NovaTec Immundiagnostica GmbH

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

17 beta-Estradiol (DNOV003)

and the following components:

MTP	Anti-17 beta-Estradiol Coated Wells
CONJ	17 beta-Estradiol-HRP Conjugate
SUB TMB	TMB Substrate Solution
WASH BUF 10x	Wash Solution 10x conc.
CONTROL	Control
CAL 0 - 5	Standards 0-5
SOLN STOP	Stop Solution

are in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct. 27, 1998 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures in

Annex III (2–5).

Dietzenbach: 2018-11-21

Digitally signed by Borca Petru
Date: 2024.08.26 15:29:11 EEST
Reason: MoldSign Signature
Location: Moldova

Dr. Claudia Rezmer
Management Representative

The conformity of the above mentioned product is checked at least every 3 years. This is documented by rechecking and signing the general requirements.

NovaTec Immundiagnostica GmbH

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

Progesterone (DNOV006)

and the following components:

MTP	Anti-Progesterone IgG Coated Wells
CONJ	Progesterone-HRP Conjugate
SUB TMB	TMB Substrate Solution
WASH BUF 10x	Wash Solution 10x conc.
CONTROL	Progesterone Control
CAL 0 - 4	Progesterone Standards 0-4
SOLN STOP	Stop Solution

are in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct. 27, 1998 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures in

Annex III (2–5).

Dietzenbach: 2018-11-21

Dr. Claudia Rezmer
Management Representative

The conformity of the above mentioned product is checked at least every 3 years. This is documented by rechecking and signing the general requirements.

NovaTec Immundiagnostica GmbH

Progesterone

CE

Enzyme immunoassay for the quantitative determination of Progesterone in human serum or plasma

Dosage immunoenzymatique pour la détermination quantitative de Progesterone dans le sérum ou le plasma humain

Inmunoensayo enzimático para la determinación cuantitativa de Progesterona en suero o plasma humano

Only for in-vitro diagnostic use

Product Number: DNOV006 (96 Determinations)

ENGLISH

CE

1. INTRODUCTION

Progesterone is a C-21 steroid hormone involved in the female menstrual cycle, pregnancy (supports gestation) and embryogenesis of humans and other species. Progesterone is the major naturally occurring human progestagen.
Progesterone is important for aldosterone (mineralocorticoid) synthesis, as 17-hydroxyprogesterone is for cortisol (glucocorticoid).
Progesterone levels are relatively low in children and postmenopausal women. Adult males have levels similar to those in women during the follicular phase of the menstrual cycle.
In women, progesterone levels are relatively low during the preovulatory phase of the menstrual cycle, rise after ovulation, and are elevated during the luteal phase. If pregnancy occurs, progesterone levels are maintained at luteal levels initially. After delivery of the placenta and during lactation, progesterone levels are very low. The fall in progesterone levels following delivery is one of the triggers for milk production.
Progesterone is produced in the adrenal glands, the gonads (specifically after ovulation in the corpus luteum), the brain, and, during pregnancy, in the placenta.
Progesterone converts the endometrium to its secretory stage to prepare the uterus for implantation. If pregnancy does not occur, progesterone levels will decrease, leading, in the human, to menstruation.
Progesterone belongs to the group of neurosteroids that are found in high concentrations in certain areas in the brain and are synthesized there. Neurosteroids affect synaptic functioning, are neuroprotective, and affect myelinization.
Progesterone has multiple effects outside of the reproductive system. Progesterone is thermogenic; it reduces spasm and relaxes smooth muscle. Bronchi are widened and mucus regulated. Progesterone acts as an antiinflammatory agent and regulates the immune response. Progesterone also assists in thyroid function, in bone building by osteoblasts.
Measurement of serum progesterone concentrations have been used in evaluating ovarian function.

2. INTENDED USE

Competitive immunoenzymatic colorimetric method for quantitative determination of Progesterone in serum or plasma.

3. PRINCIPLE OF THE ASSAY

Microtiter strip wells are precoated with anti-Progesterone antibodies (solid-phase). Progesterone in the sample competes with added horseradish peroxidase labelled Progesterone (enzyme-labelled antigen) for antibody binding. After incubation a bound/free separation is performed by solid-phase washing. The immune complex formed by enzyme-labelled antigen is visualized by adding Tetramethylbenzidine (TMB) substrate which gives a blue reaction product. The intensity of this product is **inversely** proportional to the amount of Progesterone in the sample. Sulphuric acid is added to stop the reaction. This produces a yellow endpoint colour. Absorption at 450 nm is read using an ELISA microwell plate reader.

4. MATERIALS

4.1. Reagents supplied

- **Anti-Progesterone IgG Coated Wells:** 12 breakapart 8-well snap-off strips coated with anti-Progesterone IgG; in resealable aluminium foil.
- **Stop Solution**: 1 bottle containing 15 ml sulphuric acid, 0.15 mol/l (avoid any skin contact).
- **Progesterone-HRP Conjugate:** 1 bottle containing 22 ml of horseradish peroxidase labelled Progesterone.
- **TMB Substrate Solution**: 1 bottle containing 15 ml 3, 3´, 5, 5´-tetramethylbenzidine (H_2O_2-TMB 0.26 g/l) (avoid any skin contact).
- **Wash solution 10x conc**.: 1 bottle containing 50 ml of a 10x concentrated solution of phosphate buffer 0.2 M, Proclin < 0.0015%
- **Progesterone control**: 1 bottle containing 1 ml of a lot-specific control solution. The concentration is indicated on the label of the bottle.
- **Progesterone Standards:** 5 bottles, 1 ml each

  Standard 0: 0 ng/ml
  Standard 1: 0.2 ng/ml
  Standard 2: 1.0 ng/ml
  Standard 3: 8.0 ng/ml
  Standard 4: 40.0 ng/ml

4.2. Materials supplied

- 1 Strip holder
- 1 Cover foils
- 1 Test protocol
- 1 Distribution and identification plan

4.3. Materials and Equipment needed

- ELISA microwell plate reader, equipped for the measurement of absorbance at 450 nm, 620-630 nm
- Manual or automatic equipment for rinsing wells
- Pipettes to deliver volumes between 10 and 1000 µl
- Distilled water
- Timer
-

5. STABILITY AND STORAGE

The reagents are stable up to the expiry date stated on the label when stored at 2...8 °C in the dark.

6. REAGENT PREPARATION

It is very important to bring all reagents, samples and standards to room temperature (22…28°C) for at least 30 minutes before starting the test run! At the end of the assay, store immediately the reagents at 2-8°C; avoid long exposure to room temperature.

6.1. Coated snap-off Strips

The ready to use break apart snap-off strips are coated with anti-Progesterone IgG antibodies. Store at 2…8°C. Open the bag only when it is at room temperature. *Immediately after removal of strips, the remaining strips should be resealed in the aluminium foil along with the desiccant supplied and stored at 2…8 °C; stability until expiry date.*

6.2. Progesterone-HRP Conjugate

Progesterone-HRP Conjugate is a ready to use solution.

6.3. Progesterone Standards

The standards are ready to use. Before using leave 5 min on a rotating mixer. After first opening stable for another 6 months at 2...8°C.

6.4. TMB Substrate Solution

The bottle contains 15 ml of a tetramethylbenzidine/hydrogen peroxide system. The reagent is ready to use and has to be stored at 2...8°C in the dark. *The solution should be colourless or could have a slight blue tinge. If the substrate turns into blue, it may have become contaminated and should be thrown away*.

6.5. Stop Solution

The bottle contains 15 ml 0.15 M sulphuric acid solution (R 36/38, S 26). This ready to use solution has to be stored at 2...8°C.

6.6. Wash Solution

Dilute the content of the concentrated Wash Solution with distilled water to a final volume of 500 ml prior to use. For smaller volumes respect the 1:10 dilution ratio. The diluted wash solution is stable for 30 days at 2…8°C. In concentrated wash solution it is possible to observe the presence of crystals, in this case mix at room temperature until complete dissolution of crystals, for greater accuracy dilute the whole bottle of concentrated wash solution to 500ml on taking care also to transfer crystals with washing of the bottle, then mix until crystals are completely dissolved.

6.7. Progesterone Control

The bottle contains 1 ml of a lot-specific control solution. The concentration is indicated on the label.

7. SPECIMEN COLLECTION AND PREPARATION

The determination of Progesterone can be performed in plasma as well as in serum. Store the sample at -20°C if the determination is not performed on the same day as the sample collection. If samples are stored frozen, mix thawed samples well before testing. *Avoid repeated freezing and thawing.*

8. ASSAY PROCEDURE

8.1. Test Preparation

Please read the test protocol carefully **before** performing the assay. Result reliability depends on strict adherence to the test protocol as described. Prior to commencing the assay, the distribution and identification plan for all specimens and standards should be carefully established on the result sheet supplied in the kit. Select the required number of microtiter strips or wells and insert them into the holder. Please allocate at least:

1 well	(e.g. A1)	for the substrate blank
2 wells	(e.g. B1+C1)	for standard 0
2 wells	(e.g. D1+E1)	for standard 1
2 wells	(e.g. F1+G1)	for standard 2
2 wells	(e.g. H1+A2)	for standard 3
2 wells	(e.g. B2+C2)	for standard 4
2 wells	(e.g. D2+E2)	for control

It is necessary to determine standards, control and patient samples in duplicate.

Perform all assay steps in the order given and without any appreciable delays between the steps.

A clean, disposable tip should be used for dispensing each standard and each patient sample.

1. Dispense 20 µl standards, control and samples into their respective wells.
2. Add 200 µl Progesterone-HRP Conjugate to each well. Leave well A1 for substrate blank.
3. Cover wells with the foil supplied in the kit.
4. **Incubate for 1 hour at 37 °C.**
5. When incubation has been completed, remove the foil, aspirate the content of the wells and wash each well three times with 300 µl diluted wash solution. Avoid overflows from the reaction wells. **Important note:** During each washing step, gently shake the plate for 5 seconds and remove excess solution by tapping the inverted plate on an absorbent paper towel.

   Automatic washer: In case you use automatic equipment, wash the wells at least 5 times.

   Note: Washing is critical! Insufficient washing results in poor precision and falsely elevated absorbance values.
6. Dispense 100 µl TMB Substrate Solution into all wells.
7. **Incubate for exactly 15 min at room temperature (22…28°C) in the dark.**
8. Dispense 100 µl Stop Solution into all wells in the same order and at the same rate as for the TMB Substrate Solution. Shake the microplate gently.
   Any blue colour developed during the incubation turns into yellow.
9. Measure the absorbance of the specimen at 450 nm against a reference wavelength of 620-630 nm or against blank within 5 minutes.

8.2. Measurement

Adjust the ELISA Microwell Plate Reader **to zero** using the **substrate blank in well A1**.

If - due to technical reasons - the ELISA reader cannot be adjusted to zero using the substrate blank in well A1, subtract the absorbance value of well A1 from all other absorbance values measured in order to obtain reliable results!

Measure the absorbance of all wells at **450 nm** and record the absorbance values for each standard and patient sample in the distribution and identification plan.

Where applicable calculate the **mean absorbance values** of all duplicates.

9. RESULTS

9.1. Calculation of results

Calculate the mean absorbance for each point of the standard curve and each sample. Plot the mean value of absorbance of the standards against concentration. Draw the best-fit curve through the plotted points. (Four Parameter Logistic).
Interpolate the values of the samples on the standard curve to obtain the corresponding values of the concentrations expressed in ng/ml.

9.2. Reference values

The following value for serum or plasma Progesterone should be considered as a guideline:

Men		< 0.1 ng/ml	
Women	follicular phase	0.1 – 1.4 ng/ml	
	mid luteinic phase	4.0 – 25.0 ng/ml	
	menopause	<1.0 ng/ml	
	pregnancy	<u>week</u>	<u>ng/ml</u>
		18-21	53-76
		22-25	60-86
		26-29	71-133
		30-33	86-142
		34-37	104-175
		38-41	117-187

Please pay attention to the fact that the determination of a range of expected values for a “normal” population in a given method is dependent on many factors, such as specificity and sensitivity of the method used and type of population under investigation. Therefore each laboratory should consider the range given by the manufacturer as a general indication and produce their own range of expected values based on the indigenous population where the laboratory works.

