sample of serum or plasma is added to the sample port. A blood cell separation membrane transfers the sample fluid onto the porous membrane. After a short incubation running buffer is added to the buffer port. This buffer mobilizes the colloidal gold particles from the conjugate pad. The gold particles and the sample move by capillary force across the membrane.

If the sample contains anti-CCP antibodies they will bind to the peptide-antigens and a red line will appear in the test zone (marked T). If the sample does not contain any anti-CCP antibodies no line will appear. With any sample a red control line should appear in the control zone (marked C). The control ensures that the coated colloidal gold is still active.

IV. Legally marketed device to which equivalence is claimed: Immunoscan RA anti-CCP test kit, K052133.

V. Intended use of the device: The Euro-Diagnostica CCPoint® test is a visually read, qualitative rapid lateral flow test for the detection of IgG antibodies to Cyclic Citrullinated Peptides (CCP) in human serum or plasma. The results of the test are to be used as an aid to the diagnosis of Rheumatoid Arthritis (RA), in conjunction with other laboratory and clinical findings. For use by trained laboratory professionals. For in vitro diagnostic use.

VI. Comparison of technological characteristics: CCPoint® is a qualitative rapid lateral flow test. Immunoscan RA anti-CCP is an enzyme-linked immunosorbent assay (ELISA).

Similarities

Item	Device	Predicate Device
	CCPoint®	**Immunoscan RA anti-CCP**
Intended use	The results of the test are to be used as an aid to the diagnosis of Rheumatoid Arthritis (RA), in conjunction with other laboratory and clinical findings.	The results of the assay are to be used as an aid to the diagnosis of Rheumatoid Arthritis (RA), in conjunction with other laboratory and clinical findings.
Intended user	For use by trained laboratory professionals	For use by health care professionals
Type of test	Qualitative	Qualitative and semi-quantitative
Analyte measured	Anti-CCP	Anti-CCP
Coated antigen	Synthetic CCP	Synthetic CCP
Conjugate	Anti-human IgG	Anti-human IgG

Differences

Item	Device	Predicate Device
	CCPoint®	**Immunoscan RA anti-CCP**
Method	Lateral flow	ELISA
Test matrix	Serum and plasma	Serum
Type of test	Qualitative	Qualitative and semi-quantitative
Sample dilution	Undiluted	Diluted 1:50
Measuring of results	Visually read	ELISA plate reader

VI. Summary of performance: CCPoint® is substantially equivalent to the Immunoscan RA anti-CCP test kit. Equivalence is demonstrated by the following comparative results.

Table 1a. Percent agreement of the CCPoint® compared to the Immunoscan RA anti-CCP test kit. A total of 1062 frozen retrospective sera were assayed. 606 from RA patients and 456 samples were apparently healthy blood donors.

		Predicate device (Immunoscan RA anti-CCP)	
New device	N = 1052	Positive	Negative
CCPoint®	Positive	444	4
	Negative	2	612

Positive Percent Agreement:	444/446	= 99.6%	95% CI = 98.4 - 99.9%
Negative Percent Agreement:	612/616	= 99.4%	95% CI = 98.3 - 99.8%
Overall Percent Agreement:	1056/1062	= 99.4%	95% CI = 98.8 - 99.8%

Table 1b.Percent agreement of the CCPoint® compared to the Immunoscan RA anti-CCP test kit. Samples extracted from table 1a in the range 15-1600 U/mL with the ELISA

		Predicate device (Immunoscan RA anti-CCP)	
New device	N = 399	Positive	Negative
CCPoint®	Positive	377	4
	Negative	2	16

Positive Percent Agreement:	377/379	= 99.5%	95% CI = 98.1 - 99.9%
Negative Percent Agreement:	16/20	= 80.0%	95% CI = 56.3 - 94.3%
Overall Percent Agreement:	393/399	= 98.5%	95% CI = 96.8 - 99.4%

The 95% confidence interval (CI) was calculated using the exact method.

Table 2. Clinical sensitivity and specificity. A total of 1815 frozen retrospective sera with clinical characterisation were assayed. The following table summarizes the results.

	n	negative	positive	Sensitivity
Patients with clinically defined RA	596	158	438	73.5%

Clinical sensitivity

RA	438/596	= 73.5%	95% CI = 69.9 - 77.0%

Clinical specificity for the CCPoint® for non-RA diseased patients and asymptomatic individuals (healthy blood donors).

