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DIAGNOSTICS

Fertility & Eugenic Testing Products Manual

Nantong Egens Biotechnology Co.,Ltd

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TÜV SÜD EN ISO 13485

Nantong Egens Biotechnology Co., Ltd.

EGENS

Focus on rapid diagnosis, worthy of your trust and good partners!

Company profile

Nantong Egens Biotechnology Co., Ltd. is a high-tech bio-technology company, and was founded in 1999. We are engaged in researching, developing and manufacturing in-vitro diagnostic reagents and instrument, and now have 8400m^2 standard workshops and 500m^2 laboratory for piloting.

At present, the company Nantong Egens Biotechnology Co., Ltd. regards human health as its own ideal, and continues to study for the public to make more accurate and faster and more convenient products to facilitate the disease diagnosis. At present, it has been developing the four series of rapid diagnostic products of infectious disease, tumor markers, drug detection and pregnancy prepotency diagnosis, and is developing the products of glucose monitoring system, heart disease marker and Quantitative Measurement of colloidal gold test , etc..

The company products are applying for American **FDA** certification and the Canada **CMDCAS** certification

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Directory

fFN

Diagnostic kit for fetal fibronectin (fFN) (colloidal gold)
The preterm fetus detector

Product principle:

Fetal fibronectin (fFN) is secreted by amnion, decidua, and chorion. It exists in glycosidoprotein between the decidua and chorion, playing a role in the adhesion to the caul. After the pregnant for 21 weeks, the release of fFN is prevented by the integration of chorion and decidua. Therefore, when the normal pregnant women are at their 22 to 35 weeks of gestation, the content of fFN is very low. When the chorion separates with decidua, the extracellular matrix on the interface of both chorion and decidua are damaged by mechanical damage, and the proteolytic enzymes degradate, the fFN leaks into the secretion of the posterior fornix. The level of fFN in cervicovaginal secretions during 22 to 35 weeks of pregnancy have a good correlation with the premature labour.
Diagnostic kit for fetal fibronectin (colloidal gold) adpots the principle of double antibody sandwich method and colloidal gold immune chromatography.

Sample requirements

1. Before the colposcopy or some other inspections and operations, the vaginal fluid is taken out from the posterior fornix with a special sterile swab for about 10min. The action to the operation should be light, and should not be as forced as sampling the microbial cultivation.
2. The liquid obtained from the cervix and vagina should not be polluted by lubricants, soap, disinfectant, or pastes (such as K-Y Jelly lubricant, Betadine disinfectant, Monistat cream, and hexachlorophene). These substances may interfere in the process of specimen collection or antigen-antibody reaction of strips'.
3. After sampling, the operation is advised to be performed according to the instructions within 15 min. Samples can not be stored for use.

Characteristics of product technology

1. Minimum detectable amount: the standard of minimum detectable amount is determined by fFN, and the limit of identification is 50 ng/ml 15 min later.
2. Repeatability: the precision of reference materials are detected parallelly (n=10). They are all positive with uniform degrees of color.
In cervical secretions, some potential interfering substances can be tested. The following materials in this concentration will not interfere with test results.

Materials	Concentrations
Oxytocin	10IU/ml
PGF 2α	0.033 mg/ml
PGE2	0.033 mg/ml
Human serum fibronectin	0.1mg/ml

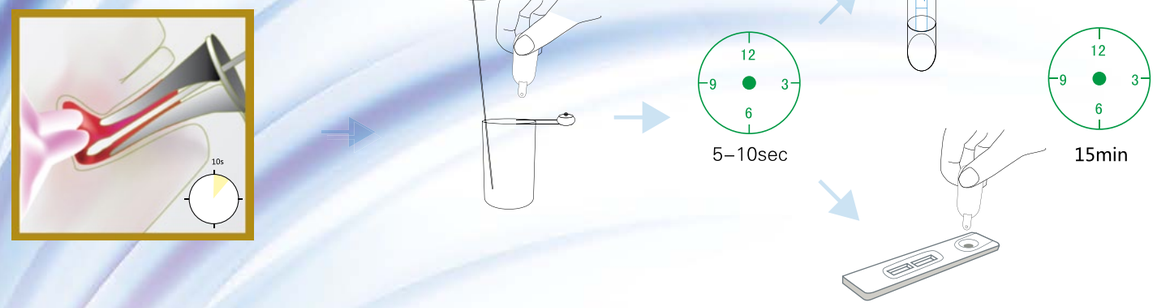
Technical indicators:

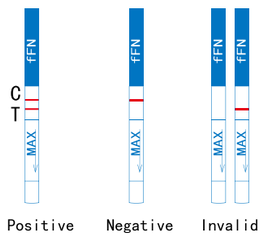
Statistical results of Egens reagent on 240 samples

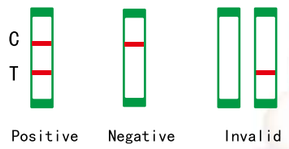
Egens reagent	Control reagent kit		Total
	Positive	Negative	
Positive	60	0	60
Negative	0	180	180
Total	60	180	240

Sensitivity: Se=100%
Specificity: Sp=100%
False positive rate =0%
False negative rate =0%
Total accordance rate = 100%

Procedure and result analysis







Sperm concentration

The Kit for Sperm Density Detection (Colorimetric method)
Operating Instructions

Name of the product

Common name: The kit for sperm density detection (Colorimetric method)
English Name: Fast diagnostic screening test for sperm concentration

Package, specifications

One person share /bag, 1~100 person share/box

Principle of the test

The kit for sperm density detection (Colorimetric method) is using the inert glass fiber membrane with high water absorption and the pore size of less than 0.5um to filter the semen, and sperm cells will be trapped on surface of the first layer of the membrane, and we use the staining fluid that can quickly dye sperm cells, the darker of the color, the more of sperm count on the filter membrane, and the density of sperm in the semen will be higher. Through comparing with the reference color (20million/ml specified by WHO) of B hole on the test board, we know that if color of the reaction hole is lighter than color of the color card, the sperm density is positive, and if cooler of the reaction hole is darker than the color card, the sperm density is negative.

Storage conditions and validity

To store it in dry environment, avoid light at the temperature of 2-30 , and it shall not be frozen. The product is valid for 24 months from the date of production. After opening the package, the product shall be continuously stored in a dry environment, avoid light at the temperature of 2-30 , and it shall be used within an hour as soon as possible.

Applicable instruments

In the process of use, the kit needs not supporting instruments.

Requirements of the specimen

1. Before testing, the subject shall mortify for 3-7 days, the abstinence time is too short or too long will affect the accuracy of diagnosis;
2. Using masturbation to expel the semen directly into a sperm collecting cup, and adopting water bath of 37 to liquefy for 15 minutes(the semen collecting room in hospital) or using a condom to collect semen during the sex life (family environment), to pour all the semen into the semen collecting cup, and liquefy it for 15 minutes at room temperature, that is, the semen is changed into fluid liquid from glue frozen state, which shows that the liquidation is completed;
3. After collection of the semen, semen shall be carried out a test within 2 hours. And if it needs to be tested again later, the specimen of semen shall be stored in a refrigerator at 2 to 8 , but the storage time shall not be more than 12 hours. If the specimen needs to be stored for a long time, please store it in a refrigerator, but it can only be dissolved and used for one time.
4. When the test is completed, we'd better read the results within 5 minutes. Over time, the color will fade slowly, if we want to compare the results with test of the next time, we can take the results with a camera to save them.

Main components

Specifications	Name of the components	Quantity	Main biochemical components
Type of the cards	The test board packed with aluminum foil	1~100PCS	It is consisted of the test board; desiccant, disposable pipette and aluminum foil bags. And the central test board is consisted of the card board and glass fiber membrane.
	Instructions	1 copy	Printed with paper
	Staining fluid	1bottle	Methylene blue
	Cleaning solution	1bottle	The normal saline with ethanol of 5%
	Semen collection cup	1~100PCS	The plastic cup containing Chymotrypsin

Intended use

Used for qualitatively detecting sperm density of human semen in vitro, and conducting auxiliary clinical diagnosis of the infertility and self-evaluation of pre-pregnancy male fertility.