10. QUALITY CONTROL

Each laboratory should assay controls at normal, high and low levels range of Progesterone for monitoring assay performance. These controls should be treated as unknowns and values determined in every test procedure performed. Quality control charts should be maintained to follow the performance of the supplied reagents. Pertinent statistical methods should be employed to ascertain trends. The individual laboratory should set acceptable assay performance limits. Other parameters that should be monitored include the 80, 50 and 20% intercepts of the standard curve for run-to-run reproducibility. In addition, maximum absorbance should be consistent with past experience. Significant deviation from established performance can indicate unnoticed change in experimental conditions or degradation of kit reagents. Fresh reagents should be used to determine the reason for the variations.

11. SPECIFIC PERFORMANCE CHARACTERISTICS

11.1. Precision

Intra Assay Variation
Within run variation was determined by replicate determination (20x) of three different control sera in one assay. The within assay variability is ≤ 4%.

Inter Assay Variation
Between run variation was determined by replicate measurements (10x) of three different control sera in different lots. The between assay variability is ≤ 9.3 %.

11.2. Cross Reactivity

The cross reaction of the antibody calculated at 50% according to Abraham is:

Progesterone	100%
Testosterone	0.37%
17 α OH Progesterone	0.29
17 β Estradiol	0.0013%
Estrone	0.00053%
Estriol	< 0.0001%
Cortisol	< 0.0001%

11.3. Analytic Sensitivity

The lowest detectable concentration of Progesterone that can be distinguished from the zero standard is 0.05 ng/ml at the 95 % confidence limit.

11.4. Accuracy

The recovery of 1.0 – 2.0 – 4.0 – 8.0 ng/ml Progesterone added to sample gave an average value (±SE) of 100.88% ± 8.29 % with reference to the original concentrations.

11.5. Method comparison

The NovaTec Progesterone ELISA was compared to Adaltis Progesterone EIAGen. Serum samples of 31 serum samples were analysed according in both test systems.
The linear regression curve was calculated.

Progesterone NovaTec = 0.97 * Progesterone Adaltis + 0.04
$r^2 = 0.887$

12. PRECAUTIONS AND WARNINGS

- In compliance with article 1 paragraph 2b European directive 98/79/EC the use of the in vitro diagnostic medical devices is intended by the manufacturer to secure suitability, performances and safety of the product. Therefore the test procedure, the information, the precautions and warnings in the instructions for use have to be strictly followed. The use of the testkits with analyzers and similar equipment has to be validated. Any change in design, composition and test procedure as well as for any use in combination with other products not approved by the manufacturer is not authorized; the user himself is responsible for such changes. The manufacturer is not liable for false results and incidents for these reasons. The manufacturer is not liable for any results by visual analysis of the patient samples.
- Only for in-vitro diagnostic use.
- All components of human origin used for the production of these reagents have been tested for anti-HIV antibodies, anti-HCV antibodies and HBsAg and have been found to be non-reactive. Nevertheless, all materials should still be regarded and handled as potentially infectious.

- Do not interchange reagents or strips of different production lots.
- No reagents of other manufacturers should be used along with reagents of this test kit.
- Do not use reagents after expiry date stated on the label.
- Use only clean pipette tips, dispensers, and lab ware.
- Do not interchange screw caps of reagent vials to avoid cross-contamination.
- Close reagent vials tightly immediately after use to avoid evaporation and microbial contamination.
- After first opening and subsequent storage check conjugate and control vials for microbial contamination prior to further use.
- To avoid cross-contamination and falsely elevated results pipette patient samples and dispense conjugate without splashing accurately to the bottom of wells.
- The ELISA is only designed for qualified personnel who are familiar with good laboratory practice.
- Maximum precision is required for dispensation of the reagents.
- The TMB Substrate contains an irritant, which may be harmful if inhaled, ingested or absorbed through the skin. To prevent injury, avoid inhalation, ingestion or contact with skin and eyes.
- Avoid the exposure of TMB substrate to direct sunlight, metal or oxidants.
- The Stop Solution consists of a diluted sulphuric acid solution. Sulphuric acid is poisonous and corrosive and can be toxic if ingested. To prevent chemical burns, avoid contact with skin and eyes.
- For higher values, for example in pregnancy, dilute the sample; consider the dilution factor when calculating the result.
- Treatment of the patient with cortisone, natural or synthetic steroids can impair Progesterone determination.
- Addition of the TMB Substrate solution initiates a kinetic reaction, which is terminated by the addition of the Stop Solution. Therefore, the TMB Substrate and the Stop Solution should be added in the same sequence to eliminate any time deviation during the reaction.
- Observe the guidelines for performing quality control in medical laboratories by assaying controls and/or pooled sera.
- Microbiologically contaminated samples should not be used in the assay. Highly lipemic or haemolysed specimens should also not be used.
- Plate readers measure vertically. Do not touch the bottom of the wells.
- It is important that the time of reaction in each well is held constant for reproducible results. Pipetting of samples should not extend beyond ten minutes to avoid assay drift. If more than 10 minutes are needed, follow the same order of dispensation. If more than one plate is used, it is recommended to repeat the dose response curve in each plate.
- The incomplete or inaccurate liquid removal from the wells could influence the assay precision and/or increase the background. To improve the performance of the kit on automatic systems is recommended to increase the number of washes.
- Some reagents contain small amounts of Proclin 300® as preservative. Avoid contact with skin or mucosa.
- This method allows the determination of Progesterone from 0.2 ng/ml to 40 ng/ml.

12.1. Disposal Considerations

Residues of chemicals and preparations are generally considered as hazardous waste. The disposal of this kind of waste is regulated through national and regional laws and regulations. Contact your local authorities or waste management companies which will give advice on how to dispose hazardous waste.

13. ORDERING INFORMATION

Prod. No.:	DNOV006	Progesterone (96 Determinations)

FRANÇAIS

CE

1. INTRODUCTION

La progestérone (C21) est une hormone stéroïdienne adaptée au cycle menstruelle, à la grossesse (support à la gestation) et à l'embryogenèse des êtres humains et des autres espèces.
La progestérone est importante pour la synthèse de l'aldostérone (minéralcorticoïde) et le 17-OH progestérone pour le cortisol (glycocorticoïde). Les taux de progestérone sont relativement bas chez les enfants et les femmes en post-ménopause. Les hommes adultes présentent des taux analogues à ceux des femmes pendant la phase folliculaire du cycle menstruel.
Chez les femmes, les taux de progestérone sont relativement bas pendant la phase pré-ovulatoire, ils augmentent après l'ovulation et sont élevés pendant la phase lutéale. En cas de grossesse, les taux de progestérone se rapprochent des taux lutéaux. Après l'accouchement et pendant l'allaitement, les taux de progestérone sont très bas. La chute des taux de progestérone qui suivent l'accouchement est l'un des déclencheurs de la production de lait.
La progestérone est produite dans les glandes adrénales, dans les gonades (en particulier après l'ovulation, dans le corps jaune), dans le cerveau et, pendant la grossesse, dans le placenta.
La progestérone est nécessaire pour la « conversion » de l'endomètre en phase sécrétoire afin de préparer l'utérus pour l'implant. Si la grossesse n'a pas lieu, les taux de progestérone diminuent en débouchant, chez l'être humain, à la période menstruelle.
La progestérone appartient au groupe des neurostéroïdes qui sont présents dans certaines zones du cerveau. La progestérone est impliquée dans le fonctionnement synaptique, elle a des effets neuroprotecteurs et elle affecte le processus de myélinisation.
La progestérone a de nombreux effets même en-dehors du système de reproduction. La progestérone est thermogénique, réduit les spasmes et détend le muscle lisse. Les bronches sont dilatées et la sécrétion du mucus est régulée. La progestérone est un agent anti-inflammatoire et elle régule la réponse immunitaire. Elle est impliquée dans la fonction thyroïdienne et dans l'ostéogenèse.
La mesure des concentrations de progestérone dans le sérum sert à l'évaluation de la fonction ovarienne.

2. INDICATION D'UTILISATION

Méthode immunoenzymatique colorimétrique par compétition pour la détermination quantitative de la concentration de la progestérone dans le sérum ou le plasma humain.

3. PRINCIPE DU DOSAGE

La progestérone (antigène) présent dans l'échantillon rentre en compétition avec la progestérone antigénique marquée à la peroxydase de raifort (HRP, Conjugué) par rapport à l'anticorps anti-progestérone adsorbé sur microplaque (phase solide). Après de la incubation, la séparation libre-lié est obtenue par simple lavage de la phase solide.
Après, l'enzyme HRP présent dans la fraction liée catalyse la réaction entre le substrat (H_2O_2) et le substrat TMB, en développant une coloration bleue qui vire au jaune après ajout de la solution d'arrêt (H_2SO_4). L'intensité de la couleur développée est inversement proportionnelle à la concentration de progestérone dans l'échantillon. La concentration de la progestérone dans l'échantillon est calculée sur la base d'une courbe d'étalonnage. Un lecteur de microplaques ELISA permet la lecture de l'absorption à 450 nm.

4. MATERIELS

4.1. Réactifs fournis

- **Puits recouverts d'IgG d'Anti Progesterone :** 12 bandes détachables enduites d'IgG d'Anti-Progesterone de 8 puits, en sachet d'aluminium refermable.
- **Solution stop :** 1 flacon contenant 15 ml d'acide sulfurique, 0.15 mol/l (éviter tout contact avec la peau).
- **Conjugué Progesterone HRP :** 1 flacon contenant 22 ml de Progesterone marqué à la peroxydase de raifort.
- **Solution de TMB :** 1 flacon contenant 15 ml de 3, 3´, 5, 5´-Tétraméthylbenzidine (H_2O_2-TMB 0.26g/l) (éviter tout contact avec la peau).
- **Solution de lavage (concentrée x 10) :** 1 flacon contenant 50 ml d'une solution de tampon phosphate concentrée 10 fois Tampon phosphaté 0,2 M, Proclin < 0.0015%.
- **Contrôle Progesterone :** 1 flacon contenant 1 ml d'un lot spécifique solution de contrôle. La concentration est indiquée sur l'étiquette.
- **Etalons de Progesterone:** 5 flacons, 1 ml chaque

Etalon 0:	0 ng/ml
Etalon 1:	0.2 ng/ml
Etalon 2:	1.0 ng/ml
Etalon 3:	8.0 ng/ml
Etalon 4:	40.0 ng/ml

4.2. Matériels fournis

- 1 support de plaque
- 1 jeu de feuilles de recouvrement
- 1 mode d'emploi
- 1 schéma de distribution et d'identification

4.3. Matériels et équipements requis

- Lecteur de microplaques ELISA, pour mesure l'absorbance à 450 nm, 620-630 nm
- Equipement manuel ou automatique pour le rinçage des puits
- Pipettes permettant de délivrer un volume de 10 à 1000 µl
- Eau distillée
- Chronomètre

5. STABILITÉ ET CONSERVATION

Les réactifs sont stables jusqu'à la date de péremption indiquée sur l'étiquette s'ils sont conservés entre 2°C et 8 °C à l'obscurité.

6. PREPARATION DES REACTIFS

Il est très important que tous les réactifs, échantillons et contrôles soient portés à température ambiante (22°C – 28 °C) pour au moins 30 minutes. À la fin de l'essai conservent les réactifs immédiatement à 2-8 ° C ; évitez la longue exposition à température ambiante.

6.1. Bandes détachables enduites

Les bandes détachables sont enduites d'anticorps d'IgG anti-Progesterone et sont prêtes à l'emploi. Conserver entre 2°C et 8℃. N'ouvrir l'emballage que si la pièce est à température ambiante. *Après avoir prélevé les bandes nécessaires, refermer immédiatement les autres dans le sachet d'aluminium avec le déshydratant fourni et les conserver entre 2°C et 8°C ; elles sont stables jusqu'à la date de péremption.*

6.2. Conjugué Progesterone-HRP

Solution de conjugué Progesterone-HRP prête à l'emploi.

6.3. Etalons de Progesterone

Les étalons sont prêts à l'emploi. Mettre à agiter délicatement sur un agitateur rotatif pendant au moins 5 minutes. Stable 6 mois à 2÷8°C à compter de l'ouverture du flacon.

6.4. Solution TMB

Le flacon contient 15 ml d'un mélange de peroxyde d'hydrogène et de tétraméthylbenzidine. Le réactif est prêt à l'emploi et doit être conservé 2°C et 8℃ à l'obscurité. *La solution doit être incolore ou avoir une légère teinte bleue. Si le substrat devient bleu, il a pu être contaminé et doit être remplacé*.

