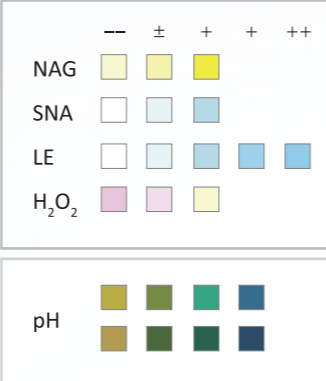


## Result Interpretation Standards

NAG(N-Acetyl-β-glucosaminidase)	No color change in NAG denotes negative, marked as “-” Light yellow in NAG denotes weakly positive, marked as “± or +” Yellow in NAG denotes positive, marked as “+”	
SNA ( Sialidase )	No color change in SNA denotes negative, marked as “-” Light blue in SNA denotes weakly positive, marked as “±” Blue-green in SNA denotes positive, marked as “+”	
LE ( (Leukocyte Esterase )	No color change in LE denotes negative, marked as “-” Light blue in LE denotes negative, marked as “±” Blue-green in LE denotes positive, marked as “+ or + +”	
H <sub>2</sub> O <sub>2</sub> ( Perhydrol )	Fuchsia in H <sub>2</sub> O <sub>2</sub> denotes negative, marked as “-” Very light red in H <sub>2</sub> O <sub>2</sub> denotes weakly positive, marked as “±” No color change in H <sub>2</sub> O <sub>2</sub> denotes positive, marked as “+”	
pH value	Interpret results contrasting standard color card	

## Explanations on Results

**NAG(N-Acetyl-β-glucosaminidase):** NAG negative denotes normality. NAG weakly positive or positive denotes that it's infected with fungi, mycoplasmas or trichomonad, in this case the microscopy should be applied as supplementary means, the fungi or trichomonad can be discerned with microscope if there are those kind of microbes, when both fungi and trichomonad can not be observed the mycoplasma infection should be taken into consideration, it's recommended to proceed to mycoplasma culturing.

**SNA( Sialidase ):** SNA negative denotes normality, SNA positive denotes Bacterial Vaginosis.


**LE( Leukocyte Esterase ):** LE negative denotes normality, LE positive denotes there is inflammation.

**H<sub>2</sub>O<sub>2</sub> ( Perhydrol ):** H<sub>2</sub>O<sub>2</sub> negative denotes normality, H<sub>2</sub>O<sub>2</sub> weakly positive or positive denotes that H<sub>2</sub>O<sub>2</sub> concentration is a little low and vaginal microecology is unbalanced.


**pH value:** pH value is the auxiliary index which reflects vaginal microecology, when pH value deviates from 3.8-4.5, it denotes vaginal microecology is unbalanced.

## Clinical Verification of Vaginitis Diagnostic Kit

Items	Sensitivity	Specificity	Accuracy	Positive Predictive Values	Negative Predictive Values
N-Acetyl-β-glucosaminidase ( NAG )	92.3%	97.7%	96.5%	92.3%	97.7%
Sialidase (SNA)	93.3%	99.0%	98.2%	93.3%	99.0%
Leukocyte Esterase (LE)	92.0%	95.3%	93.9%	93.9%	96.8%
Perhydrol (H <sub>2</sub> O <sub>2</sub> )	98.1%	93.4%	95.6%	92.9%	98.3%

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# LTS-V400

## Vaginitis Detection System

- Patented Technology
- Auto Adding Sample
- Auto Interpretation of Result
- Auto Printing Report



## Introduction



LTS-V400 Vaginitis Detection System has unique designs and scientific & reasonable portfolio of test items to really realize the transit from manual operation to intelligent automation, which is innovative breakthrough in the clinical laboratory of gynecological infection.