Test methods

Before testing, we must read the instructions completely first
1. Specimen collection of semen: Using masturbation to expel the semen directly into the sperm collecting cup, or using a condom to collect semen during the sex life, to pour all the semen into the semen collecting cup.
2. Liquefaction: To shake evenly the semen in the semen collecting cup, and standing it for 15 minutes, until the semen becomes fluid liquid;
3. Add the specimen: To take out an experimental board from a aluminum foil bag, and place it on the operation platform horizontally, using an accessory specimen-absorption pipe to absorb a tube of semen from the semen collecting cup, and dropping three drops of the semen into the white A hole, and then the semen saturates to surface of the membrane and dry;
4. Add blue staining fluid: To add one drop of blue staining solution to A hole, and let it soak for 1-2 minutes;
5. Add transparent cleaning solution: Add two drops of transparent cleaning solution to A hole, and let it soak for 1-2 minutes, and then read the results immediately;
6. Read the results: Read the color of A hole, compare colors of A hole to B hole, the darker of the color, the more of sperm count, and report the results.

Reference value (reference range)

The laboratory test manual for interaction between WHO human semen and sperm- cervical mucus recommends using Neubauer blood cell counting plate as a tool for semen analysis. At present, the value is set in domestic and abroad: In normal semen, count of the sperm is more than 20 million/ml; the case that the count of sperm is less than 20million /ml belongs to oligozoospermia; the case between 5 million to 10million/ml belongs to moderate oligozoospermia disease; and the case of less than 5million/ml belongs to severe oligozoospermia.

Repeated test		Correction test	Explanation
A	C	D	
All are negative		Need not to do	Density of the sperm≥20million/ml
Positive and negative can not be defined		Negative	17million≤Density of the sperm≤21million/ml, to consult the doctors
Positive and negative can not be defined		Positive	Density of the sperm<20million/ml, to consult the doctors
All are positive		Need not to do	Density of the sperm<20million/ml, to consult the doctors

Interpretation of the test results

Results of naked eye observation: Compare colors of A hole of the test board to B hole.
Negative reactive results: The color of A hole is darker than standard color of B hole, and which shows that density of sperm ≥20million/ml, and density of the sperm is normal.
Positive reaction results: The color of A hole is lighter than standard color of B hole, and which shows that density of the sperm≤20million /ml, such case belongs to oligospermatism (5million/ml≤ density of the sperm≤20million/ml); If A hole is colorless, and which shows that density of the sperm≤5million/ml, such case belongs to severe oligozoospermia or azoospermia.
The subject whose test result is positive or can not be judged shall be repeated the test in C hole, the testing result of A hole shall be the same with C hole. If the results are different, and the correction shall be conducted in D hole (to add 4 drops of semen into D hole), and the results can be explained as the following table. The subject shall be repeatedly examined in 3-7 days after the first test, and consult male doctors about the obtained results.

Performance indicators of the products

The product meets requirements of the standards for registered products of the kit for sperm density detection (Colorimetric method)

Descriptions and precautions

1. This kit can only be used for diagnosis tests in vitro. To test human semen specimen, and it does not apply to specimen of other body fluids.
2. The kit shall be stored at room temperature, to avoid moisture. If the foil packaging is damaged, please not use.
3. If the test card's package is opened, it shall be used as soon as possible, to avoid to be placed in the air for a long time, resulting in damp and failure.
4. The kit is a kind of product used for primary test, any measured positive results shall be determined with other methods.
5. When the tests are carried out for a large number of specimens, please make marks, to avoid confusion.
6. Adding specimens and cleaning shall try to avoid bubbles, resulting effects to the test results.
7. To observe the reaction results strictly according to time requirements of the instructions.
8. This kit can only be used for one-time diagnosis in vitro, and the semen taken from different subjects or from the same subject at different times can not be used repeatedly.
9. The kit must not be frozen or used after the expiry.

TORCH

ONE STEP CASSETTE STYLE TORCH IgM TEST (COLLOID GOLD)

INTRODUCTION

The one step cassette style TORCH test is a rapid test based on the principle of immunoassay combined with conjugated colloid gold technology. The test is a diagnostic device for qualitative detection of specific antibody IgM of TORCH in human serum (or plasma) specimen.

SUMMARY

TORCH is a group of pathogenes including Toxoplasma (TOX), Rubella virus (RV), Cytomegalo-virus (CMV), Herpes simplex virus (HSVand HSV). TORCH test is one of the prenatal examinations to prevent teratism.
Purified recombinant antigens of TORCH pathogenes are precoated onto membrane as a capture reagent on the test band region. If TORCH IgM is present in the sample in concentration above the labeled anti-human IgM-dye complex will be formed. This complex is then captured by antigens immobilized in the Test Zone of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will depend on the concentration of TORCH IgM present in the sample. This one step test is very sensitive and only takes about 15-20 minutes. Test results are read visually without any instrument.