6.5. Solution stop

Le flacon contient 15 ml d'une solution d'acide sulfurique 0.15 M (R 36/38, S 26). Cette solution est prête à l'emploi et doit être conservée entre 2°C et 8 °C

6.6. Solution de lavage

Diluer le contenu de la solution de lavage concentrée avec de l'eau distillée jusqu'à un volume final de 500 ml avant utilisation. Pour les petits volumes respecter la dilution au $10^{ème}$. La solution de lavage diluée est stable pendant 30 jours entre 2°C et 8 °C. Il est possible d'observer la présence de cristaux dans la solution de lavage concentrée, dans ce cas, mélanger à température ambiante jusqu'à la dissolution complète des cristaux, pour une meilleure efficacité diluer tout le flacon de solution de lavage jusqu'à 500 ml en surveillant le transfert de cristaux avec le lavage de la bouteille, puis mélanger jusqu'à la dissolution complète des cristaux.

6.7. Contrôle Progesterone

Le flacon contient 1 ml d'une solution de contrôle prête à l'emploi. La concentration est indiquée sur l'étiquette.

7. PRELEVEMENT ET PREPARATION DES ECHANTILLONS

La détermination de Progesterone peut être effectuée sur du plasma ou du sérum humain. Conserver les échantillons à -20°C si la détermination n'est pas effectuée le jour du prélèvement. Si les échantillons sont conservés congelés, bien mélanger les échantillons décongelés avant le dosage. *Eviter les cycles répétés de congélation et de décongélation.*

8. PROCEDE DU DOSAGE

8.1. Préparation du dosage

Lire attentivement la notice d'emploi **avant de** réaliser le dosage. La fiabilité des résultats dépend du suivi strict du protocole. Avant de commencer le dosage, déterminer, sur le formulaire fourni dans le kit, le plan de distribution et d'identification des échantillons et des contrôles. Sélectionner le nombre de bandes ou de puits nécessaires et les placer sur le support. Réserver au moins :

1 puits	(ex. A1)	Pour le blanc
2 puits	(ex. B1+C1)	Pour l'étalon 0
2 puits	(ex. D1+E1)	Pour l'étalon 1
2 puits	(ex. F1+G1)	Pour l'étalon 2
2 puits	(ex. H1+A2)	Pour l'étalon 3
2 puits	(ex. B2+C2)	Pour l'étalon 4
2 puits	(ex. D2+E2)	Pour le contrôle

Il est recommandé de déterminer les contrôles et les échantillons du patient en doublets.

Réaliser toutes les étapes du dosage dans l'ordre donné et sans interruption entre les étapes.

Un cône de pipette propre et jetable doit être utilisé pour distribuer chaque contrôle et échantillon.

1. Pipeter 20 µl des étalons, de contrôle et des échantillons dans leurs puits respectifs.
2. Ajouter 200 µl de conjugué Progesterone-HRP dans chaque puits. Garder le puits A1 pour le blanc.
3. Couvrir les puits avec le couvercle fourni dans le kit.
4. **Incuber pendant 1 heure à 37 °C.**
5. À la fin de l'incubation, enlever le couvercle, aspirer le contenu des puits et laver chaque puits et trois fois avec 300 µl de lavage diluée. Eviter les débordements de puits de réaction. Pendant chaque pas de lessive secouez doucement la plaque depuis 5 secondes et enlevez la solution d'excès en tapant la plaque inversée sur un essuie-mains en papier absorbant. (Si vous utilisez l'équipement automatisé, lavez les puits au moins 5 fois).

   Note : L'étape de lavage est très importante ! Un lavage insuffisant peut conduire à une précision faible et des valeurs d'absorbance faussement élevées.
6. Pipeter 100 µl de solution de TMB dans tous les puits.
7. **Incuber pendant exactement 15 min à température ambiante (22 – 28°C) à l'obscurité.**
8. Pipeter 100 µl de solution stop dans tous les puits dans le même ordre à la même vitesse que pour la solution de TMB. Secouer doucement la microplaque.
   La couleur bleue développée pendant l'incubation vire au jaune.
9. Mesurer l'absorbance (E) des échantillons à 450 nm contre une longueur d'onde de référence de 620-630 nm ou contre le blanc au cours de 5 minutes.

8.2. Mesure

Faire le **zéro** du lecteur ELISA **à l'aide du blanc dans le puits A1**.

Si - pour des raisons techniques - le lecteur d'ELISA ne peut pas être ajusté à zéro en utilisant le blanc dans le puits A1, soustraire la valeur d'absorbance du puits A1 de toutes les autres valeurs d'absorbance mesurées afin d'obtenir des résultats fiables !

Mesurer l'absorbance de tous les puits **à 450 nm** et enregistrer les valeurs d'absorbance pour chaque contrôle et échantillon de patient dans le plan de distribution et d'identification.

Calculer **les valeurs moyennes d'absorbance pour tous les doublets, si nécessaires**.

9. RESULTATS

9.1. Calcul des résultats

Calculer l'absorbance moyenne pour chaque point du courbe étalon et de chaque échantillon. Tracer la valeur d'absorbance moyenne des étalons par rapport à la concentration. Dessiner le meilleur ajustement de la courbe sur les points tracés (4 paramètres logistiques).
Interpoler les valeurs des échantillons sur le courbe étalon pour obtenir les valeurs de concentrations correspondantes en pg/ml.

9.2. Valeurs de Référence

Les concentrations de progestérone dans le sérum ou le plasma sont comprises dans les intervalles suivants :

			ng/ml
HOMMES :			< 1,0
	phase folliculaire		0,1 - 1,4
	phase mi-lutéale		4,0 - 25,0
	ménopause		< 1,0
		Semaines	
FEMMES :		18 - 21	53 - 76
		22 - 25	60 - 86
	grossesse	26 - 29	71 - 133
		30 - 33	86 - 142
		34 - 37	104 - 175
		38 - 41	117 - 187

Il est important de noter que la détermination d'une gamme de valeurs attendues dans une méthode donnée pour une population de «normal» est tributaire de nombreux facteurs, tels que la spécificité et la sensibilité de la méthode en usage, et la population étudiée. Par conséquent, chaque laboratoire devrait examiner la gamme spécifiée par le fabricant comme un guide général et de produire leur propre gamme de valeurs attendues sur la base des laboratoires où la population autochtone habite.

10. CONTROLE QUALITE

Chaque laboratoire devrait analyser les échantillons dans la gamme des niveaux élevés, normaux et bas de progestérone pour vérifier les prestations de l'analyse. Ces échantillons devraient être traités comme inconnus et les valeurs déterminées devraient être dans chaque test effectué. Les tableaux de contrôle de la qualité devraient être observés afin de suivre les prestations des réactifs fournis. Des méthodes statistiques appropriées devraient être employées pour vérifier la tendance. Le laboratoire devrait définir des limites d'acceptabilité des prestations d'analyse. Les autres paramètres qui devraient être contrôlés incluent les interceptions de 80, 50 et 20% de la courbe d'étalonnage pour évaluer la reproductibilité. De plus, la capacité d'absorption maximale devrait être constante avec l'expérience précédente. La déviation significative par rapport aux prestations établies peut indiquer un changement non observé des conditions expérimentales ou une dégradation des réactifs du coffret. Des réactifs frais doivent être utilisés pour déterminer le motif des variations.

11. PERFORMANCE DU DOSAGE

11.1. Précision

Variation Intra Dosage

La variation intra dosage a été déterminée par un répliquant (20x) sur trois sérums différents dans un dosage. La variation intra dosage est ≤ 4%.

Variation Inter Dosage

La variation inter dosage a été déterminée en répliquant la mesure (10x) de trois sérums de contrôle différents en lots différents. La variation inter dosage est ≤ 9,3 %.

11.2. Spécificité analytique

La réaction croisée des anticorps calculée à 50% selon Abraham :

Progestérone	100 %
Testostérone	0,37 %
17 OH-progestérone	0,29 %
17-beta Estradiol	0,0013 %
Estrone	0,00053 %
Estriol	< 0,0001 %
Cortisol	< 0,0001 %

11.3. Sensibilité Analytique

La plus petite concentration détectable de Progesterone par l'étalon 0 est 0.05 ng/ml avec une limite de confiance de 95%.

11.4. Exactitude

L'épreuve de récupération conduite sur des échantillons enrichis avec 1.0 – 2.0 – 4.0 – 8.0 ng/ml de Progesterone la donné une valeur moyenne (±SD) de 100.88 % ± 8.29 %.

11.5. Comparaison de méthode

Le coffret NovaTec ELISA pour la Progestérone a été comparé avec le coffret Adaltis EIAGen à la Progestérone disponible en commerce. 31 échantillons de sérum ont été testés.

La courbe de régression est :

(Progesterone. NovaTec) = 0,97*(Progesterone Adaltis) + 0,04

r^2 = 0,887

12. PRECAUTIONS ET AVERTISSEMENTS

- En accord avec l'article 1 paragraphe 2b de la directive européenne 98/79/EC, l'utilisation des dispositifs médicaux de diagnostic in vitro est destinée par le fabricant à garantir la pertinence, les performances et la sécurité du produit. Par conséquent, la procédure de dosage, l'information, les précautions et mises en garde du mode d'emploi doivent être suivies de façon stricte. L'utilisation de ces kits avec des automates ou dispositifs similaires doit être validée. Aucun changement de la conception, composition et procédure de dosage, ainsi que l'utilisation avec d'autres produits non approuvés par le fabricant, ne sont autorisés ; seul l'utilisateur est responsable de tels changements. Le fabricant n'est pas responsable des faux résultats et des incidents dus à ces modifications. Le fabricant n'est pas responsable des résultats fournis par analyse visuelle des échantillons des patients.
- Uniquement pour diagnostic in vitro. Ne pas utiliser pour usage interne ou externe chez les Humains ou les Animaux.
- Suivre les Bonnes Pratiques de Laboratoires (BPL) pour la manipulation de produits sanguins.
- Tous les composants d'origine humaine utilisés pour la fabrication de ces réactifs ont été analysés et ont été testés non réactifs aux antigènes HBs, en anticorps anti-VIH et en anticorps anti-VHC. Néanmoins, tous les produits doivent être considérés et traités comme étant potentiellement infectieux.
- Ne pas échanger les réactifs ou les bandes provenant de différents lots de production.
- Ne pas utiliser de réactifs provenant d'autres fabricants avec les réactifs de ce kit.
- Ne pas utiliser les réactifs après la date de péremption indiquée sur l'étiquette.
- Utiliser seulement des cônes de pipette, des distributeurs et du matériel de laboratoire propres.
- Ne pas échanger les bouchons des flacons, pour éviter la contamination croisée
- Fermer les flacons de réactifs immédiatement après l'utilisation pour éviter l'évaporation et la contamination microbienne.
- Avant une nouvelle utilisation, vérifier les flacons de conjugué et de contrôle, déjà utilisés, pour exclure une contamination microbienne.
- Pour éviter la contamination croisée et des résultats faussement élevés, introduire les échantillons de patients et le conjugué exactement au fond des puits en évitant les éclaboussures.
- Quand l'utilisation a automatisé l'équipement, l'utilisateur a la responsabilité de s'assurer que le kit a été convenablement évalué.
- Certains réactifs contiennent de petites quantités de Proclin 300^R comme conservateur. Eviter tout contact avec peau et les muqueuses.
- Le TMB est irritant, ce qui peut être nocif s'il est inhalé, ingéré ou absorbé à travers la peau. Eviter toute inhalation, ingestion ou contact avec la peau et les yeux pour prévenir de ces risques.
- La solution stop est une solution d'acide sulfurique diluée. L'aide sulfurique est un poison corrosif et peut être toxique s'il est ingéré. Eviter tout contact avec la peau ou les yeux pour prévenir des brûlures chimiques.
- Suivre la notice pour les contrôles qualité dans les laboratoires médicaux en dosant les contrôles et/ou les sérums.
- Les échantillons microbiologiquement contaminés ne doivent pas être utilisés pour le dosage. Les échantillons hautement lipémiques ou hémolysés ne doivent pas être utilisés non plus.
- Les lecteurs de microplaques mesurent verticalement. Ne pas toucher le fond des puits.
- Si le liquide n'est pas complètement extrait des puits, cela peut influence la précision du dosage et/ou augmenter le bruit de fond. Pour améliorer la performance du kit sur les systèmes automatiques ELISA, on recommande d'augmenter le nombre de se lave.
- La méthode ELISA de NovaTec est destinée à un personnel qualifié qui est familiarisé avec les Bonnes Pratiques de Laboratoire.
- L'addition de la solution de substrat initie la réaction cinétique qui se termine par l'ajout de solution stop. Par conséquent, l'addition de solution de substrat et de solution stop doit être faite durant la manipulation pour éliminer tous risques de dépassement de la durée de réaction.
- Cette méthode permet de déterminer des concentrations de Progesterone de 0.2 ng/ml à 40 ng/ml.

