iGFBP-1 Rapid Test Cassette (Vaginal Secretion) Package Insert

REF FIG-502	English

For professional in vitro diagnostic use only.

INTENDED USE

The Insulin-like growth factor-binding protein 1 (iGFBP-1) rapid test cassette (vaginal secretion) is a visually interpreted, qualitative immunochromatographic 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.

SUMMARY

Insulin-like growth factor-binding protein 1 (iGFBP-1) known as placental protein 12 (PP12) is a protein that in humans is encoded by the IGFBP-1 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, 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.

The iGFBP-1 Rapid Test Cassette is a rapid test that qualitatively detects the presence of iGFBP-1 in vaginal secretion specimen at the sensitivity of 25ng/ml.

PRINCIPLE

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 interacts with reagents on the membrane. If there was enough iGFBP-1 in specimens, a colored band will form in 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 in the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials provided

- Individually packed test cassettes
- Package insert
- Specimens collection swabs
- Specimens dilution tubes with buffer

Materials Required But Not Provided

- Timer

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- 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.

STORAGE AND STABILITY

- 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.

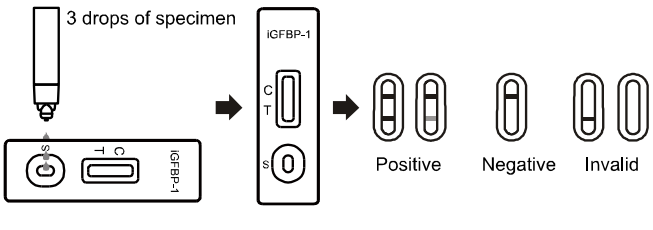
SPECIMEN COLLECTION AND STORAGE

- The Insulin-like growth factor-binding protein 1 (iGFBP-1) rapid test cassette (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 fomix 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.

DIRECTIONS FOR USE

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 cassette with patient or control identification. To obtain a best result, the assay should be performed within one hour.
2. Insert the swab into the dilution tube, rotate for 20 times. Then press the swab against the side of the tube and squeeze the bottom of the tube as the swab is withdrawn. Discard the swab.
3. Fit the cap onto the tube. Remove the top part of the cap. Place the test cassette on a clean and level surface. **Add 3 full drops of solution** (approx. 100 µL) to the specimen well (S), and then start the timer.
4. Wait for the colored band to appear. The result should be **read at 5 minutes**. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

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

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

INVALID: 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.

QUALITY CONTROL

1. 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.
2. 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.

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

EXPECTED VALUES

The iGFBP-1 Rapid Test Cassette (Vaginal secretion) has been compared with a leading commercial iGFBP-1 test. The correlation between these two systems is 98.0%.

PERFORMANCE CHRACTERISTICS

Sensitivity and Specificity

The iGFBP-1 Rapid Test Cassette (vaginal secretion) has been tested with a leading commercial iGFBP-1 Rapid Test using clinical specimens.

Method		Other iGFBP-1 Rapid Test		Total Results
iGFBP-1 Rapid Test Cassette	Results	Positive	Negative	
	Positive	102	3	105
	Negative	2	147	149
Total Results		104	150	254

Relative Sensitivity: 98.1% (95%CI:*93.2%-99.8%)
Relative Specificity: 98.0% (95%CI:*94.3%-99.6%)
Overall Accuracy: 98.0% (95%CI:*95.5%-99.4%) *Confidence Intervals

Precision

Intra-Assay

Assays were carried out to determine assay reproducibility using replicates of 10 tests in three different runs for each of three lots using iGFPB-1 antigen levels at 0 ng/mL, 25 ng/mL, 50ng/mL. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by using the three iGFBP-1 antigen levels at 0ng/mL, 25ng/mL and 50ng/mL of iGFBP-1 in 3 independent assays. Three different lots of the iGFBP-1 Rapid Test Cassette (vaginal secretion) have been tested using these specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

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4. Rutanen E M, Pekonen F, Kärkkäinen T. Measurement of insulin-like growth factor binding protein-1 in cervical/vaginal secretions: comparison with the ROM-check Membrane Immunoassay in the diagnosis of ruptured fetal membranes Clinica chimica acta; international journal of clinical chemistry, 1993, Vol.214 (1), pp.73-81.

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions For Use

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