

In vitro Diagnostics

INTENDED USE

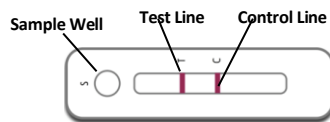
Sensit Vitamin D Rapid Test Kit is a qualitative immunochromatographic assay for the detection of Vitamin D from patient throat swab specimens.

SUMMARY & TEST DESCRIPTION

Vitamin D helps regulate the amount of calcium and phosphate in the body. These nutrients are needed to keep bones, teeth and muscles healthy. Vitamin D -deficiency occurs when the body doesn't get enough vitamin D from sunlight or diet. Vitamin D deficiency can cause loss of bone density, osteoporosis, broken bones and rickets in children. Vitamin D is sometimes called the sunshine vitamin because your body makes it from cholesterol when your skin is exposed to sunlight. Before your body can use vitamin D, your liver must change it into another form called 25 hydroxyvitamin D, or 25(OH)D. The Vitamin D Rapid Test measures the level of 25(OH)D in your blood in order to determine whether your body has deficient, insufficient, sufficient or excess levels of vitamin D in your blood to enable/prevent your body from working well

TEST PRINCIPLE

Sensit Vitamin D Rapid Test works on chromatographic immunoassay. Basic components of each test strip includes: a) Conjugate pad which contains colloidal gold conjugate; b) a nitrocellulose membrane strip containing two lines T: Test line and C: Control line.



Test sample that is added to the sample well (S), with adequate amount of buffer migrates from the sample pad along the conjugate pad where Vitamin D present in the sample will bind to Colloidal Gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zones where the complex accordingly will bind to the immobilized antibodies (on test line) producing a visible line on the membrane. If the respective antigen is not present in the sample, no reaction occurs in the capture zones and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

REAGENTS & MATERIALS PROVIDED

1. Each sealed in a foil pouch containing following items:
 - a. One test card
 - b. Dessicant
2. Assay Diluent- In dropper bottle
3. Swab
4. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTIONS & WARNING

1. Use within 10 minutes after opening pouch.
2. Do not touch result window.
3. Use only the buffer supplied along with the kit.
4. Do not mix components from different kits.
Use only for in-vitro diagnostic purpose.

SAMPLE COLLECTION & PREPARATION

- Collect blood sample, often via a fingerstick (capillary blood) or from a venous draw
- If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.
- For storage period longer than 5 days, freezing is recommended. Store at -20°C
- The specimen should be brought to room temperature prior to use.

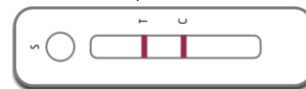
Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 10 µL of the extracted blood sample to the sample well "S".
3. When fully sample is fully absorbed, add 2 drops of diluent provided with the assay to the sample hole
4. Wait 10 minutes, read and interpret the results. The result is considered invalid after 15 minutes. All results where control band does not appear are considered invalid.

INTERPRETATION OF TEST RESULT

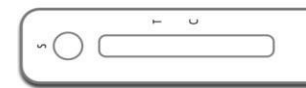
Positive: Color bands at position C and T.



Negative: Color band at position C.



Invalid: Color band at C does not appear



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