12.1. Elimination des déchets

Les résidus des produits chimiques et des préparations sont considérés en général comme des déchets dangereux. L'élimination de ce type de déchet est réglementée par des lois et réglementations nationales et régionales. Contacter les autorités compétentes ou les sociétés de gestion des déchets pour obtenir des renseignements sur l'élimination des déchets dangereux.

13. INFORMATION POUR LES COMMANDES

Prod. No.:	DNOV006	Progesterone (96 Dosages)

ESPANOL CE

1. INTRODUCCIÓN

La progesterona es una hormona esteroide C-21 que participa en el ciclo menstrual femenino, el embarazo (apoya la gestación) y la embriogénesis de los seres humanos y otras especies. La progesterona es el principal progestágeno natural humano.
La progesterona es importante para la síntesis de la aldosterona (mineralcorticoide), como la 17-hidroxyprogesterone, es para el cortisol (glucocorticoide).
Los niveles de progesterona son relativamente bajos en los niños y las mujeres posmenopáusicas. Los hombres adultos tienen niveles similares a los de las mujeres, durante la fase folicular del ciclo menstrual.
En las mujeres, los niveles de progesterona son relativamente bajos durante la fase pre-ovulatoria del ciclo menstrual, aumentan después de la ovulación, y son elevados durante la fase lútea. Si se produce el embarazo, los niveles de progesterona se mantienen a niveles se la fase lútea inicial. Después de la entrega de la placenta y durante la lactancia, los niveles de progesterona son muy bajos. La caída en los niveles de progesterona después del parto es uno de los desencadenantes de la producción de leche.
La progesterona se produce en las glándulas suprarrenales, las gónadas (específicamente después de la ovulación en el cuerpo lúteo), el cerebro y, durante el embarazo, en la placenta.
La progesterona convierte el endometrio a su fase de secreción para preparar el útero para su implantación. Si no ocurre el embarazo, los niveles de progesterona se reducen, lo que, en el ser humano, desencadena en la menstruación.
La progesterona pertenece al grupo de los neuroesteroides que se encuentran en altas concentraciones en ciertas las áreas del cerebro y donde se sintetiza. Los neuroesteroides afectan el funcionamiento sináptico, son neuroprotectores y afectan a la mielinización.
La progesterona tiene múltiples efectos fuera del sistema reproductivo. La progesterona es termogénica, reduce los espasmos y relaja el músculo liso. Ensancha los bronquios y regula la producción de moco. La progesterona actúa como un agente antiinflamatorio y regula la respuesta inmunitaria. La progesterona también ayuda en la función tiroidea, en la construcción de hueso por los osteoblastos. La medición de las concentraciones de progesterona sérica es utilizada en la evaluación de la función ovárica.

2. USO

Método inmunoenzimático competitivo y colorimétrico para la determinación cuantitativa de progesterona en suero o plasma humano.

3. FUNDAMENTO DE LA PRUEBA

Los pozos de microtitulación de las tiras se encuentran recubiertos con anticuerpos anti-progesterona. La Progesterona presente en la muestra compite por la unión a éstos anticuerpos con progesterona marcada con peroxidasa de rábano picante (HRP por sus siglas en ingles *horseradish peroxidase*) o antígeno marcado con enzima. Una vez finalizada la incubación, se lleva a cabo una separación del complejo unido/libre mediante el lavado de la fase sólida. El complejo inmune formado por el antígeno marcado con enzima se visualiza mediante la adición de tetrametilbencidina (TMB), la cual produce un producto de reacción azul. La intensidad de este producto es **inversamente** proporcional a la cantidad de progesterona presente en la muestra. El ácido sulfúrico se agrega para detener la reacción. Esto produce un color amarillo estable. La absorción a 450 nm se lee con un lector de microplacas de ELISA.

4. MATERIALES

4.1. Reactivos suministrados

- **Pozos recubiertos con anti-progesterona IgG:** 12 tiras de 8 pozos separables. Los pozos están recubiertas con anti-progesterona IgG, empacados en una bolsa de papel de aluminio resellable.
- **Solución de parada:** 1 vial con 15 ml de ácido sulfúrico 0,15 mol/l (evitar cualquier contacto con la piel).
- **Conjugado Progesterona-HRP:** 1 vial contiene 22 ml de progesterona marcada con peroxidasa de rábano.
- **Solución de sustrato TMB:** 1 vial con 15 ml de 3, 3 ', 5, 5'-tetrametilbenzidina (H_2O_2-TMB 0,26 g/l) (evitar cualquier contacto con la piel).
- **Solución de lavado 10x conc.:** 1 vial con 50 ml en concentración 10x de solución de buffer de fosfato 0.2M Proclin <0.0015%
- **Control de Progesterona:** 1 vial con 1 ml de una solución específica para el lote de control. La concentración se indica en la etiqueta de la botella
- **Estándares de Progesterona:** 5 botellas, de 1 ml cada una

  Estándar 0: 0 ng/ml
  Estándar 1: 0.2 ng/ml
  Estándar 2: 1.0 ng/ml
  Estándar 3: 8.0 ng/ml
  Estándar 4: 40.0 ng/ml

4.2. Materiales suministrados

- 1 Soporte para tiras
- 1 Lámina sellante
- 1 Protocolo de procesamiento
- 1 Plan de distribución e identificación

4.3. Materiales y equipos necesarios

- Lector de ELISA equipado para medir absorbancia a 450 nm, 620-630 nm
- Equipo manual o automático para el lavado de los pozos
- Pipetas para agregar volúmenes de entre 10 y 1.000 µl
- Agua destilada
- Temporizador
-

5. ESTABILIDAD Y ALMACENAMIENTO

Los reactivos son estables hasta la fecha de caducidad indicada en la etiqueta cuando se almacenan a 2...8 °C en oscuridad.

6. PREPARACION DE LOS REACTIVOS

¡Es muy importante tener todos los reactivos, muestras y patrones a temperatura ambiente (22…28 °C) durante al menos 30 minutos antes de iniciar la ejecución de la prueba! ¡Al final del ensayo inmediatamente poner todos los reactivos a 2 – 8° C para evitar largos periodos a temperatura ambiente !

6.1. Tiras recubiertas rompibles

Las tiras vienen listas para ser usadas y se rompen para separar los pozos. Están recubiertas con anticuerpos IgG anti-progesterona. Se deben conservar a una temperatura de entre 2...8 °C. Abra la bolsa sólo cuando ésta se encuentre a temperatura ambiente. *Inmediatamente después de retirar las tiras que va a utilizar, asegúrese de guardar las tiras que no van a ser usados dentro de la bolsa de aluminio resellable junto con el desecante suministrado y almacenarla a una temperatura entre 2...8 °C; las tiras son estables hasta la fecha de caducidad.*

6.2. Conjugado Progesterona-HRP

La solución de conjugado de Progesterona HRP está lista para ser usada.

6.3. Estándares de Progesterona

Los estándares están listos para ser usados, antes de utilizar deje 5 minutos en un mezclador. Después de abierto es estable por 6 meses almacenado de 2 a 8 ° C

6.4. Solución de sustrato TMB

El frasco contiene 15 ml de un sistema de tetrametilbencidina/peróxido de hidrógeno. El reactivo está listo para ser usado y debe ser almacenado a 2...8 °C en oscuridad. La solución debe estar incolora o puede tener un ligero tinte azul. Si el sustrato se torna azul, esto indica que puede haberse contaminado y por lo tanto debe desecharse.

6.5. Solución de parada

El frasco contiene 15 ml de solución de ácido sulfúrico 0,15 M (R 36/38, S 26). Esta solución esta lista para ser usada y debe ser almacenada a 2...8 °C.

6.6. Solución de lavado

Diluir la solución de lavado concentrada con agua destilada o desionizada hasta un volumen final de 500ml antes de uso. Para volúmenes más pequeños, asegúrese de respetar la relación de 1:10. La solución de lavado diluida es estable durante 30 días almacenado a 2...8 °C. En la solución de lavado concentrada, es posible observar la presencia de cristales, en este caso mantener la mezcla a temperatura ambiente hasta la completa disolución de los cristales, para una mayor precisión diluir todo el frasco de solución de lavado concentrado a 500 ml teniendo especial cuidado en la transferencia de los cristales, luego mezclar hasta que los cristales se hayan disuelto completamente.

6.7. Control de Progesteroma

El vial contiene 1 ml de una solución de control específica para el lote. La concentración se indica en la etiqueta.

7. RECOLECCIÓN Y PREPARACIÓN DE LAS MUESTRAS

La determinación de progesterona se puede realizar en el plasma, así como en el suero. Almacenar las muestras a -20°C si la determinación no se realiza en el mismo día de la toma de muestras. Si las muestras son almacenadas a -20°C, mezclar muy bien las muestras al descongelarlas antes de realizar la prueba. Evite congelar y descongelar repetidamente.

8. PROCEDIMIENTO

8.1. Preparación para la prueba

Por favor, lea detenidamente el protocolo de la prueba antes de realizar el ensayo. La confiabilidad de los resultados depende del seguimiento estricto del protocolo de la prueba tal cual se describe en el inserto. Antes de comenzar el ensayo, se debe establecer cuidadosamente la distribución e identificación de las muestras y los estándares en la hoja Plan de distribución e identificación suministrada con el kit. Seleccione el número necesario de tiras de microtitulación o pozos e insértelos en el soporte. Por favor asigne por lo menos:

1 pozo (por ejemplo, A1)	para el blanco
2 pozos (por ejemplo, B1+C1)	para el estándar 0
2 pozos (por ejemplo, D1+E1)	para el estándar 1
2 pozos (por ejemplo, F1+G1)	para el estándar 2
2 pozos (por ejemplo, H1+A2)	para el estándar 3
2 pozos (por ejemplo, B2+C2)	para el estándar 4
2 pozos (por ejemplo, D2+E2)	para control

Se recomienda determinar los estándares y muestras por duplicado.

Realice todos los pasos del ensayo en el orden indicado y sin retrasos apreciables entre los pasos.

Debe usar una punta desechable limpia para la dosificación de cada estándar y cada muestra del paciente.

1. Agregue 20 µl de estándares, controles y muestras en sus respectivos pozos
2. Agregue 200 µl de conjugado Progesterona-HRP a cada pozo. Deje el pozo A1 libre para el blanco del substrato.
3. Cubra los pozos con la lámina sellante incluida en el paquete.
4. **Incube durante 1 hora a 37°C**
5. Cuando se complete el tiempo de incubación, retire la lámina sellante, aspire el contenido de los pozos y lave cada pozo tres veces con 300 µl de solución de lavado diluida. Evite desbordamientos entre los pozos de reacción.
   Nota importante: Agite suavemente la placa durante 5 segundos en cada paso del lavado. Después del último lavado asegúrese haber eliminado completamente la solución de lavado de los pozos, invierta la place y golpéela repetidas veces contra una servilleta de papel absorbente.

   Lavados automático: Si está itilizando una lavadora automática, hacer 5 lavados.

   Nota: ¡El lavado es crítico! Un lavado insuficiente resulta en una mala precisión y valores de absorbancia falsamente elevados.
6. Agregue 100 µl de solución de sustrato TMB en todos los pozos.
7. **Incube durante exactamente 15 minutos a temperatura ambiente (22...28 °C) en oscuridad.**
8. Agregue 100 µl de solución de parada en todos los pozos en el mismo orden y a la misma velocidad que agregó la solución de sustrato TMB. Agite la microplaca.

   Cualquier color azul desarrollado durante la incubación se convertirá en amarillo.
9. Mida la absorbancia de la muestra a 450 nm frente una segunda lectura de referencia a 620-630 nm o frente al blanco entre 5 minutos.

8.2. Lectura

Ajuste el lector de placas de micropozos de ELISA a cero usando el blanco de substrato del pozo A1.
Si - por razones técnicas - el lector de ELISA no se puede ajustar a cero con el blanco del substrato en el pozo A1, restar el valor de absorbancia del pocillo A1 de todos los valores de absorbancia otras medidas con el fin de obtener resultados fiables!
Mida la absorbancia de todos los pozos a **450 nm** y registre los valores de absorbancia para cada estándar y muestra de paciente indicado en el plan de distribución e identificación.
Cuando sea necesario, calcule la **absorbancia media** de los duplicados.