SPECIMEN COLLECTION

For serum or plasma , collect blood into a container without anticoagulant. If the specimen cannot be tested on the day of collection, store the serum (or plasma) specimen in a refrigerator or freezer. Bring the specimens to room temperature before testing.

TEST PROCEDURE

1. Dilute the serum (or plasma) specimen 50 times with diluent(10μl specimen add 490μl diluent).
2. Open a pouch containing a cassette, remove the test kit from the pouch and place it horizontally on the desk.
3. Pipette 1 or2 drops of diluted specimen into the sample well of the cassette.
4. Read results within 10-15 minutes. Do not read results after 20 minutes

INTERPRETATION OF RESULTS

Negative: Only one pink band appears on test region of the Cassette. This indicates that there is no detectable specific IgM in the specimen.
Positive: Two pink bands appear on test region of the Cassette. This indicates that the specimen contains detectable amount of specific IgM.
Invalid: If without colored band appears on test region, this is an indication of a possible error in performing the test. The test should be repeated using a new device.

PRECAUTION

1.Must use fresh specimen and avoid repetitive freezing, the result will be invalid
2.Use it before expiry date.
3.The package of kit should not be opened until it reaches the room temperature if it taken out from the refrigerator. Use the test kit as soon as possible but within 1 hour after removal from pouch specially if the room temperature is more than 30℃ and in high humidity environment.
4.Old Serum can not be used. If the serum is thick, it can be used only after being separated.

LIMITATIONS

1.The test is for in-vitro diagnostic use only.
2.The test is qualitative filter detection it can not be used as the final test for blood donor.

STORAGE AND STABILITY

The test kit can be stored at room temperature (18 to 30C) in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

HCG

Very early pregnancy test strip/ card / pen
Human chorionic gonadotropin (HCG) diagnostic test strips (colloidal gold)
EU CE Certification

Product principle:

HCG is a kind of glycoprotein hormone produced by placenta in pregnant women, and abounds in the urine of them. The series products of early pregnancy detection adopt the principle of chromatographic double antibody sandwich method, using the colloidal gold as an indicating marker. The concentration of HCG in urine is detected to confirm whether a woman become pregnant or not for an early pregnancy diagnosis.

Characteristics of product technology

It can detect the early pregnancy, and can be determined 2 to 3 days after the implantation of zygote with the interpretation of results for 3 to 5 minutes.
Products is in various form with human oriented design and is suitable for all levels of medical units and home self-test.
It is stored at room temperature, easy to carry, and valid for 24 months.
Sensitivity: 10 mIU/ml.
Specificity: the test results are not interfered by hLH, hFSH, hTSH and so on in a certain concentration.

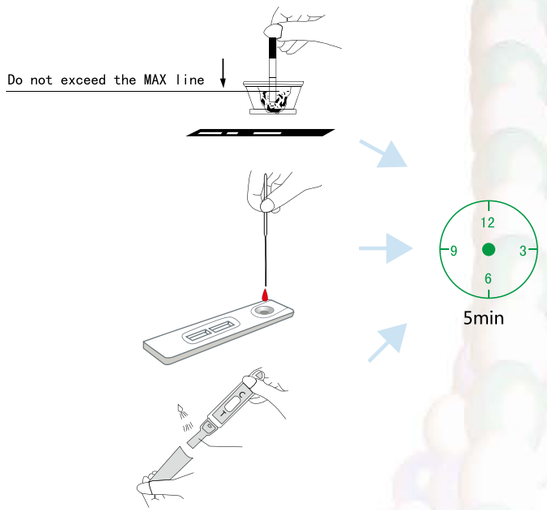
Technical indicators:

Statistical results of Egens reagent on 240 samples

Egens reagent	Control reagent kit		Total
	Positive	Negative	
Positive	100	0	100
Negative	0	140	140
Total	100	140	240

Sensitivity: Se=100%
Specificity: Sp=100%
False positive rate=0%
False negative rate =0%
Total accordance rate = 100%

