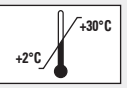
CanDia5®
Rapid Candida Test

TEST PROCEDURE INSTRUCTIONS

STORAGE

a. Store CanDia5® Test Kit at room temperature (2°C to 30°C)
b. Test kit components must be kept sealed until use



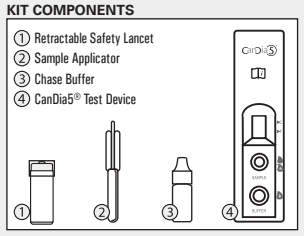
PRECAUTIONS

a. For in vitro diagnostic use only
b. Do not intercharge components between test kits
c. Do not use kit components after the expiry date

IMPORTANT!

a. Strict adherence to the test procedure will ensure optimal performance
b. Gloves must be worn when performing the test on a patiant
c. All test kit components must be used at room temperature (20°C to 30°C) to ensure optimal performance
d. Read ALL instructions before commencing test procedure
e. Remove the test device and all accessories from their pouches and place them on a flat, dry surface.

KIT COMPONENTS

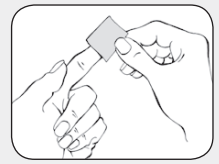


Step by Step Test Procedure Instructions

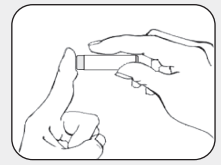
IMPORTANT:
Read ALL instructions before commencing test procedure

Video demonstration available at www.rockeby.com

STEP 1

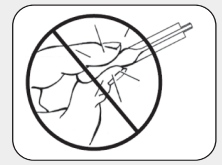


1a. A drop of blood needs to be collected from the tip of a finger using the safety lancet supplied. Clean or swab the tip of the finger to be punctured and allow it to dry.

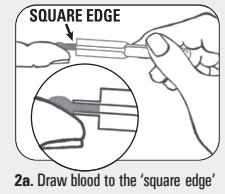


1b. Remove the protective lancet cap and press the lancet body firmly against the tip of cleaned finger until a 'click' sound is heard. IF REQUIRED, APPLY SLIGHT PRESSURE NEAR THE PUNCTURE SITE TO OBTAIN THE REQUIRED AMOUNT OF BLOOD.

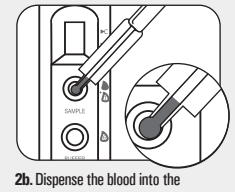
STEP 2 **DO NOT SQUEEZE** the bulb of the sample applicator when drawing or dispensing BLOOD!



IMPORTANT: DO NOT SQUEEZE the bulb of the sample applicator when drawing or dispensing blood! Blood draws automatically to correct volume when tip touches the blood with applicator held horizontally.

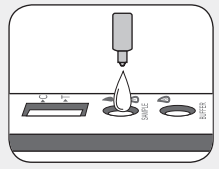


2a. Draw blood to the 'square edge' by holding the sample applicator horizontally **(DO NOT SQUEEZE BULB)** with the tip touching the drop of blood.

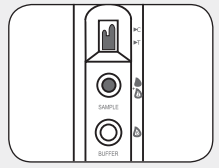


2b. Dispense the blood into the **"SAMPLE"** well by touching the membrane at the bottom of the sample well with the tip of the sample applicator. Hold in this position until all blood is released onto the membrane. **DO NOT SQUEEZE BULB.**

STEP 3 **KEEP TEST DEVICE ON A FLAT SURFACE THROUGHOUT THE TEST**

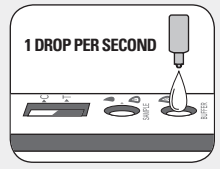


3a. Remove cap from chase buffer bottle and add one drop of chase buffer in the **"SAMPLE"** well.



3b. Allow the chase buffer to flow to the Control Line (up to the "C" mark). If flowing to the control Line not seen within 30 seconds, add 1 more drop of chase buffer in the **"SAMPLE"** well.

STEP 4 **KEEP TEST DEVICE ON A FLAT SURFACE THROUGHOUT THE TEST**



4a. Add 6 drops of chase buffer to the **"BUFFER"** well at a rate of **ONE DROP PER SECOND.**

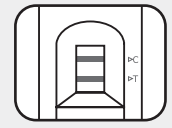
6 drops
6 secs.

4b. Observe for **pink-coloured solution** to flow from the bottom of the result window towards the top.

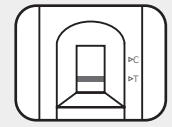
If the pink-coloured solution is **not seen** within 30 seconds, **add 2 more drops** of chase buffer into the **"BUFFER"** well.

4c. WAIT 5 - 6 MINUTES then read the results. Do not read the results after 10 minutes to avoid misinterpretation of the results.