9. RESULTADOS

9.1. Cálculo de los resultados

Calcule la absorbancia media para cada punto de la curva estándar y cada muestra. Grafique el valor medio de absorbancia de los estándares versus la concentración. Dibuje la curva que mejor se ajuste a los puntos trazados (Ej.: Logística de cuatro parámetros). Interpole los valores de las muestras en la curva estándar para obtener los valores correspondientes para las concentraciones expresadas en ng/ml.

9.2. Valores de referencia

El siguiente valor de progesterona en suero o plasma debe ser considerado como una guía:

Hombres		<0.1 ng/ml	
Mujeres	Fase Folicular	0,1-1,4 ng/ml	
	Fase media lutea	4.0-25.0 ng/ml	
	Menopausia	<1.0	
	Embarazo	week	ng/ml
		18-21	53-76
		22-25	60-86
		26-29	71-133
		30-33	86-142
		34-37	104-175
		38-41	117-187

Es importante señalar que la determinación de un rango de valores esperados en un método dado para una población "normal" depende de muchos factores, tales como la especificidad y sensibilidad del método en uso, y la población en estudio. Por lo tanto, cada laboratorio debe considerar el intervalo especificado por el fabricante como una guía general y producir su propio rango de valores calculados en base al estadístico obtenido por el laboratorio, donde reside la población local.

10. CONTROL DE CALIDAD

Cada laboratorio debe evaluar sus controles que correspondan a niveles normal, alto y bajo de la progesterona para supervisar el desempeño del ensayo. Estos controles deben ser tratados como muestras desconocidas y se deben determinar sus valores cada vez que se realice el ensayo. Se deben llevar gráficas de éstos controles de calidad para hacerle seguimiento al desempeño de los reactivos. Se deben emplear los métodos estadísticos pertinentes para verificar las tendencias. Cada laboratorio debe establecer los límites aceptables de desempeño para el ensayo. Otros parámetros que se deben controlar son los interceptos al 80, 50 y 20% de la curva estándar para evaluar la reproducibilidad intercorrida. Además, la absorción máxima debe ser consistente con la experiencia del laboratorio. Una desviación significativa del desempeño establecido puede indicar un cambio en las condiciones experimentales o la degradación de los reactivos. Deben usarse reactivos frescos para determinar la razón de las variaciones.

11. CARACTERÍSTICAS ESPECÍFICAS DE DESEMPEÑO

11.1. Precisión

Variación intraensayo
La variación intracorrida fue determinada por mediciones repetidas (20x) de tres sueros control diferentes en un mismo ensayo. La variación intracorrida del ensayo es ≤ 4%.

Variación interensayo
La variación intercorrida fue determinada por mediciones repetidas (10x) de tres sueros control diferentes con lotes distintos.
La variabilidad interensayo es ≤ 9.3%.

11.2. Reacciones Cruzadas

La reacción cruzada de los anticuerpos fue calcula para el 50% de acuerdo con Abraham y es la siguiente:

Progesterona	100%
Testosterona	0.37%
17 OH Progesterona	0.29%
17 β Estradiol	0.0013%
Estrona	0.00053%
Estriol	< 0.0001%
Cortisol	< 0.0001%

11.3. Sensibilidad Analítica

La concentración detectable más baja de Progestrona que se puede distinguir del estándar 0 es 0,05 ng/ml con un límite de confianza del 95%.

11.4. Exactitud

La recuperación de 1.0 – 2.0 – 4.0 – 8.0 ng/ml de Progesterona añadidos a una muestra resulto en un valor medio (± DE) de 100,88% ± 8.29% con respecto a la concentración original.

11.5. Comparación de Métodos

La progesterona de NovaTec por ELISA, fue comparada con la Progesterona de Adaltis por EIAgen. Se analizaron 31 muestras de suero de acuerdo a los procedimientos de cada uno de los kits. La curva de regresión lineal se calculó:

Progesterona Novatec=0.97*Progesterona Adaltis + 0.04

r^2 = 0 0.887

12. PRECAUCIONES Y ADVERTENCIAS

- En cumplimiento con el Artículo 1, Párrafo 2b de la Directiva 98/79/CE del Parlamento Europea sobre el uso de dispositivos médicos para diagnóstico in vitro, es responsabilidad del fabricante asegurar la idoneidad, desempeño y seguridad del producto. Por lo tanto, el procedimiento de prueba, la información, precauciones y advertencias contenidas en las instrucciones de uso deben ser seguidas estrictamente. El uso de los kits con analizadores y equipos similares debe ser validado. No esta autorizado realizar ningún cambio en el diseño, composición y procedimiento del ensayo, así como ningún uso en combinación con otros productos no aprobados por el fabricante; el usuario es responsable de tales cambios. El fabricante no se hace responsable por resultados falsos o por cualquier incidente causado por esta razón. El fabricante no se responsabiliza por los resultados obtenidos mediante el análisis visual de las muestras de los pacientes.
- Sólo para uso en diagnóstico in vitro.
- Todos los componentes de origen humano utilizados para la producción de estos reactivos han sido examinado para determinar la presencia de anticuerpos anti-VIH, anticuerpos anti-HCV y anticuerpos anti-HBsAg y se ha determinado que no son reactivos. Sin embargo, todo el material debe ser considerado y tratado como potencialmente infeccioso.
- No intercambiar reactivos o tiras de diferentes lotes de producción.
- No se deben utilizar reactivos de otros fabricantes en combinación con los reactivos de este kit.
- No utilizar los reactivos después de la fecha de caducidad indicada en la etiqueta.
- Use sólo puntas para micropipeta, dispensadores y material de laboratorio limpio.
- No intercambie las tapas de los viales. Esto evita la contaminación cruzada.
- Cierre los viales de los reactivos con fuerza inmediatamente después de usarlos para evitar la evaporación y contaminación microbiana.
- Después de abrir el kit por primera vez y almacenarlo, verifique que los viales del conjugado y los estándares no presenten contaminación microbiana antes continuar usándolo.
- Para prevenir la contaminación cruzada y la obtención de resultados falsamente elevados, pipetee las muestras de los pacientes y dispense el conjugado con precisión hacia el fondo de los pozos evitando que se produzcan salpicaduras.
- La prueba ELISA es una metodología para personal calificado que esté familiarizado con buenas prácticas de laboratorio.
- La máxima precisión es necesaria para la dispensación de los reactivos.
- El sustrato de TMB contiene un irritante, que puede ser nocivo si es inhalado, ingerido o absorbido por la piel. Para evitar lesiones, evite la inhalación, ingestión o contacto con la piel y los ojos.
- Evitar la exposición del substrato TMB a la luz solar directa, metales u oxidantes.
- La solución de parada consiste en una solución de ácido sulfúrico diluido. El ácido sulfúrico es venenoso y corrosivo y se puede tóxico si se ingiere. Para evitar quemaduras, evitar contacto con la piel y los ojos.
- Para valores superiores, por ejemplo en el embarazo, diluir la muestra y, considerando el factor de dilución en el cálculo del resultado.
- El tratamiento del paciente con cortisona, esteroides naturales o sintéticos pueden afectar la determinación de progesterona.
- Además de la solución de sustrato TMB inicia una reacción cinética, que es terminada por la adición de la solución de parada. Por lo tanto, el sustrato TMB y la solución de parada debe ser añadido en la misma secuencia para eliminar cualquier desviación de tiempo durante la reacción.
- Tenga en cuenta las directrices del control de calidad en los laboratorios médicos para los controles de ensayo y / o combinados sueros para determinar su desempeño.
- Muestras con contaminación microbiana no debe ser utilizado en el ensayo. Muestras altamente hemolizadas o lipémicas
- Tampoco deben ser utilizados lectores de la placa miden verticalmente. No toque el fondo de los pozos.
- Es importante que el tiempo de reacción en cada pozo se mantiene constante para obtener resultados reproducibles. El Pipeteo de las muestras no debe prolongarse más de diez minutos para evitar la deriva del análisis. Si hay más de 10 minutos son necesarios, siga el mismo orden de dispensación. Si más de una placa se utiliza, se recomienda repetir la curva dosis-respuesta en cada placa.
- La eliminación de líquidos incompleta o inexacta de los pozos podría influir en la precisión del ensayo y / o aumentar el background. Para mejorar el rendimiento del kit en los sistemas automatizados de ELISA, se recomienda aumentar el número de lavados.
- Algunos reactivos contienen pequeñas cantidades de Proclin 300® como conservante. Evite el contacto con la piel o mucosa.
- Este método permite la determinación de progesterona de 0,2 ng/ml a 40 ng/ml.

12.1. CONSIDERACIONES PARA EL DESCARTE

Los residuos de productos y preparaciones químicos generalmente son considerados como residuos peligrosos. La eliminación de éste tipo de residuos está regulada por leyes y regulaciones nacionales y regionales. Póngase en contacto con las autoridades locales o empresas de manejo de residuos para que lo asesoren sobre cómo eliminar los residuos peligrosos.

13. INFORMACIÓN PARA PEDIDOS

Prod. No.:	DNOV006	Progesterone (96 Determinations)

LITERATURE/ BIBLIOGRAPHIE/ BIBLIOGRAFÍA

Wisdom G.B. (1976) Clin. Chem. 22 (8), 1243 – 1255.
De Villa G.O. et al. (1972) J. Clin. Endoc. Metab. 35, 458.
Joyce,B.G. et al. Steroids 29, no 6, 761, (1977)
Winkel P. et al. Clin. Chem. 22 (4), 422 (1976)
Rajkowski K.N et al. Steroids 29, no 5 (1977)

Symbols Key/ Symbolschlüssel/ Explication des symboles / Legenda / Símbolos/ Tabela de símbolos	
	Manufactured by / Hergestellt von/ Fabriqué par/ Prodotto da/ Fabricado por / Fabricado por
IVD	In Vitro Diagnostic Medical Device/ In Vitro Diagnosticum/ Dispositif médical de diagnostic *in vitro*/ Diagnostico *in vitro*/ Producto para diagnóstico In vitro / Dispositivo Médico para Diagnóstico In Vitro
LOT	Lot Number/ Chargenbezeichnung/ Numéro de lot/ Lotto/ Número de lote / Número de lote
	Expiration Date/ Verfallsdatum/ Date de péremption/ Scadenza/ Fecha de caducidad / Data de Validade
	Storage Temperature/ Lagertemperatur/ Température de conservation/ Temperatura di conservazione / Temperatura de almacenamiento / Temperatura de Armazenamento
	Keep away from sunlight / Vor direkter Sonneneinstrahlung schützen / Protéger de rayonnement solaire / Mantener alejado de la luz solar
CE	CE Mark/ CE-Zeichen/ Marquage CE / Marchio CE/ Marca CE / Marca CE
REF	Catalogue Number/ Katalog Nummer/ Référence du catalogue/ Numero di codice/ Número de Catálogo / Número de Catálogo
	Consult Instructions for Use/ Gebrauchsanweisung beachten/ Consulter la notice d'utilisation/ Consultare le istruzioni/ Consulte las Instrucciones de Uso / Consultar as Instruções de Utilização
MTP	Microplate/ Mikrotiterplatte/ Microplaque/ Micropiastra/ Microplaca / Microplaca
CONJ	Conjugate/ Konjugat/ Conjugué/ Coniugato/ Conjugado / Conjugado
CONTROL	Control/ Kontrolle/ contrôle / controllo / control / controle/ controlo
CAL	Calibrator resp. Standard/ Kalibrator bzw. Standard/ Callibrateur resp Etalon / Calibratore ossia Standard / Calibrador o bien Estándar
SOLN STOP	Stop solution/ Stopplösung/ Solution d'arrêt/Soluzione bloccante / Solução de paragem
SUB TMB	TMB Substrate solution/ TMB-Substratlösung/ Substrat TMB/ soluzione substrato TMB/ solución substrato TMB / Solução substrato TMB
WASH BUF 10x	Washing solution 10x concentrated/ Waschlösung 10x konzentriert/ Solution de lavage concentré 10 x/ soluzione di lavaggio concentrazione x10/ solución de lavado concentrado x10 / Solução de lavagem concentrada 10x
	Contains sufficient for "n" tests/ Ausreichend für "n" Tests/ Contenu suffisant pour "n" tests/ Contenuto sufficiente per "n" saggi/ Contenido suficiente para "n" tests / Conteúdo suficiente para "n" testes

SCHEME OF THE ASSAY

Progesterone

Test Preparation

Prepare reagents and samples as described.
Establish the distribution and identification plan for all specimens and controls on the result sheet supplied in the kit.
Select the required number of microtiter strips or wells and insert them into the holder.

