

送信者 :  
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Approval No. 21300AMY00003000

Certificate of Approval for Import of Medical Supplies

Name of the Firm : Ramco Japan Co., Ltd.

This certifies that the firm has obtained approval for import of its medical detection system which the firm applied on February 26, 1997 according to the Pharmaceutical Law (No.145, 1960 ) section 14 article 1 applied to section 23.

Date : January 12, 2001

Tsutomu Sakaguchi  
the Minister of Health and Welfare

Classification No. 744  
2720900001052

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Medical Supplies (manufacture and import) Application

Form

Classification No. : 101 Medical Supply (manufacture and import)  
application

Application submitted to the Ministry of Health and Welfare  
or Prefecture : 1 the Ministry of Health and Welfare

Date of Submission : 2090226 (February 26, 1997)

Applicant

Firm Code : 84002900

Control No. : 001

Address : Ohizumi Hights 5-7-726 Shinkanaoka-cho Sakai City  
Osaka, Japan

Name : Ramco Japan Co., Ltd.

the Parson in Charge : Masaji Ogura  
Director of the Technical Department

Phone & FAX No. : TEL 072-257-3309 FAX 072-257-3699

Resubmission Information

Resubmission No. : 2 (resubmission)

System Acceptance No. : 2720900001052

Date : 2121128 (November 28, 2000)

#### Classification of Application

Medical Supplies, Cosmetics, or Others : 1 Medical Supplies

Manufacture or Import : 2 Import

#### Name

Trade name : MycoDot,  
anti-mycobacterium (Lipoarabinomannan)  
antibody detection system kit

#### Components, Quantity and Quality

##### (1) Component reagents

1. Coagulative antigen
2. Signal generating reagent
3. Sample diluent
4. Undiluted rinse buffer
5. Positive control serum
6. Negative control serum

##### (2) Component related to reaction

Among reagents stated in (1)

(Coagulative Antigen)

Lipoarabinomannan                      7.0ng / test

(Signal Generating Reagent)

Colloidal Gold                              20.0ng / test

Protein A                                      0.4ng / test

#### Manufacture Method

According to the manufacturer

1. Coagulative antigen is manufactured with Lipoarabinomannan and others
2. Signal generating reagent is manufactured with colloidal gold and others
3. Sample diluent is manufactured with NaCl and others.
4. Undiluted rinse buffer is manufactured with NaCl and others.
5. Positive control serum is manufactured with rabbit serum.
6. Negative control serum is manufactured with rabbit serum.

The kit is consisted of all the reagents (1, 2, 3, 4, 5, 6) stated above. Each reagent may be imported separately for supplement purpose.

#### Usage and Dosage

##### (1) Preparation of Rinse buffer

Rinse buffer is prepared by adding purified water to undiluted rinse buffer according to instructed titer.

##### (2) Test Procedure

1. Diluted sample is prepared by adding instructed quantity of patient sample to instructed quantity of sample diluent.
2. Add instructed quantity of coagulative antigen to instructed quantity of the diluted sample and let it react.
3. Rinse coagulative antigen and add instructed quantity of

- signal generating reagent.
4. Rinse coagulative antigen and dry it and judge the presence of color by naked eyes.

#### Effect

Detection of anti-mycobacterium (Lipoarabinomannan) antibody in serum.

#### Storage and effective duration

The kit has to be stored at 2 - 8°C

Effective duration : 12 months

#### Standard and test procedure

##### (1) Kit component

1. Coagulative antigen
2. Signal Generating Reagent
3. Sample diluted
4. Undiluted rinse buffer
5. Positive control serum
6. Negative control serum

##### (2) Quality test

The following test results as standard can be obtained when test is performed properly according to the instructions described in "Usage and Dosage."

##### 1. Sensitivity test

- a) When negative control serum is used as test material, the test result is negative.
- b) When positive control serum is diluted with sample diluent at titer 1: 2 and used as test material, the test result is positive.

##### 2. Specificity test

- a) When negative control serum is used as test material, the test result is negative.
- b) When positive control serum is used as test material, the test result is positive.

##### 3. Simultaneous reproductive test

When negative control serum and positive control serum are tested 8 times simultaneously, each test result is consistent with each other.

#### Note 1

Medical use or general use : 41 extrasomatic diagnostic detection system  
insurance application desired, medical supply

#### Note 2

Investigation of medicine structure : 1 necessary

Charge : 13 approval of medical supply manufacture (import)  
investigation target article 1 No.3 ㄱ (1) (二)

Application classification : 139 extrasomatic classification 1 medical supply

Attached paper : 1 attached

Insurance application desired : classification D-1

Kit accessories : reference comb, microplate, seal for plate

Prefecture of application : Osaka