Sperm antibody latex agglutination test

Description:
By means of the sperm-antibody latex agglutination test even smallest amounts of sample material (ejaculate, serum) can be examined for the presence of sperm antibodies (anti-spermatozoa antibodies, sperm antibodies).

EU registration number
DE/CA81/IVD1707

Order Code No.: BS-10-10

Shelf Life: 15 months after date of manufacture

Principle of the test:
Only if antibodies directed against sperm antigens are present in sample materials to be examined, latex particles coated with this antigen will agglutinate within 1 - 2 minutes. The test is carried out on special slides delivered with the kit. All steps are easy to follow, diagnosis is quickly achieved and the titer of the sperm antibodies can subsequently be determined.

Sample materials:
- Serum, Seminal Plasma
Sperm antibody ELISA for use with serum

Description:
Quantitative ELISA for the detection of anti-sperm antibodies (anti-spermatozoa antibodies, sperm antibodies). This anti-sperm ELISA has been optimized for the detection of anti-sperm antibodies in human serum.

EU registration number:
DE/CA81/IVD1696

Order Code No.:
BS-10-20

Shelf Life:
12 months after date of manufacture

Principle of the test:
Anti-sperm antibodies of the patient's sample material bind to sperm antigens immobilized on a 96-well-ELISA plate. In a second step enzyme-linked antibodies directed against human immunoglobulins are added. The antibody concentration in the patient's serum correlates directly with the extinction values of the subsequent photometric measurements.

Sample materials:
- Serum
Sperm antibody ELISA for use with seminal plasma

Description:
Quantitative ELISA for the detection of anti-sperm antibodies (anti-spermatozoa antibodies, sperm antibodies). This anti-sperm ELISA has been optimized for the detection of anti-sperm antibodies in human seminal plasma.

EU registration number
DE/CA81/mv-i1809

Order Code No.: BS-10-21

Shelf Life: 12 months after date of manufacture

Principle of the test:
Anti-sperm antibodies of the patient's sample material bind to sperm antigens immobilized on a 96-well-ELISA plate. In a second step enzyme-linked antibodies directed against human immunoglobulins are added. The antibody concentration in the patient's serum correlates directly with the extinction values of the subsequent photometric measurements.

Sample materials:
- Seminal Plasma
Sperm antibody haemagglutination test

Description:
With this test sperm antibodies (anti-spermatozoa antibodies, sperm antibodies) possibly causative for fertility disorders in the serum of men and women are diagnosed and the titer is determined.

Principle of the test:
The test is based upon specially pretreated and sensitized red blood cells (SRBC) coated with sperm antigen. Antibodies in the sample agglutinate with coated SRBC within 120 min.

Sample materials:
- Serum
Sperm antibody ELISA – Ig-classifying (Ig-typing)

Description:
Quantitative ELISA for the class-specific (anti-sperm IgA, anti-sperm Ig-G) detection of anti-sperm antibodies (anti-spermatozoa antibodies, sperm antibodies). After determination of anti-sperm antibodies (anti-spermatozoa antibodies, sperm antibodies) with the BIOSERV anti-sperm ELISA a classification of these immunoglobulins (IgG, IgA, IgM) may be carried out.

EU registration number
DE/CA81/IVD1700

Order Code No.: BS-10-50

Shelf Life: 9 months after date of manufacture

Principle of the test:
Anti-sperm antibodies (anti-spermatozoa antibodies, sperm antibodies) of the patient's sample material bind to sperm antigens immobilized on a 96-well-ELISA plate. In the second step enzyme-linked antibodies directed against human immunoglobulins of the classes IgG, IgM and IgA are used. The antibody concentration in the patient's serum correlates directly with the extinction values of the subsequent photometric measurements.

Sample materials:

- Serum
**Anti-zona pellucida antibody latex agglutination test**

**Description:**
By means of the ZP-antibody latex agglutination test even smallest amounts of serum can be examined for the presence of zona pellucida antibodies.