Assay Procedure

	Substrate blank	Standard 1 – 4	Control	Sample
Standard 1 – 4	-	20 µl	-	-
Control	-	-	20 µl	-
Sample	-	-	-	20 µl
Conjugate	-	200 µl	200 µl	200 µl
Cover wells with foil supplied in the kit **Incubate for 1 hour at 37 °C** Wash each well three times with 300 µl diluted wash solution				
TMB Substrate	100 µl	100 µl	100 µl	100 µl
Incubate for exactly 15 min at room temperature (22…28°C) in the dark				
Stop Solution	100 µl	100 µl	100 µl	100 µl
Shake the microplate gently Photometric measurement at 450 nm, 620-630 nm				

NovaTec Immundiagnostica GmbH

Technologie & Waldpark

Waldstr. 23 A6
D-63128 Dietzenbach, Germany

Tel.: +49 (0) 6074-48760 Fax: +49 (0) 6074-487629
Email : info@NovaTec-ID.com
Internet: www.NovaTec-ID.com

DNOV006-engl,es,fr-29052015-CS

NovaTec Immundiagnostica GmbH

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

LH (DNOV030)

and the following components:

MTP	Coated Wells
CONJ	Anti-LH-HRP Conjugate + Anti LH-Biotin Conjugate
SUB TMB	TMB Substrate Solution
WASH BUF 50x	Wash Solution 50x conc.
CONTROL	LH Control
CAL 0 - 5	LH Standards 0-5
SOLN STOP	Stop Solution

are in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct. 27, 1998 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures in

Annex III (2–5).

Dietzenbach: 2018-11-21

Dr. Claudia Rezmer
Management Representative

The conformity of the above mentioned product is checked at least every 3 years. This is documented by rechecking and signing the general requirements.

NovaTec Immundiagnostica GmbH

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

FSH (DNOV031)

and the following components:

MTP	Coated Wells
CONJ	Anti-FSH Conjugate
SUB TMB	TMB Substrate Solution
WASH BUF 10x	Wash Solution 10x conc.
CONTROL	FSH Control
CAL 0 - 5	FSH Standards 0-5
SOLN STOP	Stop Solution

are in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct. 27, 1998 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures in

Annex III (2–5).

Dietzenbach: 2018-11-21

Dr. Claudia Rezmer
Management Representative

The conformity of the above mentioned product is checked at least every 3 years. This is documented by rechecking and signing the general requirements.

Certificate

mdc medical device certification GmbH
certifies that

NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

for the scope

development, manufacturing and distribution of in-vitro diagnostics as well as installation and service of IVD analyzers for infectious disease diagnostics, autoimmune diagnostics, tumor diagnostics and for clinical chemistry

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2021-12-04
Valid until	2024-12-03
Registration no.	D1055500017
Report no.	P21-01539-215852
Stuttgart	2021-12-01

Head of Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Bio-Optica
Improving Pathology

Data Sheet

CE

COVERGLASSES

CODE	DIMENSIONS (mm) (±0.15)	PACKAGING	UDI-DI
09-2040	24 X 40	1000 pcs (10 boxes x 100 pcs)	08034120272551
09-2050	24 x 50	1000 pcs (10 boxes x 100 pcs)	08034120272568
09-2060	24 x 60	1000 pcs (10 boxes x 100 pcs)	08034120272575
09-5065	50 x 65	1000 pcs (10 boxes x 100 pcs)	08034120278089

IVD

In vitro Diagnostic – Medical Device
IVD **Class A**, Reg. UE 2017/746

Manufacturer: Bio-Optica Milano S.p.A.

Basic UDI: 080341202W0503900202Q2

Disposable

Date of issue: 16/05/2022
Rev. 001

Bio-Optica Milano S.p.A. Via San Faustino 58 - 20134 Milano - Phone +39 02.21.27.13.1
Fax Italia +39 02.21.53.000 - Fax Export +39 02.21.54.155
www.bio-optica.it

Bio-Optica
Improving Pathology

Data Sheet

Coverglasses, standard thickness 0.13 – 0.16 mm

GENERAL FEATURES

Bio-Optica coverglasses are cleaned and degreased, completely clear without any selective absorbency effect.
The surface is uniformly flat without grooves, bubbles or scratches thanks to automated production.
Perfect for the use with the automated coverslipper available on the market.

Technical data

Technical features	Chemical composition	Borosilicate 3.3 Glass in accordance with ISO 8255 standards
	Refraction index:	1.513 – 1.523 (measured between λ= 546.07 nm and λ= 643.85 nm)
	Density:	(2.47 ± 0.01) kg/dm^3
Packaging	Primary packaging	10 plastic boxes with 100 coverglass each
	Secondary packaging	Carton box
Conservation	Storage	Keep the slides in a fresh and dry environment. Avoid large variations in temperature during both storage and usage. Cooling of the product can cause condensation and lead to condensed water forming between the glasses
	Validity	Not applicable
Warning and precautions	Instruction for use	Not provided for this product.
	Classification of the product	The product is intended for professional laboratory use for healthcare professionals. The product is not chemically dangerous. No warning measures and precautions are required.
	Disposal	Observe all state and local environmental regulations regarding waste disposal.
	Recommendations	In the event of a serious accident, we recommend that you immediately inform Bio-Optica Milano S.p.A. and the competent authorities.

REVISION N°	REASON	REVISION DATE
001	Regulation adjustment UE 2017/746 - IVDR	16/05/2022

Date of issue: 16/05/2022
Rev. 001

Bio-Optica Milano S.p.A. Via San Faustino 58 - 20134 Milano - Phone +39 02.21.27.13.1
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Bio - Optica
Improving Pathology

Fișa tehnică a produsului

CE

LAMELE DE ACOPERIRE

COD	DIMENSIUNI (mm) (± 0,15)	AMBALAJUL	UDI-DI
09-2040	24 X 40	1000 buc. (10 cutii x 100 buc.)	08034120272551
09-2050	24 x 50	1000 buc. (10 cutii x 100 buc.)	08034120272568
09-2060	24 x 60	1000 buc. (10 cutii x 100 buc.)	08034120272575
09-5065	50 x 65	1000 buc. (10 cutii x 100 buc.)	08034120278089

IVD

Dispozitiv medical pentru diagnosticare in-vitro
IVD (dispozitiv de diagnosticare in vitro) **Clasa A**, Reg. UE 2017/746

Producător: Bio-Optica Milano S.p.A.

Basic UDI: 080341202W0503900202Q2

Dispozabilă

Data publicării:16/05/2022
Rev. 001

Bio-Optica Milano S.p.A. Via San Faustino 58 - 20134 Milano - Phone +39 02.21.27.13.1
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Bio-Optica
Improving Pathology

Fișa tehnică a produsului

Lamele de acoperire, grosime standard 0,13 – 0,16 mm

CARACTERISTICI GENERALE

Lamelele de acoperire Bio-Optica sunt curățate și degresate, complet transparente, fără niciun efect de adsorbție selectivă.
Au o suprafața uniform plată, fără striuri, bule sau zgârieturi mulțumită producției automate.
Perfecte pentru utilizarea cu automatele de acoperit lamele din comerț.

Date tehnice

Caracteristici tehnice	Compoziția chimică	Sticlă borosilicat 3.3 în conformitate cu standardele ISO 8255
	Indice de refracție:	1,513 – 1,523 (măsurat între λ= 546,07 nm și λ= 643,85 nm)
	Densitate:	(2,47 ± 0,01) kg/dm^3
Ambalaj	Ambalaj primar	10 cutii de plastic cu câte 100 de lamele de acoperire fiecare
	Ambalaj secundar	Cutie de carton
Conservare	Depozitare	Păstrați lamelele într-un mediu răcoros și uscat. Evitați variațiile mari de temperatură, atât la depozitare, cât și la utilizare. Răcirea produsului poate produce condens și la formarea de apă de condens între lamele.
	Valabilitate	Nu se aplică
Avertizări și măsuri de precauție	Instrucțiuni de utilizare	Nu sunt furnizate pentru acest produs.
	Clasificarea produsului	Produsul este destinat utilizării de către profesioniștii din domeniul medical în laboratoare profesioniste. Produsul nu este periculos din punct de vedere chimic. Nu sunt necesare avertizări și măsuri de precauție.
	Eliminarea	Respectați toate reglementările de mediu, de stat și locale, privind eliminarea deșeurilor.
	Recomandări	În caz de accident grav, vă recomandăm să informați imediat Bio-Optica Milano S.p.A și autoritățile competente.

REVIZUIREA nr.	MOTIV	DATA REVIZUIRII
001	Modificare a Regulamentului UE 2017/746 - IVDR	16/05/2022