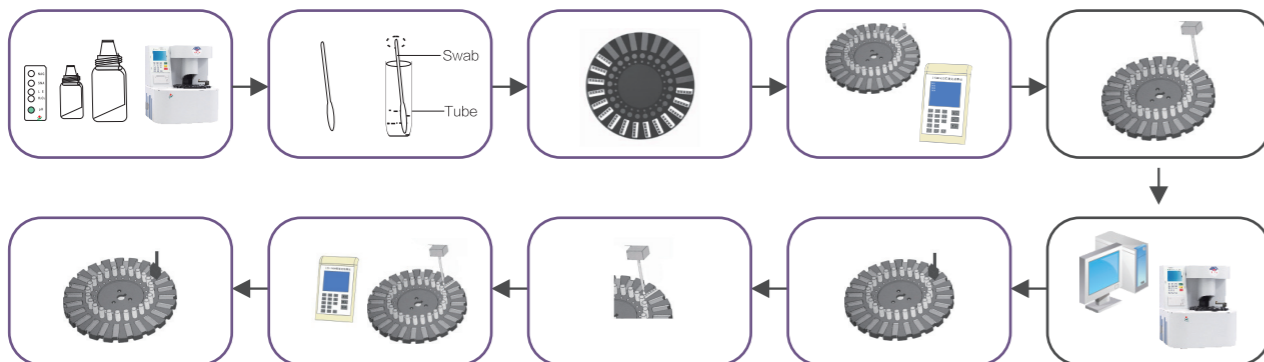
## Features

- Patented Technology**  
Awarded Invention Patent Certificate.
- Quick**  
Continuous & batch detection, 50 seconds/ specimen.
- Real-time**  
Real-time detection, samples can be tested whenever it's loaded.
- Accurate**  
Applies the unique color identification module to ensure the accuracy and reproducibility.

- Full Automatic**  
Auto adding sample, auto incubation, auto interpretation of results, auto printing results, high intelligence, protection from artificial errors.
- Informatizational**  
Able to save 1000 records, be connected with hospital database management system to share detection results and standardize records.
- Intelligent**  
Simple interface displays test process of each specimen in real time which it's convenient to monitor.

## Operation Procedures

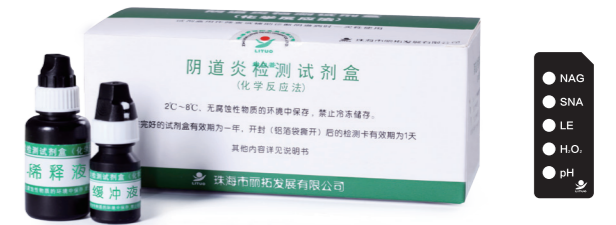
Recover the reagent to room temperature → Collect sample and squeeze swab repeatedly to make specimen flow out → Load test card and specimen → Input test numbers → Auto dripping specimens → Auto interpreting pH value → Auto incubation → Auto dripping NAG buffer solution → Auto interpreting results → Auto printing reports, auto saving and uploading results.



## Ancillary Reagent Kits



Vaginitis Diagnostic Kit Contents (Single Test Item):  
1、Diluent 2、Test Card 3、Instructions For Use  
4、Standard Color Card



Vaginitis Diagnostic Kit Contents (Five Test Items):  
1、Diluent 2、Buffer Solution 3、Test Card  
4、Instructions For Use 5、Standard Color Card

## Clinical Significance

### NAG (N-Acetyl-β-Glucosaminidase) activity detection

N-Acetyl-β-glucosaminidase is the enzyme discharged by Monilia Albanian, Trichomonas Vaginalis, Mycoplasma Hominis etc., the enzyme is able to damage the mucin barrier on surface of vaginal mucosa that has the protective function, normal vaginal secreta doesn't have NAG, just under circumstance of infection of those pathogenic bacterium the enzyme can be detected. If NAG indicates positive, it means that vagina was infected by pathogenic bacterium, vaginal protective mucin barrier was damaged and vaginal mucosa is in the susceptible or infected situation.

### SNA (Sialidase) activity detection

Sialidase is the specific enzyme discharged by pathogenic bacterium like Gardnerella Vaginalis, Mobiluncus etc., the positive denotes that it's infected with Bacterial Vaginosis.

### LE (Leukocyte Esterase) activity detection

The Leukocyte Esterase is the carboxylesterase released by polymorphonuclear leucocytes, when inflammation takes place polymorphonuclear leucocytes gather at the focus and release much leukocyte esterase, for bacterial and fungal vaginal infection the polymorphonuclear leucocytes can be discerned obviously. The LE activity reflects vaginal cleanliness and is an auxiliary index to diagnose inflammation degree.

### H<sub>2</sub>O<sub>2</sub> (Perhydrol) concentration detection

The perhydrol is the specific product of vaginal bacillus acidi lactici, its concentration indicates whether the beneficial bacterium are normal in vagina, negative denotes that the bacillus acidi lactici that maintains vaginal microecological balance is normal and positive means that the balance was broken and the microecology is in imbalance.

### pH Value

pH value is auxiliary index for diagnosis of vaginal infection. The vagina pH value of healthy woman is 3.8 - 4.5.