Procedure and result analysis



LH

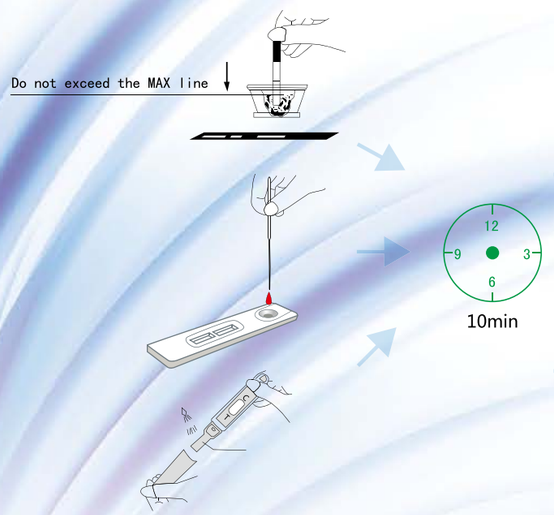
Ovulation test strip / card / pen
Luteinizing hormone (LH) diagnostic kit (colloidal gold)
EU CE Certification

Product principle:

LH is a kind of hormone, the content of which changes periodically with the female menstrual cycle. Its effect is to stimulate the release of mature eggs within the ovaries. When its peak appears, LH abounds in the blood and urine of female. Hence, the detection of LH in urine is a reliable criterion for the prediction of ovulation. The ovulation test strip adopts the principle of chromatographic double antibody sandwich method to detect the level of LH, and is adequate for family self-test. It is helpful to improve the success ratio of pregnancy or can be used as a reference to contraception and an auxiliary diagnosis for clinical prediction of ovulation cycle.

Characteristics of product technology

The product homogeneity is good, and the interpretation is accurate.
It is applicable to the bearing and rearing better children, infertility, physical contraception and so on for the related medical units and family self-test.
It is stored at room temperature, easy to carry, and valid for 24 months.
Sensitivity: 25 mIU/ml.
Specificity:The colour of those whose (HCG hFSH hTSH, etc.) concentration are below the detection line of 200 mIU/ml are significantly lighter than those at the control line.



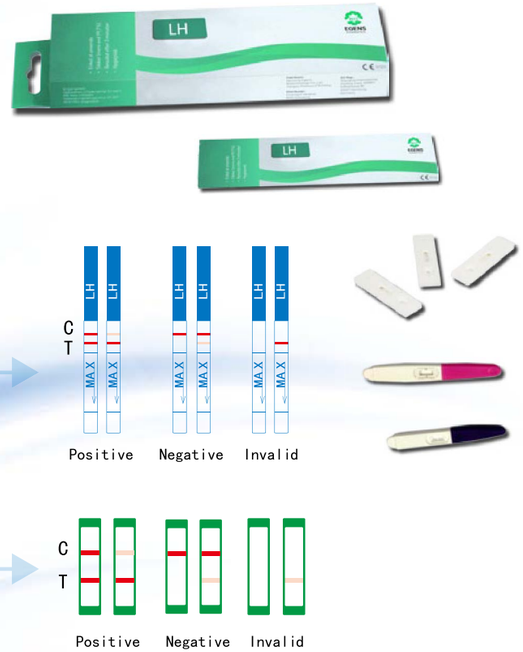
Technical indicators:

Statistical results of Egens reagent on 240 samples

Egens reagent	Control reagent kit		Total
	Positive	Negative	
Positive	100	0	100
Negative	0	140	140
Total	100	140	240

Sensitivity: Se=100%
Specificity: Sp=100%
False positive rate =0%
False negative rate =0%
Total accordance rate = 100%

Procedure and result analysis



FSH

Diagnostic kit for follicle stimulating hormone (colloidal gold)
Ovarian function test for female dimacteric state

Product principle:

In vitro, the qualitative detection of FSH in human urine is used as an auxiliary diagnosis for female climacteric state. In the menstrual cycle, the FSH concentrations in blood and the amount of FSH exerted from urine daily change with the cycle. After the menopause, the excretion of FSH in both blood and urine increases.
Diagnostic kit for follicle stimulating hormone (colloidal gold) adpots the principle of double antibody sandwich method and colloidal gold immune chromatography to detect the level of FSH in human urine as the criteria for menopause.