Data publicării:16/05/2022
Rev. 001

Bio-Optica Milano S.p.A. Via San Faustino 58 - 20134 Milano - Phone +39 02.21.27.13.1
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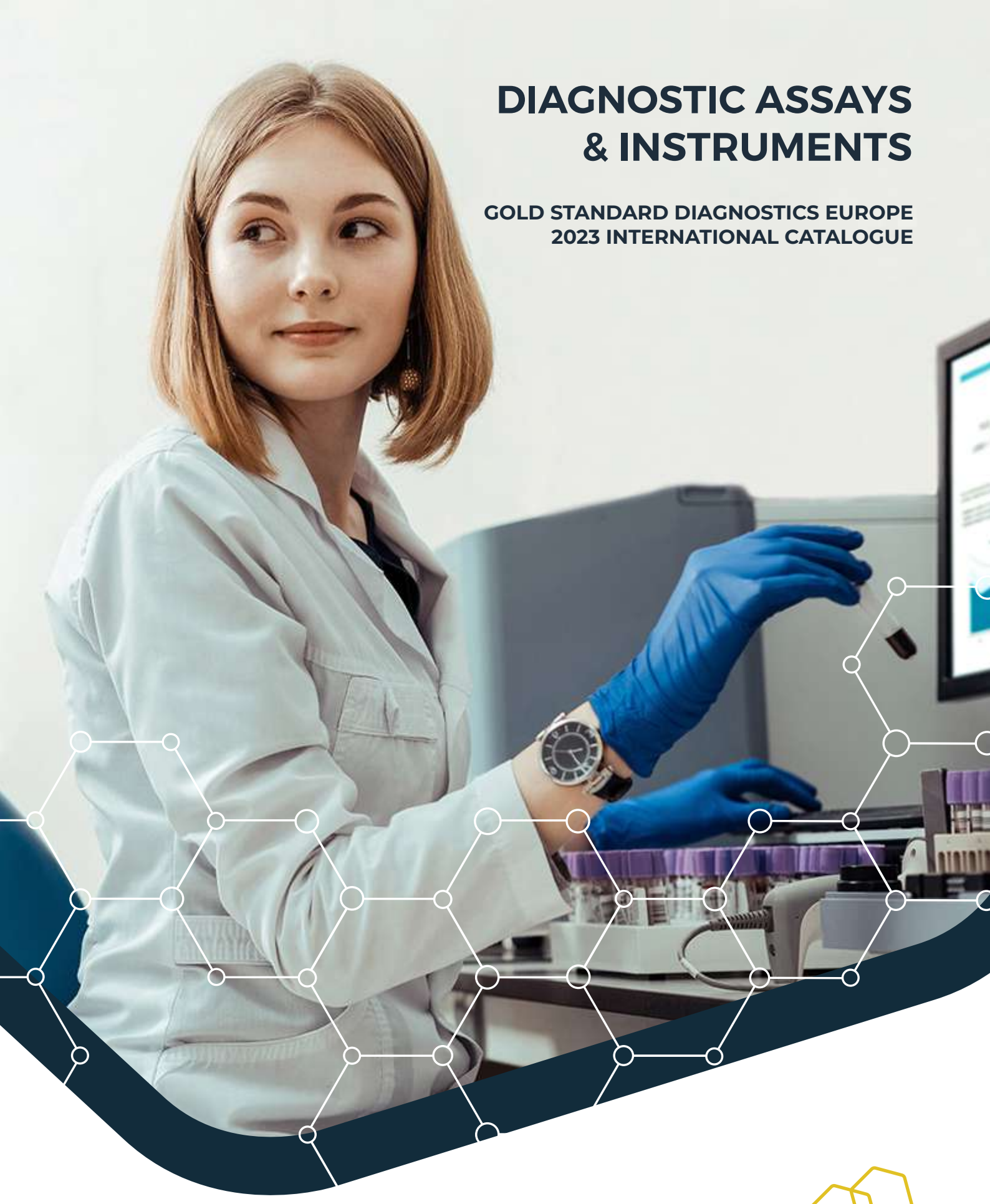
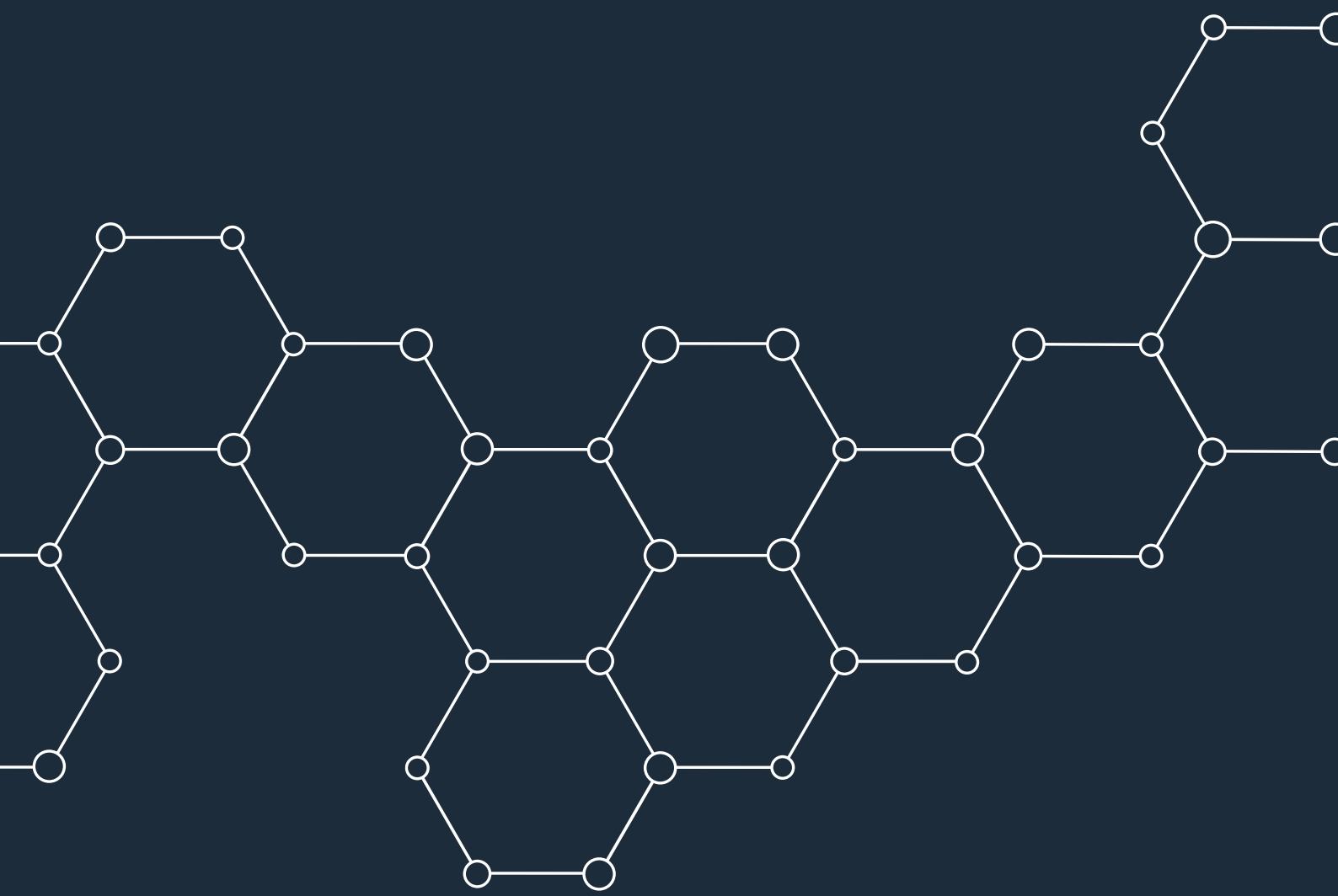
www.bio-optica.it



DIAGNOSTIC ASSAYS & INSTRUMENTS

GOLD STANDARD DIAGNOSTICS EUROPE 2023 INTERNATIONAL CATALOGUE

GOLD STANDARD DIAGNOSTICS




ThinkPad

ABOUT US

The Gold Standard Diagnostics Group is a leading healthcare provider of diagnostic solutions composed of three companies with extensive experience in the clinical market: Gold Standard Diagnostics Inc., Novatec Immundiagnostica GmbH, and Virotech Diagnostics GmbH. The European branch, located in Dietzenbach (Germany), concentrates the business of the Group outside the United States of America.

Gold Standard Diagnostics Europe provides automated platforms and a broad menu of diagnostic tests in the fields of virology, bacteriology, parasitology, mycology, tumor markers, hormones, and autoimmune diseases.

The company is engaged in innovative development, quality manufacturing, and outstanding commercialization of diagnostic solutions. Our aim is to be at the forefront of what the laboratories need, and we are committed to delivering best-in-class assays and services to our vast network worldwide. We will continue to devote all our efforts to improving patient care.

Novatec Immundiagnostica and Virotech Diagnostics are ISO 13485:2016 certified, and most of the products in this catalogue are CE marked, fulfilling the European Directive 98/79/CE on *in vitro* diagnostic medical devices.

Additionally, we participate in several External Quality Assessment Control Programs such as:

- INSTAND
- UK NEQAS
- ESfEQA
- RfB
- Labquality
- College of American Pathologists

IMMUNOLOGY

ELISA • SEROLOGY

- Complete kits, IgA sets to complement IgG/IgM kits, and standards and controls for CSF
- Ready-to-use, color-coded reagents, and breakable strip plates
- Standardized methods suitable for automated procedures
- Avidity and µ-capture tests available for some parameters
- Special IgM-buffer to avoid interferences with rheumatoid factor
- Validated for cerebrospinal fluid testing where diagnostically relevant
- CE marked

Note: Multiple order numbers per product separated by a slash correspond to the Novatec and Virotech format respectively.

VIROLOGY • Complete Kits

Order No.	Product Description	Format
ADVA0010	**Adenovirus IgA** *Highly purified native antigen.*	96 tests
ADVG0010	**Adenovirus IgG** *Highly purified native antigen.*	96 tests
EC121.00	**Adenovirus IgG/IgM** *Additional IgA set available with order number EC121.08.*	96 tests
ADVM0010	**Adenovirus IgM** *Highly purified native antigen.*	96 tests
CHIG0590	**Chikungunya Virus IgG Capture** *Capture-technology for IgG to increase specificity.*	96 tests
CHIM0590	**Chikungunya Virus IgM µ-Capture** *Capture-technology for IgM to increase specificity.*	96 tests
CMVG0110	**Cytomegalovirus IgG**	96 tests
ACMV7110	**Cytomegalovirus IgG Avidity** *As an aid in the differentiation between primary and past infection.*	48 tests
EC113.00	**Cytomegalovirus IgG/IgM** *Mix of native and purified antigens. Validated for cerebrospinal fluid testing.*	96 tests
CMVM0110	**Cytomegalovirus IgM**	96 tests
DENG0120	**Dengue Virus IgG** *Allows detection of antibodies against all 4 DENV types.*	96 tests
DENM0120	**Dengue Virus IgM** *Allows detection of antibodies against all 4 DENV types.*	96 tests
DVM0640	**Dengue Virus IgM µ-Capture** *Allows detection of antibodies against all 4 DENV types.* *Capture-technology to increase specificity.*	96 tests
NS1D4020	**Dengue Virus NS1 Antigen** *Detects acute infections.*	96 tests
EC116A00	**Enterovirus IgA** *Screening assay for the detection of heterotypic IgA antibodies with coxsackievirus B5 and echovirus 24 antigens.*	96 tests
EC116G00	**Enterovirus IgG** *Screening assay for the detection of heterotypic IgG antibodies with coxsackievirus B5 and echovirus 24 antigens.*	96 tests
EC116M00	**Enterovirus IgM** *Screening assay for the detection of heterotypic IgM antibodies with coxsackievirus B5 and echovirus 24 antigens.*	96 tests

Order No.	Product Description	Format
EBVG0080/ EC202.00	**Epstein-Barr Virus EA-D IgG**	96 tests
EBVG0580/ EC204.00	**Epstein-Barr Virus EBNA IgG** *EC204.00 provides a special formula that allows a distinction between primary and past infection in unclear cases.*	96 tests
EC102.00	**Epstein-Barr Virus IgG/IgM** *Validated for cerebrospinal fluid testing.*	96 tests
EBVA0150	**Epstein-Barr Virus VCA IgA**	96 tests
EBVG0150/ EC205G00	**Epstein-Barr Virus VCA IgG** *EC205G00 includes gp125 and p18 as highly specific markers.*	96 tests
AEBV7150	**Epstein-Barr Virus VCA IgG Avidity** *As an aid in the differentiation between primary and past infection.*	48 tests
EBVM0150/ EC203M00	**Epstein-Barr Virus VCA IgM** *EC203M00 provides a special formula that allows a distinction between primary and past infection in unclear cases.*	96 tests
HANG0670	**Hantavirus IgG** *Recombinant antigen, contains four species/serotypes to detect it worldwide.*	96 tests
HANM0670	**Hantavirus IgM** *Recombinant antigen, contains four species/serotypes to detect it worldwide.*	96 tests
HEVG0780	**Hepatitis E Virus IgG** *Recombinant antigen for high sensitivity and specificity.*	96 tests
HEVM0780	**Hepatitis E Virus IgM** *Recombinant antigen for high sensitivity and specificity.*	96 tests
EC130.00	**Herpes Simplex Virus 1 (gG1) IgG/IgM** *Highly-specific recombinant glycoprotein gG1 antigen, validated for cerebrospinal fluid testing.*	96 tests
HSV1G0500	**Herpes Simplex Virus 1 IgG** *Highly-specific recombinant glycoprotein gG1 antigen.*	96 tests
HSV1M0500	**Herpes Simplex Virus 1 IgM** *Highly-specific recombinant glycoprotein gG1 antigen.*	96 tests
HSVG0250	**Herpes Simplex Virus 1+2 IgG**	96 tests
HSVM0250	**Herpes Simplex Virus 1+2 IgM**	96 tests
EC108.00	**Herpes Simplex Virus Screen IgG/IgM** *Validated for cerebrospinal fluid testing.*	96 tests
EC131.00	**Herpes Simplex Virus 2 (gG2) IgG/IgM** *Highly-specific affinity-purified glycoprotein gG2 antigen, validated for cerebrospinal fluid testing.*	96 tests
HSV2G0540	**Herpes Simplex Virus 2 IgG** *Highly-specific recombinant glycoprotein gG2 antigen.*	96 tests
HSV2M0540	**Herpes Simplex Virus 2 IgM** *Highly-specific recombinant glycoprotein gG2 antigen.*	96 tests
INFA0290/ EC118A00	**Influenza Virus A IgA** *EC118A00 with seasonal updated antigens.*	96 tests
INFG0290	**Influenza Virus A IgG**	96 tests
EC118.00	**Influenza Virus A IgG/IgM** *Seasonal updated antigens.*	96 tests
INFM0290	**Influenza Virus A IgM**	96 tests
INFA0300/ EC119A00	**Influenza Virus B IgA** *EC119A00 with seasonal updated antigens.*	96 tests
INFG0300	**Influenza Virus B IgG**	96 tests
EC119.00	**Influenza Virus B IgG/IgM** *Seasonal updated antigens.*	96 tests
INFM0300	**Influenza Virus B IgM**	96 tests