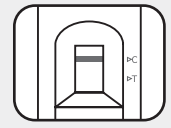
STEP 5 **INTERPRETATION OF THE RESULTS**



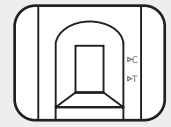
POSITIVE



INVALID



NEGATIVE



INVALID

CE IVD

CanDia5®
Rapid Candida Test
Candida Diagnosis in 5 simple steps

INTRODUCTION

Candida infections can occur in the vagina, mouth, gastrointestinal tract, and other places in the body. For example vaginitis is the most frequent gynaecological diagnosis encoubtered by clinicians who provide primary care to women[1]. Symptoms of vulvovaginal candidiasis are non-specific and neither self-diagnosis, nor diagnosis by a physician is reliable without laboratory confirmation[2]. the presence of IgG antibodies increases sharply with infection and the detection of an increase in the antibodies can be used to characterize infection[3].

INTENDED USE

The Candia5® Rapid Candida Test is a qualitative immunochromatographic point-of-care test device intended for clinical detection of antibodies of the IgG class in human whole blood or serum that react with purified cellular Candida antigens.

Individual whole blood or serum may be used to establish serological evidence of a current or recent Candida infection. The device will detect antibodies against most medically important Candida species.

PRINCIPLE OF THE ASSAY

A sample of whole blood is separated chromatographically and serum enters the test region where it can interact with a band of purified cellular Candida antigens. When sufficient antibodies to Candida species are bound to the purified antigens, antihuman IgG labeled with colloidal gold will interact with the bound IgG yielding a red colour. A control band is provided to determine that the device is functioning correctly.

PERFORMANCE CHARACTERISTICS

In a multi-site clinical study involving a total of 163 subjects, 45 evaluable subjects were enrolled with symptoms and clinical history of vulvvovaginal candidiasis and 35 (78%) were confirmed positive by microscopy and/or cultures[4].

Sensitivity	**77%**
Specificity	**70%**
Positive Predictive Value	**90%**
Negative Predictive Value	**47%**

Test Variability

Two positive sera with values near and slightly above the cut-off limit of the test from culture-positive subjects and one serum from a culture-negative subject were tested in duplicate five times on each of three separate days by individual physicians for a total of 270 tests. One test had a negative result with a positive serum (0.4%). All other valid tests yielded the expected positive or negative result.

LIMITATIONS OF PROCEDURE

Candia5® detects antibodies to four clinically important species, C. albican, C. glabrata. C. tropicalis and C. parapsilosis, but reacts weakly with antibodies to C. krusei. No cross-reactions with other species of fungi or bacteria have been observed.

A weak clinically-positive, a moderate clinically-positive and a clinically-negative serums were tested against a variety of biological substances for possible interference with Candia5® test results. Concentrations of lipid or bilirubin that were 50% above normal levels found in te blood interfered with the test results with the weak positive serum. The same reactants did not alter the results with the moderate clinicaly-positive or negative derums even at 2x the normal concentrations. In the same evaluation, none of the results were affected by concentrations of albumin or hemoglobin that were 2x the normal concentrations[4].

Candia5® Rapid Candida Test provides a preliminary analytical result. Clinical consideration should be observed, particularly if there is a positive result.

LIMITED WARRANTY

The manufacturer makes or express warranty other than the diagnostic kit will measure Candida specific antibodies when used in accordance with the manufacturer's instructions. The use of the kit for any other purpose or for clinical diagnosis of a disease state is outside the intended use of this product.

The manufacturer disclaims any and all implied warranties of merchantability, fitness for use or implied utility for any other purposes. Any and all damages for failure of the diagnostic kit to perform according to its instructions are limited to the replacement value of the kit.

REFERENCES

1. Egan ME. Lipsky MS. Diagnosis of Vaginitis. American Family Physician; Kansas City; Sep 1, 2000; 62(5): 1095-1104

2. Sobel, JD.Vaginitis. New Eng J Med, 1997; 337(26): 1896-1903.

3. Tan, SW et al. A serological test for vulvovaginal candidiasis. J. Gynecol. & Obstet. 2003; 82:79-81

4. Confidential data-on-file, Rockebybiomed Ltd

EC REP
MT-Promedt Consulting GmbH
Altenhoftstrasse 80
D-66386 St. Ingbert
Germany

PATENTS
Australia 2,002,248,996
United Kingdom 1,381,864
Japan 3,969772
USA 6,916,626
Pending elsewhere

KEY TO COMPONENT LABELING

LOT	Batch Code
STERILE R	Stearilized using irradiation
NON STERILE	Non-sterile
Σ	Contains sufficient for <n> tests
	Do not re-use
REF	Catalogue number
	Use by YYYY-MM
IVD	In Vitro diagnostic medical device
	Manufactured by
	Temperature limitation
i	Consult instructions for use
EC REP	European Authorized Representative
CE	CE Mark = Conform with EEC directives

Component Manufacturers

1. Retractable Safety Lancet
Suzhou Zhen Wu Medical Sutures & Suture Needles
No.3 Donghuan Road, Beishe, Wujiang City, China
CE 0434
EC REP Wellkang ©Tech Consulting
Suite B, 29 Harley Street, LONDON W1G 9QR, UK

STERILE R - Lancet (Gamma Ray Sterilization)

PATHWAY BIOMED
Pathway Biomed Trading Pte Ltd
60 Kaki Bukit Place
#03-01 Eunos Techpark
Singapore 415979
Email: enquires@pathwaybiomed.com
Web: www.pathwaybiomed.com

Candia5 IFU (Professional Test) -English
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