Characteristics of product technology

1. The minimum detectable amount is not higher than 25 mIU/ml.
2. The colour of those whose concentration are below 200 mIU/ml are all lighter than those at the control line.

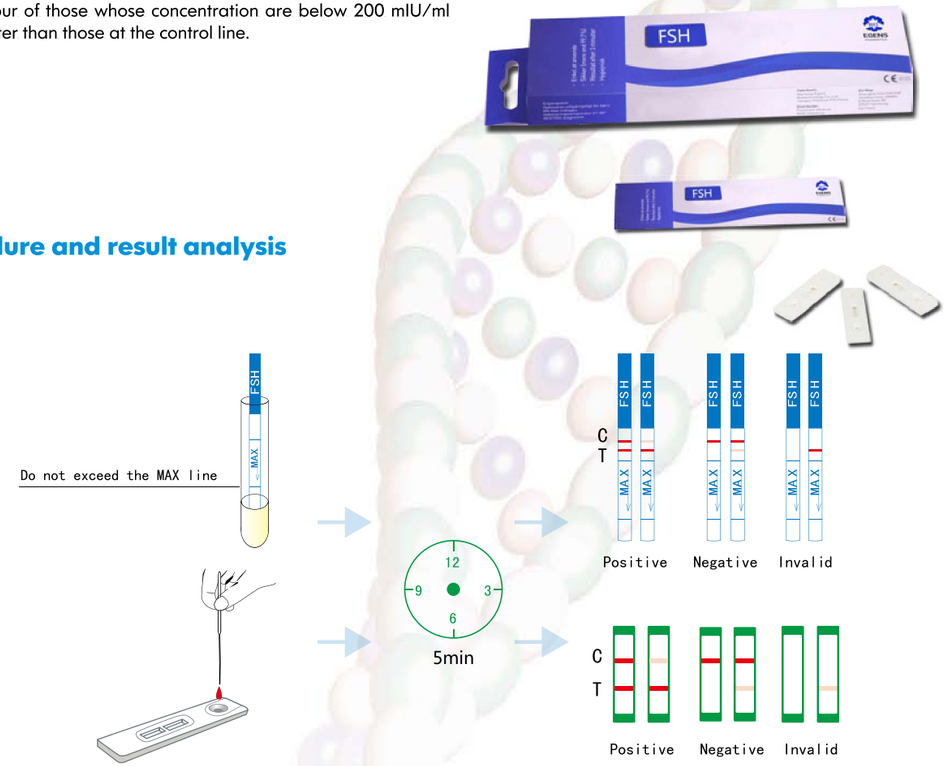
Technical indicators:

Statistical results of Egens reagent on 240 samples

Egens reagent	Control reagent kit		Total
	Positive	Negative	
Positive	60	1	61
Negative	0	179	179
Total	60	180	240

Sensitivity: Se=100%
Specificity: Sp=99.44%
False positive rate =0.56%
False negative rate =0%
Total accordance rate = 99.58%

Procedure and result analysis



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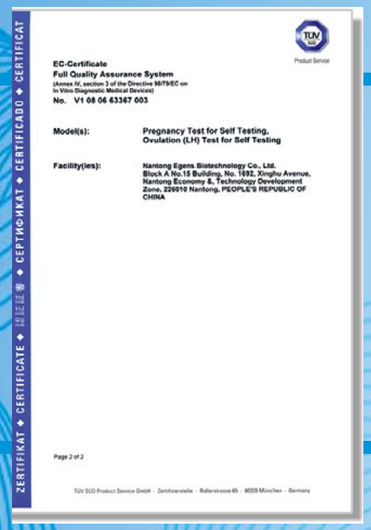
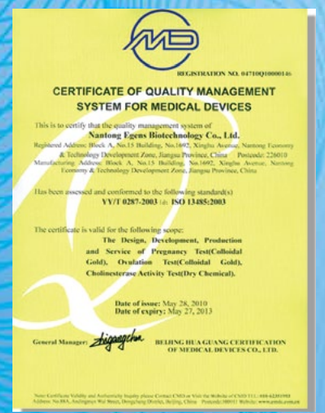
Focus on rapid diagnosis, worthy of your trust and good partners!

