



DIAGNOSTIC AUTOMATION, INC.

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MATERIAL SAFETY DATA SHEET

OneStep Gonorrhea RapiCard™ InstaTest

IDENTIFICATION OF THE PREPARATION AND COMPANY NAME.

Supplier: Diagnostic Automation Inc.
21250 Califa St. Suite 102 and 116
Woodland Hills, CA 91367 USA

Emergency Telephone number: Please contact the local hospitals.

Product Name: OneStep Gonorrhea RapiCard™ InstaTest
Product classification: In-Vitro diagnostics
Catalog No: 176510-1

Active Ingredients:

Coated Antibodies:

Control region: Goat anti-mouse (IgG) polyclonal antibody 0.80 µg/test
Test region: Mouse monoclonal anti-gonococcus antibody A 0.62 µg/test

Labeled Antibodies:

Colloidal gold conjugate of monoclonal anti-gonococcus antibody B 0.75 µg/test

Principle of the test:

OneStep Gonorrhoea RapiCard™ InstaTest is a rapid, direct RapiCard™ InstaTest for the visual detection of gonorrhoea antigen, in the secretory specimen from urogenital system. It is used as an aid in the diagnosis of gonococcus infection. The test is based on the principle of double sandwich immunoassay for the detection of gonorrhoea antigen in the secretory specimen or urine. Monoclonal and polyclonal antibodies are employed to identify gonorrhoea specifically. Both sensitivity and specificity of the test are higher than those of the present methods, which often involve long hours of culturing the collected specimen. Test results are not affected by any medication that is being taken. Results are read visually without any instrumentation. This test is ideal for screening specimen samples containing at least 1×10^5 bacteria per mL.

Assay Protocol:

Assay Procedure:

Read the test instructions for DACD OneStep Gonorrhoea RapiCard™ InstaTest carefully before starting the assay. Allow samples and device to warm up to room temperature before testing.

Remove the test device from its foil pouch, place it on a flat surface and label it. Use the device as soon as possible.

Using a pipette, dispense 3-4 drops (0.2 mL) of diluted swab sample into the sample well on the cassette.

Wait 10-20 minutes and read results. It is important that the background is clear before the result is read. Results obtained after 30 minutes should be considered invalid.

Interpretation of Results:

Negative: Only one color band appears on the control region. No apparent band on the test region.

Positive: In addition to a pink colored control band, a distinct pink colored band will also appear in the test region.

Invalid: No visible band at all or no colored line appears on the control region. Repeat test with a new test kit.

Cut off Value: 1×10^5 bacteria/mL.

Specificity:

Cross Reactivity

Cross reactivity has been tested with bacteria listed in Table 1.

Table 1 - Cross-reactivity study of One-step Gonorrhoea test kit

CROSS REACTANT	CROSS REACTIVITY
E.Coli	-
Salmonella Typhi	-
Staphylococcus Aureus	-
Pseudomonas Aeruginosa	-
Shigella	-
Proteus	-

Storage: 2 to 30°C

Expiration Dating: 12 months from date of manufacture

Method of Manufacture:

Nitrocellulose Membrane Manufacture:

The purified monoclonal antibody, diluted in phosphate buffer saline, is coated on the test region. Simultaneously, goat anti- mouse IgG polyclonal antibody, diluted in phosphate buffer saline, is coated on the control region.

The coated membrane is dried for a minimum of 24 hours then sealed in an aluminum bag which contains silica gel desiccant.

Anti-Gonococcus colloidal gold conjugate pad manufacture:

A buffer solution containing mouse Anti-Gonococcus monoclonal antibody/colloidal gold conjugate is coated onto non-woven cloth sheets.

The coated non-woven cloth is dried for minimum 24 hours then sealed in an aluminum bag which contains desiccant.

Test Device Assembly:

The coated membrane S1, the conjugate pad S4, and an absorbent pad is applied to an adhesive-coated backing.

A 2-part waterproof label is applied over the conjugate pad and the absorbent pad, the assembled sheet of material is cut into strips. The test strips are then vacuum-dried for a minimum of 4 hours.

The assembled test strip is placed inside a plastic cassette mould and then sealed in an aluminum pouch along with a desiccant packet and a disposable plastic pipette.

Clinical Trials:

To establish the sensitivity and specificity of DACD OneStep Gonorrhoea RapiCard™ InstaTest relative to other rates of qualitative gonococcus tests, 205 clinical samples were studied. Another commercially qualitative test kit (PCR-gonorrhoea) was used to compare with DACD OneStep Gonorrhoea RapiCard™ InstaTest for relative sensitivity and specificity in 205 swab samples. Only 2 samples were discordant, the agreement is 99.02%. The detailed results are shown in Table 2.

Table 2 - Comparison of One-Step Gonorrhoea with PCR product for 205 cases

	Results of DACD kits		Subtotal	
	+	-		
Results of	+	78	1	79
PCR kits	-	1	125	126
Subtotal		79	126	205

Stability Studies:

It is well known that immunochemicals are quite stable at room temperature if the materials are kept in dry condition. The chemicals used in the One-Step Gonorrhoea device are either dried on the membrane or chemical pad. The final test device is then sealed in an aluminum pouch with a desiccant. Accelerated stability testing has been carried out in this study to establish the shelf life and predict the expiration date of the test.

Three lots of One-Step Gonorrhoea test kit have been used for this study. The test devices in aluminum pouches were kept in the incubator at 42°C or room temperature. The test kits were removed from their storage and tested with positive and negative control panels. The results are shown in Table 3 and 4.

Table 3 - Results of Stability study on One-Step Gonorrhea test kits at 42°C

Gonorrhea conc. (bacteria/ml)	Lot #	1 mo.	2 mo.	3 mo.	4 mo.	6 mo.	8 mo.	10 mo.	12 mo.
0	G01261C5	-	-	-	-	-	-	-	-
	G02011C5	-	-	-	-	-	-	-	-
	3-G01221	-	-	-	-	-	-	-	-
1x10 ⁵	G01261C5	+	+	+	+	+	+	+	+
	G02011C5	+	+	+	+	+	+	+	+
	3-G01221	+	+	+	+	+	+	+	+
1x10 ⁶	G01261C5	+	+	+	+	+	+	+	+
	G02011C5	+	+	+	+	+	+	+	+
	3-G01221	+	+	+	+	+	+	+	+

Table 4 - Results of Stability study on One-Step Gonorrhea test kits at room temperature

Gonorrhea conc. (bacteria/ml)	Lot #	1 mo.	2 mo.	4 mo.	6 mo.	8 mo.	10 mo.	12 mo.
0	G01261C5	-	-	-	-	-	-	-
	G02011C5	-	-	-	-	-	-	-
	3-G01221	-	-	-	-	-	-	-
1x10 ⁵	G01261C5	+	+	+	+	+	+	+
	G02011C5	+	+	+	+	+	+	+
	3-G01221	+	+	+	+	+	+	+
1x10 ⁶	G01261C5	+	+	+	+	+	+	+
	G02011C5	+	+	+	+	+	+	+
	3-G01221	+	+	+	+	+	+	+

The data collected to date DACD OneStep Gonorrhea RapiCard™ InstaTest are stable for at least 12 months at 2-30°C.

Date Adopted	Reference No.
2016-04-21	176510-1



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