



Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by Confidential Pathology

I, Simon Waters, Delegate of the Secretary to the Department of Health, on receipt of an application from Confidential Pathology, have approved under section 42DF of the *Therapeutic Goods Act 1989* (the Act) the restricted representations described in paragraph (a) below for use in advertisements directed to consumers, for the product identified in paragraph (b), provided the condition identified in paragraph (c) is met:

(a)

1. *STI Screen tests for Chlamydia, Neisseria (gonorrhoeae), mycoplasma, ureaplasma and Trichomonas*
2. *Currently we test for chlamydia, gonorrhoea, mycoplasma, ureaplasma and trichomonas*
3. *Laboratory testing of your sample for chlamydia, gonorrhoea, mycoplasma, ureaplasma and trichomonas.*

(b) Vaginal self-sampling kit (ARTG No. 235564)

(c) This approval is subject to the condition that the restricted representations in an advertisement for the Device **must** be accompanied by information on the expected time line for the delivery and testing of the sample and the reporting of the results to an appropriate healthcare professional

Dated this 28th day of February 2018

Signed electronically

Simon Waters
Delegate of the Secretary to the Department of Health; and
Advertising Compliance Unit
Regulatory Practice, Education and Compliance Branch