Top products are originated from rate quality control.Egens considers the product qualify as the company's lifeline and the company is a champion.always in pursuit of topnotch quality as company principle.We undertake quality monitol tasks are duly implemented as end-to-end procedures throughout R&D.production,delivery and service process flow.to reflect our quality-conscious idea with its focus on prevention.In this regars,products are contuolled by strict quality conformance via every process,to continuously imprpve inspectors to grow diversified eligibilities,firmly maintain the ideas saying that "Quality is company's life and key to competition".for continuous development of product & service quality and improvement and better customer services.





QUALIFICATION

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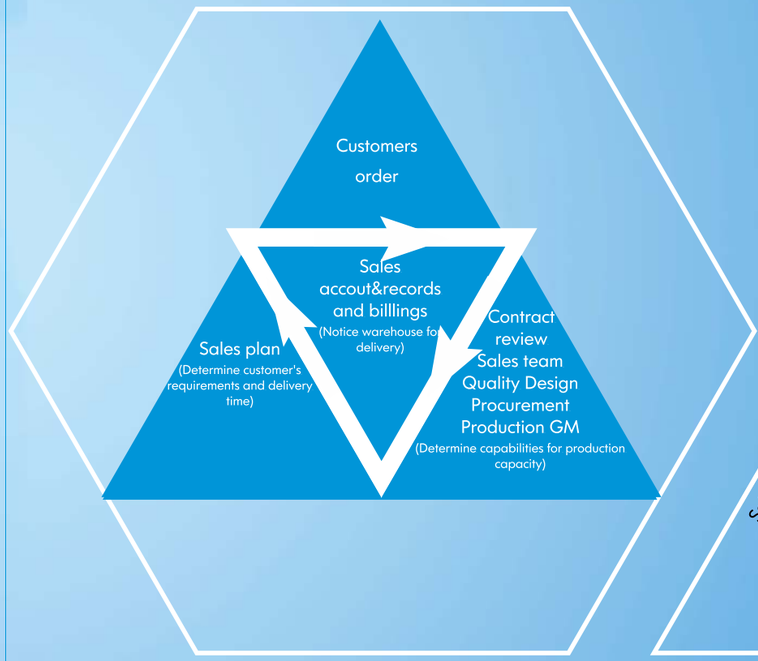
SERVICE PRINCIPLES

Nantong Egens Biotechnology LLC,is a producer of asfe and effective diagnostic regents. As a dedicated provider to the mankind for health undertakings,the company maintains the heritage of faithful philosophy as facilitating developer for company's growth by continus research of quicker,more accurate.more convenient and more favorable products to show socialcares to the mass.The company seeks to become a leading model of its kind in the circle of diagnostic reagent sector.expecting to do more for social development and bring contributive benefits.

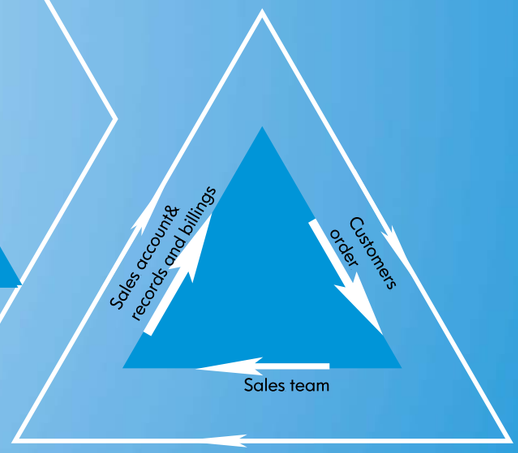
SERVICE COMMITMENTS

In persistence to the "Customer Satisfaction"as basis we commit to continuously improve working methods QC,better our skills. processing competency and escalate service quality,to provide customers all-inclusive services;we further commit to continuously consolidate R&D capabilities to develop new products.to provide customers with featured products of essier introduction and with extra value additions for better interests in favor to customers.

ORDER PROCEDURES



ONE and foreign trade products ordering process



Conventional products ordering process

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GLOBAL SERVICE NETWORK

NANTONG EGENS BIOTECHNOLOGY CO.,LTD.by virtue of its superior technology and equipment,humanized pre-sales during and after-sales service,extensive sales network andbuild a excellent network chain between NANTONG EGENS I and end-customers,timely convery and meet trends of end-customers demand,Based on excellent quality,Nantong Egens' products are sold at home and abroad.