Control and Disease groups	Total number	CCPoint positive	CCPoint negative	Specificity
Blood donors	**456**	**4**	**452**	**99.1%**
non-RA arthritis	**187**	**0**	**187**	**100%**
Psoriatic arthritis	43	0	43	
IBD (CU/Crohn)	103	0	103	
Gout	23	0	23	
CPPD	7	0	7	
Oligoarthritis	7	0	7	
Monoarthritis	3	0	3	
Palindrome arthritis	1	0	1	
Spondylarthropathy incl. AS	**21**	**0**	**21**	**100%**
Systemic collagen disease	**126**	**3**	**123**	**97.6%**
SLE/lupus like/UCTD	64	2	62	
Sjögren's syndrome	20	1	19	
PM/DM	17	0	17	
MCTD	15	0	15	
Systemic sclerosis	10	0	10	
Vasculitis/PMR	**59**	**0**	**59**	**100%**
PMR	19	0	19	
Vasculitis (anti-MPO, anti-PR3)	40	0	40	
Degenerative disease	**77**	**0**	**77**	**100%**
Osteoarthritis	77	0	77	
Pain syndrome/miscellaneous	**57**	**1**	**56**	**98.2%**
FMS	22	0	22	
Arthralgia/myalgia	28	1	27	
Enthesopathy	4	0	4	
Low back pain	3	0	3	
Other non-RA autoimmune diseases	**49**	**0**	**49**	**100%**
Thyroid disorder (anti-TPO)	20	0	20	
Multiple Sclerosis	20	0	20	
IDDM	9	0	9	
Infectious diseases	**108**	**3**	**105**	**97.2%**
Epstein Barr Virus	5	1	4	
Parvovirus	5	0	5	
Mycoplasma	9	0	9	
Toxoplasma	6	0	6	
Tuberculosis	3	0	3	
Yersinia	18	0	18	
Salmonella	11	1	10	
Chlamydia	5	1	4	
Malaria	3	0	3	
Borrelia	8	0	8	
Syphilis	5	0	5	

Infectious endocarditis	1	0	1	
Legionella	2	0	2	
AST	1	0	1	
Schistomiasis	1	0	1	
Rubella	4	0	4	
Chagas syndrome	1	0	1	
Staphylococcus aureus	10	0	10	
Helicobacter pylori	10	0	10	
Routine samples (not RA)	**79**	**2**	**77**	**97.4%**

IBD (CU/Crohn) = Inflammatory bowel disease (colitis ulcerosa/Crohn's disease)
CPPD = Calcium Pyrophosphate Deposition Disease
AS = Ankylosing spondylitis
SLE = Systemic lupus erythematosus
UCTD = Unclassified connective tissue disease
PM/DM = Polymyositis/Dermatomyositis
MCTD = Mixed connective tissue disease
PMR = Polymyalgia rheumatica
Anti-MPO = Anti-Myeloperoxidase
Anti-PR3 = Anti-Proteinase 3
FMS = Fibromyalgia syndrome
Anti-TPO = Anti-Thyroid peroxidase
IDDM = Insulin dependent diabetes mellitus
AST = Anti-Streptolysine test

Clinical specificity

Healthy controls (blood donors)	452/456	= 99.1%	95% CI = 97.8 - 99.8%
non-RA arthritis	187/187	= 100%	95% CI = 98.0 - 100%
Spondylarthropathy incl. AS	21/21	= 100%	95% CI = 83.9 - 100%
Systemic collagen disease	123/126	= 97.6%	95% CI = 93.2 - 99.5%
Vasculitis/PMR	59/59	= 100%	95% CI = 93.9 - 100%
Degenerative disease	77/77	= 100%	95% CI = 95.3 - 100%
Pain syndrome/miscellaneous	56/57	= 98.2%	95% CI = 90.6 - 100%
Other non-rheumatic autoimmune diseases	49/49	= 100%	95% CI = 92.7 - 100%
Infectious diseases	105/108	= 97.2%	95% CI = 92.1 - 99.4%
Routine samples (not RA)	77/79	= 97.4%	95% CI = 91.2 - 99.7%

The 95% confidence interval (CI) was calculated using the exact method.

Accuracy

Inter-assay performance of the CCPoint® assay was evaluated using negative, low positive and high positive samples for antibodies against anti-CCP. Six different samples tested eight times each, by three different persons. All results obtained were 100% in agreement with the expected results.

Batch-to-batch performance of the CCPoint® assay was evaluated using negative, low positive and high positive samples for antibodies against anti-CCP. Six different samples tested eight times each, with three different batches. All results obtained were 100% in agreement with the expected results.

Interference study

One anti-CCP positive sample and one anti-CCP negative sample were spiked to the following concentrations in serum samples (and with its corresponding blank); Bilirubin F at 18.8 mg/dL, Bilirubin C at 20 mg/dL, Haemoglobin at 453 mg/dL, Chyle at 23.6 U/dL and Rheumatoid Factor (IgM) at 55 IU/mL. The data indicates that the assayed concentrations do not affect the accuracy of the test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Euro-Diagnostica AB
c/o Robert Schiff, Ph.D., RAC, CQA(ASQ),
President & CEO, Schiff & Company
1129 Bloomfield Avenue
West Caldwell, NJ 07006

DEC 01 2010

Re: k093908
Trade Name: EuroDiagnostica CCPoint®
Regulation Number: 21 CFR 866.5775
Regulation Name: Rheumatoid factor immunological test system
Regulatory Class: Class II
Product Code: NHX
Dated: November 19, 2010
Received: November 22, 2010

Dear Dr. Schiff:

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 class II (Special Controls), 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). 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 Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

DEC 1 2010

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K093908
Device Name: CCPoint®

Indications for Use:

The Euro-Diagnostica CCPoint® test is a visually read, qualitative rapid lateral flow test for the detection of IgG antibodies to Cyclic Citrullinated Peptides (CCP) in human plasma or serum. The results of the test are to be used as an aid to the diagnosis of Rheumatoid Arthritis (RA), in conjunction with other laboratory and clinical findings. For use by trained laboratory professionals. For in-vitro diagnostic use.

Prescription Use X **Over-The-Counter Use**_____

(Per 21 CFR 801 Subpart D) (21 CFR 807 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

510K k093908