**EU registration number**
DE/CA81/IVD1705

**Order Code No.:**
BS-20-10

**Shelf Life:**
15 months after date of manufacture

**Principle of the test:**
Only if antibodies directed against ZP-antigens are present in sample materials to be examined, latex particles being coated with this antigen will agglutinate within 1 - 2 minutes. The test is carried out on special slides delivered with the kit. All steps are easy to follow, diagnosis is quickly archived and the titer of ZP-antibodies can be determined afterwards.

**Sample material:**
- Serum
Anti-zona pellucida antibody ELISA

Description:
This test is designed to quantify antibodies directed against zona pellucida (ZP) antigens. Application is recommended for all female patients showing fertility disorders of unknown aetiology or ovary malfunctions as well as in preparation for assisted reproduction therapy.

Principle of the test:
Anti-zona pellucida antibodies of the patient’s sample materials bind to ZP-antigens immobilized on a 96-well-ELISA plate. In the second step enzyme-linked antibodies directed against human immunoglobulins are used. The antibody concentration in the patient’s serum correlates directly to photometrically measurements.

Sample material:
- Serum
Anti-zona pellucida antibody haemagglutination test

Description:
With this test anti-zona pellucida antibodies possibly responsible for fertility disorders in the serum of subfertile women are diagnosed and the titer is determined.

EU registration number
DE/CA81/IVD1706

Order Code No.:  
BS-20-30

Shelf Life:  
4 months after date of manufacture

Principle of the test:
This test is based upon specially pretreated and sensitized red blood cells (SRBC) coated with ZP-antigen. Antibodies in the sample agglutinate with coated SRBC within 120 min.

Sample material:
- Serum
**Anti-ovary antibody haemagglutination test**

**Description:**
With this test anti-ovary antibodies possibly responsible for fertility disorders in the serum of subfertile women are diagnosed and the titer is determined.

**EU registration number**
DE/CA81/IVD1710

**Order Code No.:**
BS-40-30

**Shelf Life:**
4 months after date of manufacture

**Principle of the test:**
This test is based upon specially pretreated and sensitized red blood cells (SRBC) coated with ovarian antigens. Antibodies in the sample agglutinate with coated SRBC within 120 min.

**Sample material:**

- Serum
**Anti-zona pellucida-antibody ELISA – Ig-classifying (Ig-typing)**

**Description:**
After detection of anti-zona pellucida antibodies, immunoglobulin classification of these antibodies (IgG, IgA, IgM) should be carried out since each class indicates a different immunological pathogenesis.

**EU registration number**
DE/CA81/IVD1699

**Order Code No.:**
BS-20-50

**Shelf Life:**
9 months after date of manufacture

**Principle of the test:**
Anti-zona pellucida antibodies of the patient's sample materials bind to ZP-antigens immobilized on a 96-well-ELISA plate. In the second step enzyme-linked antibodies directed against human immunoglobulins of the classes IgG, IgM and IgA are used. The antibody concentration in the patient’s serum correlates directly to photometrically measurements.

**Sample material:**
- Serum
Sperm antibody latex agglutination test

Description:
By means of the sperm-antibody latex agglutination test even smallest amounts of sample material (ejaculate, serum) can be examined for the presence of sperm antibodies (anti-spermatozoa antibodies, sperm antibodies).

EU registration number
DE/CA81/IVD1707

Order Code No.:
BS-10-10

Shelf Life:
15 months after date of manufacture

Principle of the test:
Only if antibodies directed against sperm antigens are present in sample materials to be examined, latex particles coated with this antigen will agglutinate within 1 - 2 minutes. The test is carried out on special slides delivered with the kit. All steps are easy to follow, diagnosis is quickly achieved and the titer of the sperm antibodies can subsequently be determined.

Sample materials:
- Serum, Seminal Plasma
Anti-ovary antibody ELISA

Description:
Quantitative ELISA to determine antibodies directed against ovarian antigens.

Principle of the test:
Anti-ovary antibodies of the patient's sample material bind to ovary antigens immobilized on a 96-well-ELISA plate. In the second step enzyme-linked antibodies directed against human immunoglobulins are used. The antibody concentration in the patient's serum correlates directly to the extinction values of the subsequent photometric measurements (450 nm).

