



Bacterial Vaginosis Diagnostic Strip Sets

(Dry Chemical Enzymatic Detection)



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(Dry Chemical Enzymatic Detection)

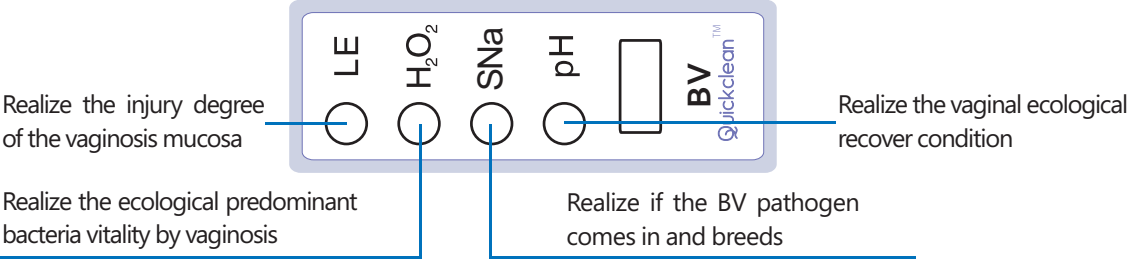


1 Introduction

Product introduction

Bacterial vaginosis diagnostic strip sets(dry chemical enzymatic detection), is an in vitro diagnostic reagents products to test female bacterial vaginosis. Through testing the H₂O₂, pH value, SNa and LE, the four indicators of female vaginal discharge, evaluate comprehensively, and get the result, it has certain guiding significance for the clinical diagnosis.

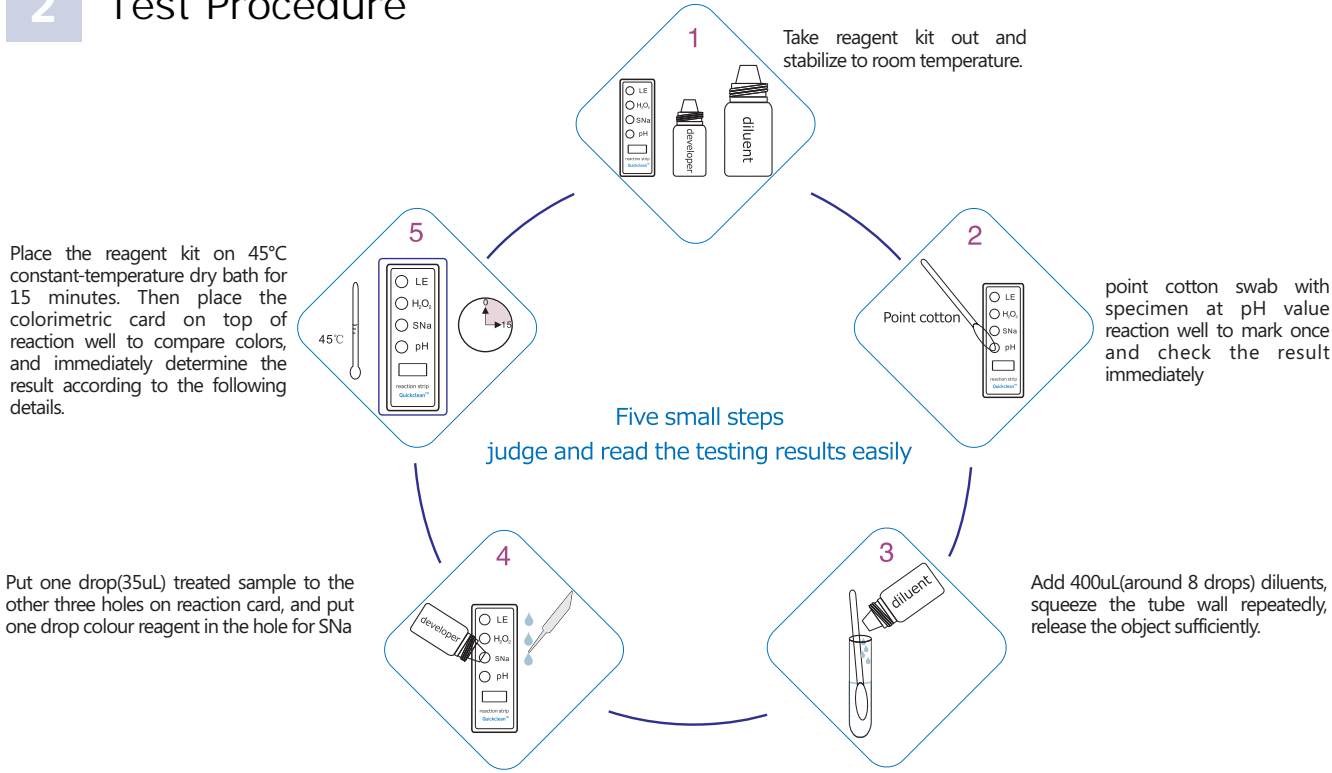
Product principle



Product application

Used to assist the diagnostic of bacterial vaginosis, evaluate the micro ecological balance in genital tract, and so to prevent the repeat disease of vaginosis.

2 Test Procedure



3 Result judgement

Clinical judgement standard

H ₂ O ₂	SNa	LE	pH
red/light red negative (prompt normal)	no color change negative (prompt normal)	no color change negative (prompt normal)	yellow/yellow-green negative
no color change positive (prompt possible dysbacteriosis)	purplegray/gray/black positive (prompt possible infection of bacterial vaginosis)	blue-green/blue positive (prompt different level of the inflammation)	dark green/blue-green/blue positive

Clinical result judgement list

No.	Testing result (- means negative, + means positive)				Clinical significance
	H ₂ O ₂	SNa	LE	pH	
1	-	-	-	-	normal
2	-	-	-	+	Vaginal micro ecological balance is broken
3	+	-	-	-	Vaginal micro ecological balance is broken
4	-	-	+	-/+	Vaginitis or cervicitis
5	+	-	+	-/+	Vaginitis or cervicitis
6	-	+	-	-/+	BV early phase
7	-	+	+	-/+	BV early phase, might be with vaginitis, cervicitis etc.
8	+	+	-	-/+	BV
9	+	+	+	-/+	BV, poor prognosis

4 Announcements

Storage and Shelf Life

Store below 2°C ~ 8°C. It expires after 12 months. , The product must be used within 8 hours after the aluminum foil bag for reaction strip is unpacked.

Cautions

1. Rotate cotton swab at vaginal fornix for 10-20 sec. Try to collect more vaginal discharge from patient until discharge is clearly visible on the cotton swab,assay the specimen after collection.
2. Don't acquire specimen during menstrual period. Don't acquire specimen if patient had sex, bath, vaginal irrigation or applied local medication within 24hours.
3. Keep it below 2°C ~ 8°C for assay latter in the day.
4. This product only can be used as assistant for in vitro diagnosis. Test results should be combined with other validated equivalent methods and clinical symptoms before comprehensive diagnosis.
5. Components from different batches of the reagent kits shall not be cross-used.
6. Please read instructions for use carefully. Compare to the standard colorimetric card to determine the color result.

