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## iGFBP-1 Rapid Test Strip

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*Cat.No: DTSXY-L5*

*Lot. No. (See product label)*

### **Intended Use**

The Insulin-like growth factor-binding protein 1 (iGFBP-1) rapid test (vaginal secretion) is a visually interpreted, qualitative immunochromatographic dipstick test for detection of iGFBP-1 in vaginal secretions during pregnancy, which is a major protein marker of the amniotic fluid in a vaginal sample. The test is intended for professional use to help diagnose the rupture of fetal membranes (ROM) in pregnant women.

### **General Description**

Insulin-like growth factor-binding protein 1 (IBP-1) known as placental protein 12 (PP12) is a protein that in humans is encoded by the IGFBP1 gene. IGF-binding proteins (IGFBPs) is believed to be important in the regulation of fetal and neonatal growth. We previously reported that the profiles of IGFBPs in fetal cord serum (FCS) were dependent on the growth/metabolic status of the fetus. It can be detected in cervical secretions of pregnant women with preterm uterine contractions, and whether their presence predicts an increased risk of preterm delivery. The abundance of insulin-like growth factor binding protein-1 at the maternal-fetal interface in severely preeclamptic pregnancies suggests that the binding protein may participate in the pathogenesis of the shallow placental invasion observed in this disorder. Low circulating insulin-like growth factor-I and elevated insulin-like growth factor binding protein-1 levels may contribute to restricted placental and therefore fetal growth.

### **Principle Of The Test**

The iGFBP-1 (vaginal secretion) has been designed to detect iGFBP-1 through visual interpretation of color development in the internal strip. The membrane was immobilized with anti-iGFBP-1 antibodies on the test region. During the test, the specimen is allowed to react with colored anti-iGFBP-1 antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough iGFBP-1 in specimens, a colored band will form at the T region of the membrane. Presence of colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

### **Reagents And Materials Provided**

**Individually packed test strip:** Each strip contains colored conjugates and reactive reagents pre-spread at the corresponding regions.

**Specimens collection swab:** For specimens regions.

**Specimens dilution tube with buffer:** 0.1 M Phosphate buffered saline(PBS) and preservative

**Package insert:** For operation instruction.

### **Materials Required But Not Supplied**

**Timer:** For timing use.

## **Specimen Collection And Preparation**

- The Insulin-like growth factor-binding protein 1 (iGFBP-1) rapid test (vaginal secretion) is intended only for use with women vaginal secretion specimens.
- The specimen is cervicovaginal secretion that is extracted into the Specimen Extraction Solution provided. A vaginal secretion sample is obtained using a sterile polyester swab from the posterior fornix of the vagina during a sterile speculum examination or, if no vaginal fluid is visible, the sample may be taken from the cervix. Take not to touch anything with the swab before taking the sample. The swab should be left in the vagina or cervix for approximately 10~15 seconds to allow it to absorb the secretion samples.
- Open the Specimen Extraction Solution tube and put it in a vertical position. The specimen is extracted immediately from the swab by swirling the swab vigorously in the extraction solution for approximately 10 seconds. Specimens should be tested as soon as possible after extraction but in any case no more than 4 hours after specimen collection and extraction. If a specimen can not be tested within this time it should be frozen. After thawing, the specimens can be tested as described below.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 72 hours.
- Bring specimens to room temperature prior to testing.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

## **Reconstitution And Storage**

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

## **Assay Procedure**

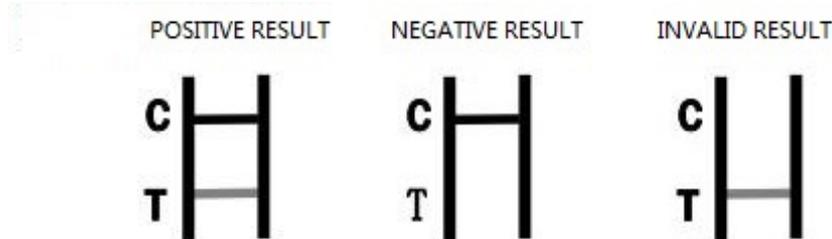
**Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.**

- 1) Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. To obtain a best result, the assay should be performed within one hour.
- 2) Hold the label area and put the strip into the extracted buffer towards the arrow label. **Leave the strip into the buffer until you see the liquid front enter the result area.** Remove the strip from the solution and place it in a horizontal position.
- 3) As the test begins to work, you will see color move across the membrane.
- 4) Wait for the colored band to appear. The result should be **read at 10 minutes**. Do not interpret the result after 20 minutes.

## **Quality Control**

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

## Interpretation Of Results



**POSITIVE RESULT:** \* A colored band appears in the control band region (C) and another colored band appears in the T band region.

**NEGATIVE RESULT:** One colored band appears in the control band region (C). No band appears in the test band region (T).

**INVALID RESULT:** Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

**NOTE:**

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

## Precautions

- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Buffered Saline contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of buffered saline or extracted samples, always flush with copious quantities of water to prevent azide build up.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.

## **Limitations**

1. The Insulin-like growth factor-binding protein 1 (iGFBP-1) rapid test (vaginal secretion) is for professional in vitro diagnostic use, and should be used for the qualitative detection of iGFBP-1 only.
2. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility.

## **References**

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