

Bacterial Vaginosis (BV) Reagent Kit

【Product Name】

Bacterial Vaginosis (BV) Reagent Kit

【Package Specifications】

1piece/pouch,20pcs/box

【Intended Use】

The reagent kit is used for in vitro qualitative detection of the female bacterial vaginosis.

【Test Principle】

The female who have BV clinical symptom, the vaginal fluid contains polyamines and diamine, polyamines and diamine reacts specifically with extracting solution of reagent to produce a gas. The gas passes through the test well and make the color of the indicator in the test well changed from light yellow to purple or red.

【Main Components】

Polyamines: 1.2g/dL

Na₂HPO₄: 1.5g/dL

Phenol Red: 0.5g/dL

KH₂PO₄: 1.5g/dL

【Storage Conditions and Validity Period】

Stored at 2-30°C, the validity period is for 12 months.

The validity period after opening a seal: The reagent kit is validity within 30 minutes after opening the seal.

【Applicable Instrument】

Not applicable

【Sample】

The sample is for vaginal secretions, take it with sterile swab by a conventional method.

【Test Methods】

1. Take vaginal secretions with sterile swab by a conventional method and place in sampling tube, drop 6-8 drops of diluent into the tube, gently squeeze the tube wall with fingers after full rinsing to make adsorbed liquid by swab back into the test tube, put down the swab, take a test tube lid to cover the test tube.
2. Take out the test cassette from the package bag, squeeze the sampling tube to make the sample processing solution completely drop in the sample well of the test cassette.
3. Gently squeeze the color liquid bottle, drop a small drop of color liquid (do not exceed 20μl) in the test well(T), at this moment, the membrane on the test

well changes from white to yellow.

4. Drop BV extracting solution into the sample well(S), read the results within 3 minutes. (The results has no clinical significance beyond 3 minutes.)

【Interpretation of Results】

It is weak positive if the membrane on the test well of the test cassette changes from yellow to red. It is strong positive if it changes to purple. It is critical state if a part changes to red. It is negative if there is no significant changes.

【The Limitations of The Test Methods】

Not applicable

【Performance Indicators】

Negative control test: 100%

Positive control test: 100%

Sensitivity: ≥90%

Repeatability: ≥90%

【Attentions】

1. Sampling should avoid the time periods that after sex and menstruation, the sample should be fresh.
2. The test cassette adopts new technique, can not see the sample entering, please do not mistake that the sample don't enter into.
3. When drop the color liquid, do not drop too much to avoid false negative.
4. Do not drop too much diluent, otherwise the test well will be moist, cause that the results are invalid and need to re-test with new test cassette.
5. The sample should be considered potentially infectious and should be handled as per infectious disease laboratory operating specifications.