Sample material:
- Serum
Anti-ovary antibody haemagglutination test

Description:
With this test anti-ovary antibodies possibly responsible for fertility disorders in the serum of subfertile women are diagnosed and the titer is determined.

Principle of the test:
This test is based upon specially pretreated and sensitized red blood cells (SRBC) coated with ovarian antigens. Antibodies in the sample agglutinate with coated SRBC within 120 min.

Sample material:
- Serum
Anti-ovary antibody ELISA - Ig-classifying (Ig-typing)

Description:
After detection of anti-ovary antibodies, a classification of these immunoglobulins (IgG, IgA, IgM) may be carried out.

Principle of the test:
Anti-ovary antibodies of the patient's sample material bind to ovary-antigens immobilized on a 96-well-ELISA plate. In the second step enzyme-linked antibodies directed against human immunoglobulins of the classes IgG, IgM and IgA are used. The antibody concentration in the patient's serum correlates directly to the extinction values of the subsequent photometric measurements at 450 nm.

Sample material:
- Serum
IGFBP-1 (placenta protein pp12) ELISA

Insulin-like growth factor binding protein-1, placenta protein 12, pp 12, BP-25, a1-pregnancy associated endometrial globulin, alpha1-PEG or a1-PEG, somatomedins-binding protein

Importance in the clinical routine for: Gynecologists (Early diagnosis of possible pregnancy risks); Pediatricians

This ready-to-use in-vitro test kit is designed to quantitatively determine the level of IGFBP-1 in human serum in order to diagnose risk pregnancies as well as to prognosticate fetal and postnatal development. Increased concentrations of IGFBP-1 impair both placental growth and fetal growth and may damage the fetus or lead to a miscarriage.

Increased IGFBP-1 concentrations are already detectable 3 to 6 weeks in advance of clinical symptoms such as fetal hypotrophy or hypoxia, pre-eclampsia or intrauterine death of the fetus. Detection of IGFBP-1 levels therefore allows an early beginning of adequate therapies.

Further indications for application of the test

- Diabetes mellitus
- Twin pregnancies
- Functional evaluation of the endometrium

To order the IGFBP-1 ELISA please refer to the BIOSERV catalogue number BS-30-10.
Principle of the test
Solid phase enzyme immunoassay for the quantitative determination of IGFBP-1 concentrations. The BIOSERV Diagnostics IGFBP-1 ELISA is based on the sandwich principle using monoclonal antibodies.

Sample material:
- serum

More details on IGFBP-1
The Insulin-like growth factor binding protein-1 (IGFBP-1) is an acid-stable protein. It is no placental protein in the true sense, but is secreted by the endometrium or the decidua, respectively.

IGFBP-1 inhibits both placental and fetal growth by minimizing the amount of IGF molecules available in the maternal organism. By binding and neutralizing free IGF, unlimited proliferation of the trophoblast into the decidual endometrium is prevented. High IGFBP-1 concentrations may lead to retardation, at the worst to the intrauterine death of the fetus and to miscarriage.

The IGFBP-1 concentration may influence the IGF concentration in serum such that in case of insulin deficiency (Diabetes mellitus type I) serum concentration of IGFBP-1 will be increased while decreased levels occur if insulin is overproduced (Insulinom).

Analysis of IGFBP-1 in amniotic fluid is considered to be the best marker for detecting fetal growth disorders. Concentrations of IGFBP-1 in the amniotic fluid are 100 to 500 times increased compared to maternal or fetal serum. By determining the titer of IGFBP-1, retardations of the fetus can be detected much earlier than by using ultrasonography. The highest concentrations of IGFBP-1 in amniotic fluid are reached in the 2nd trimester and between the 24th and 25th week of pregnancy. Elevated concentrations of IGFBP-1 show up either as relatively small peaks or over a longer period of time. In both cases complications are to be expected though, e.g., pathohistological alterations of the placenta. Repeated examinations to monitor high risk pregnancies, primarily between the 24th and 35th week of pregnancy, are strongly recommended.

Women with twin pregnancies reveal significantly higher IGFBP-1 levels, especially within the 10th to 20th week, compared to single pregnancies. Since multiple pregnancies do not show higher values than twin pregnancies, the maximum secretory capacity of the endometrium seems to be obtained in twin pregnancies.

During the stimulation phase, increased levels of IGFBP-1 combined with IGF-1 concentrations are essential in order to evaluate the corpus luteum regulation. Women found to have a polycystic ovary syndrome reveal normal IGF-1 levels and increased levels of luteinizing hormone and increased levels of insulin while the concentration of IGFBP-1 is reduced.

Furthermore, IGFBP-1 is an important indicator for recognizing ruptures of the fetal membrane. In those cases, IGFBP-1 levels of vaginal secretion are drastically increased up to 200-fold. Detection of IGFBP-1 therefore ensures a reliable diagnosis of fetal membrane ruptures with a very high diagnostic specificity.

Trisomy 18 (Edward syndrome) is also indicated by elevated IGFBP-1 values in combination with a low concentration of IGF-BP2 during the 1st trimester. In the serum of non-pregnant women as
well as men IGFBP-1 is present only in traces, approximately 20 ng/ml. Continuous evaluations of IGFBP-1 throughout the day revealed strong alterations of protein binding values in dependency of the time of day and food intake. In conclusion patients samples should always be taken at a fixed time, preferably in the morning.

**Glycodelin (placenta protein 14, pp14) ELISA**

also referred to as placenta protein14 (pp14), alpha2-uterus protein

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**EU registration number**

DE/CA81/IVD1694

**Order Code No.:**

**BS-30-20**

**Shelf Life:**

12 months after date of manufacture

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**Importance in the clinical routine for: Gynaecologists, Andrologists, Urologists**

The BIOSERV Diagnostics ELISA for the determination of Glycodelin (pp14, placenta protein 14) was designed for the quantitative determination of glycodelin

- in female serum in order to predict a possible allogeneic rejection response and consequently infertility or miscarriage
- in male seminal plasma in order to predict insemination problems because of a too low concentration

To order the test please refer to the BIOSERV catalogue number BS-30-20

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**Principle of the test**

Glycodelin levels are quantitatively determined in human sample materials such as serum and seminal fluid.

This glycodelin-ELISA is based on the sandwich principle using monoclonal anti-glycodelin antibodies of high affinity to determine the glycodelin concentration contained in the sample.
**More details on glycodelin**

Human glycodelin is a glycoprotein with strong immunosuppressive and contraceptive activities. In women glycodelin is produced and secreted by glandular epithelial cells of the endometrium while in men it is produced in the seminal vesicles. Glycodelin in seminal fluid is immunologically identical to endometrially produced glycodelin but different in glycosylation.

Human glycodelin is considered as a biochemical marker for the course of pregnancy, especially for the glandular epithelium activity at implantation and placentation. Functional evaluation of the endometrium is made possible by measurement of the glycodelin level in serum. Its highest concentration can be found during the first trimester of pregnancy. Women with irregular bleedings and a reduced glycodelin level have a five times higher risk for habitual spontaneous abortions during pregnancy compared to women with regular bleedings and a normal glycodelin level.

The concentration of glycodelin in serum is also an important parameter to monitor the menstruation cycle as it can be used to distinguish between ovulatory cycles and non-ovulatory cycles. Women predisposed for risks of habitual miscarriage during the late luteal phase show lower glycodelin values than normally fertile women. Moreover, glycodelin serum levels of ectopic pregnancies are lower than those found in intrauterine pregnancies. Moreover, a significant difference in concentration between aborts and ectopic pregnancy is detectable, while hCG levels seem to be identical in those cases. The determination of glycodelin levels in sera of pregnant women therefore is of great predictive value for the course of a risk pregnancy. During in-vitro fertilization glycodelin values are significantly increased in twin-pregnancies compared to single-pregnancies.

Glycodelin in seminal fluid (up to 2% of the total protein) also together with maternal endometrial glycodelin enables implantation and placentation by inhibiting the female immune response against the allogeneic foetus.

**Medical indications for the application of BIOSERV Diagnostics Glycodelin ELISA**

- Women predisposed for a habitual spontaneous abortion
- Preparation of women for an *in-vitro* fertilization therapy
- Suspected male subfertility and infertility