Order No.	Product Description	Format
MEAG0330/ EC105G00	**Measles Virus IgG** *Detects present and past contact with measles due to wild-virus or vaccination. EC105G00 is adjusted to the WHO standards and is validated for cerebrospinal fluid testing.*	96 tests
AMEA7330	**Measles Virus IgG Avidity** *As an aid in the differentiation between primary and past infection.*	48 tests
MEAM0330/ EC105M00	**Measles Virus IgM** *MEAM0330 detects present and past contact with measles due to wild-virus or vaccination.*	96 tests
MUMG0340	**Mumps Virus IgG** *Detects present and past contact with mumps due to wild-virus or vaccination.*	96 tests
EC106.00	**Mumps Virus IgG/IgM** *Detects acute infections in IgM, the serostatus in IgG, and is validated for cerebrospinal fluid testing.*	96 tests
MUMM0340	**Mumps Virus IgM** *Detects present and past contact with mumps due to wild-virus.*	96 tests
PAIA0360	**Parainfluenza Virus 1, 2, 3 IgA**	96 tests
PAIG0360	**Parainfluenza Virus 1, 2, 3 IgG**	96 tests
EC148.00	**ParaScreen Virus IgG/IgM** *Additional IgA set available with order number EC148.08.*	96 tests
PARG0370	**Parvovirus B19 IgG** *Recombinant antigen.*	96 tests
PARM0370	**Parvovirus B19 IgM** *Recombinant antigen.*	96 tests
RSVA0380	**Respiratory Syncytial Virus IgA**	96 tests
RSVG0380	**Respiratory Syncytial Virus IgG**	96 tests
EC107.00	**Respiratory Syncytial Virus IgG/IgM** *Additional IgA set available with order number EC107.08.*	96 tests
RSVM0380	**Respiratory Syncytial Virus IgM**	96 tests
EC109L00	**Rubella Virus CSF IgG** *For cerebrospinal fluid testing only, additional available standards and control sets.*	96 tests
RUBG0400	**Rubella Virus IgG**	96 tests
ARUB7400	**Rubella Virus IgG Avidity** *As an aid in the differentiation between primary and past infection.*	48 tests
RUBM0400	**Rubella Virus IgM µ-Capture** *Capture technology to increase specificity.*	96 tests
COVA0940	**SARS-CoV-2 (COVID-19) Virus IgA**	96 tests
COVG0940	**SARS-CoV-2 (COVID-19) Virus IgG**	96 tests
CVGQ0970	**SARS-CoV-2 (COVID-19) quantitative IgG** *Quantitative determination of antibodies to the spike (S) protein. Calibrators correlate to the "First WHO International Standard for anti SARS-CoV-2 immunoglobulin (human)".*	96 tests
TICG0440	**Tick-Borne Encephalitis IgG** *Quantitative assay with antibody titer profile to verify immune status.*	96 tests
PTICG044	**Tick-Borne Encephalitis IgG plus** *Quantitative assay with antibody titer profile to verify immune status. Contains an additional control.*	96 tests
EC117.00	**Tick-Borne Encephalitis IgG/IgM** *Detects acute/recent infection and vaccination antibodies. Validated for cerebrospinal fluid testing.*	96 tests
TICM0440	**Tick-Borne Encephalitis IgM** *Can be used to verify immune status.*	96 tests

Order No.	Product Description	Format
VZVA0490	**Varicella-Zoster Virus IgA**	96 tests
VZVG0490	**Varicella-Zoster Virus IgG** *Can be used for measuring antibody response after varicella vaccination.*	96 tests
EC110.00	**Varicella-Zoster Virus IgG/IgM** *IgG cut-off adjusted to follow Robert Koch Institute recommendations of seropositivity; IgG is aligned to the WHO standards. Additional IgA set available with order number EC110.08. Validated for cerebrospinal fluid testing.*	96 tests
VZVM0490	**Varicella-Zoster Virus IgM**	96 tests
ZVG0790	**Zika Virus IgG Capture** *Recombinant NS1 antigen. Capture-technology increases specificity and reduces cross reactivity.*	96 tests
ZVM0790	**Zika Virus IgM µ-Capture** *Recombinant NS1 antigen. Capture-technology increases specificity and reduces cross reactivity.*	96 tests

BACTERIOLOGY • Complete Kits

Order No.	Product Description	Format
BAR0900	**Bartonella** *Total antibody assay coated with highly purified native antigen.*	96 tests
EC115.00	**Bordetella pertussis (FHA+PT) IgG/IgA** *Sensitive screening assay coated with PT and FHA antigens.*	96 tests
BOPA0030	**Bordetella pertussis IgA** *Sensitive screening assay coated with PT and FHA antigens.*	96 tests
BOPG0030	**Bordetella pertussis IgG** *Sensitive screening assay coated with PT and FHA antigens.*	96 tests
BOPM0030	**Bordetella pertussis IgM**	96 tests
BPTA0610/ EC215A00	**Bordetella pertussis toxin IgA** *Pure PT antigens, adjusted to the WHO standards.*	96 tests
BPTG0610/ EC215G00	**Bordetella pertussis toxin IgG** *Pure PT antigens, adjusted to the WHO standards. EC215G00 available with additional IgG quantification set.*	96 tests
EC215M00	**Bordetella pertussis toxin IgM** *Pure PT antigens.*	96 tests
EC022G00	**Borrelia + VlsE IgG** *Antigen mix of B. afzelii PKo, B. garinii strain PBr, and B. burgdorferi strain ZS7 for high sensitivity and specificity. Validated for cerebrospinal fluid testing.*	96 tests
EC024G00	**Borrelia + VlsE IgG Europe** *Validated for cerebrospinal fluid testing.*	96 tests
EC022M00	**Borrelia IgM** *Borrelia strain Pko for high sensitivity. Validated for cerebrospinal fluid testing.*	96 tests
BORG0040	**Borrelia burgdorferi IgG** *Recombinant antigen, validated for serum, plasma, and cerebrospinal fluid testing.*	96 tests
BORM0040	**Borrelia burgdorferi IgM** *Recombinant antigen, validated for serum, plasma, and cerebrospinal fluid testing.*	96 tests
BRUG0050	**Brucella IgG**	96 tests
EC101.00	**Brucella IgG/IgM** *Additional IgA set available with order number EC101.08.*	96 tests
BRUM0050	**Brucella IgM**	96 tests

Order No.	Product Description	Format
CHLA0510	**Chlamydia pneumoniae IgA**	96 tests
CHLG0510	**Chlamydia pneumoniae IgG**	96 tests
CHLM0510	**Chlamydia pneumoniae IgM**	96 tests
CHLA0070	**Chlamydia trachomatis IgA**	96 tests
CHLG0070	**Chlamydia trachomatis IgG**	96 tests
CHLM0070	**Chlamydia trachomatis IgM**	96 tests
COX1G0600	**Coxiella burnetii phase 1 IgG**	96 tests
COX2G0600	**Coxiella burnetii phase 2 IgG**	96 tests
COX2M0600	**Coxiella burnetii phase 2 IgM**	96 tests
CORG5009	**Diphtheria toxin 5S IgG** *Quantitative assay with 5 standards for verification of immune status due to vaccination or contact with Corynebacterium diphtheriae.*	96 tests
PCORG009	**Diphtheria toxin 5S IgG plus** *Quantitative assay with 5 standards and one additional control for verification of immune status due to vaccination or contact with Corynebacterium diphtheriae.*	96 tests
CORG0090/ EC129.00	**Diphtheria toxin IgG** *Quantitative assay. CORG0090 allows verification of immune status due to vaccination or contact with Corynebacterium diphtheriae. EC129.00 is adjusted to the WHO standards.*	96 tests
EC143A00	**Helicobacter pylori IgA**	96 tests
HELG0220/ EC143G00	**Helicobacter pylori IgG** *HELG0220 is a quantitative assay with recombinant antigen.*	96 tests
PHELG022	**Helicobacter pylori IgG plus** *Quantitative assay with recombinant antigen plus one control.*	96 tests
HELM0220	**Helicobacter pylori IgM**	96 tests
LEGG0650	**Legionella pneumophila IgG** *Assay with antigens from a pool of different serovars to increase sensitivity.*	96 tests
LEGM0650	**Legionella pneumophila IgM** *Assay with antigens from a pool of different serovars to increase sensitivity.*	96 tests
LEPG0660	**Leptospira IgG**	96 tests
LEPM0660	**Leptospira IgM**	96 tests
MYCA0350	**Mycoplasma pneumoniae IgA** *Highly purified antigens.*	96 tests
MYCG0350	**Mycoplasma pneumoniae IgG** *Highly purified antigens.*	96 tests
EC114.00	**Mycoplasma pneumoniae IgG/IgM** *Detects acute infections in IgG and offers specific cut-off adjustment for infant samples. Additional IgA set available with order number EC114.08.*	96 tests
MYCM0350	**Mycoplasma pneumoniae IgM** *Highly purified antigens.*	96 tests
TETG5043	**Tetanus toxin 5S IgG** *Quantitative assay adjusted to the WHO standards with recombinant antigen and 5 standards.*	96 tests
PTETG043	**Tetanus toxin 5S IgG plus** *Quantitative assay adjusted to the WHO standards with recombinant antigen and 5 standards plus one control.*	96 tests
TETG0430	**Tetanus toxin IgG** *Quantitative assay adjusted to the WHO standards with recombinant antigen.*	96 tests
EC124.00	**Tetanus toxoid IgG** *Quantitative assay adjusted to the WHO standards.*	96 tests

Order No.	Product Description	Format
YERA0990	**Yersinia enterocolitica IgA** *Mix of purified native antigens and recombinant antigens YopD, YopB and YopE.*	96 tests
EC142.00	**Yersinia enterocolitica IgG/ IgA**	96 tests
YERG0990	**Yersinia enterocolitica IgG**	96 tests

FUNGI • Complete Kits

Order No.	Product Description	Format
ASPG0680	**Aspergillus fumigatus IgG**	96 tests
ASPM0680	**Aspergillus fumigatus IgM**	96 tests
CANA0060	**Candida albicans IgA**	96 tests
CANG0060	**Candida albicans IgG**	96 tests
EC111.00	**Candida albicans IgG/IgM** *Designed to detect acute infections, offers an additional IgA set with order number EC111.08.*	96 tests
CANM0060	**Candida albicans IgM**	96 tests

PARASITES • Complete Kits

Order No.	Product Description	Format
ASCG0020	**Ascaris lumbricoides IgG** *Native antigen for high sensitivity.*	96 tests
CHAG0560	**Chagas IgG** *Chimeric-recombinant antigens to reduce cross-reactivity to Leishmania and Malaria.*	96 tests
ECHG0130	**Echinococcus IgG**	96 tests
ENTG0140	**Entamoeba histolytica IgG**	96 tests
FIL0760	**Filariasis** *Detects antibodies against main genus of filarial worms (Onchocerca, Loa loa, and Wuchereria).*	96 tests
LEIG0310	**Leishmania infantum IgG** *Specific antigens to reduce cross reactivity to Chagas.*	96 tests
MAL0620	**Malaria** *Recombinant antigens to reduce cross reactivity to other parasites.*	96 tests
SCHG0410	**Schistosoma mansoni IgG**	96 tests
SCHM0410	**Schistosoma mansoni IgM**	96 tests
STRO0690	**Strongyloides** *Chimeric-recombinant antigen to increase specificity. Detects the main human pathogen species.*	96 tests
TAEG0420	**Taenia solium IgG** *Native antigen for high sensitivity.*	96 tests
TOCG0450	**Toxocara canis IgG**	96 tests
TOXA0460	**Toxoplasma gondii IgA**	96 tests
TOXG0460	**Toxoplasma gondii IgG** *Quantitative assay. Calibrated against WHO standards.*	96 tests
ATOX7460	**Toxoplasma gondii IgG Avidity** *As an aid in the differentiation between primary and past infection.*	48 tests
TOXM0460	**Toxoplasma gondii IgM µ-Capture** *Capture assay to reduce cross-reactivity.*	96 tests
TRIG0480	**Trichinella spiralis IgG**	96 tests

HORMONES-AUTOIMMUNITY • Complete Kits

Order No.	Product Description	Format
DNOV003	17 beta-Estradiol	96 tests
DNOV004	17-OH Progesterone	96 tests
DNOV033	AFP	96 tests
DNOV012	Aldosterone	96 tests
DNOV008	Androstenedione	96 tests
DSNOV27	Androstenedione Saliva	96 tests
ATG1010	Anti-TG	96 tests
ATPO1020	Anti-TPO *(Recombinant antigen)*	96 tests
DNOV034	beta-HCG	96 tests
DNOV061	CA 125	96 tests
DNOV062	CA 15-3	96 tests
DNOV063	CA 19-9	96 tests
DNOV060	CEA	96 tests
DNOV096	CH-50	96 tests
DNOV093	CIC C1q	96 tests
DNOV094	CIC C3d	96 tests
DNOV001	Cortisol	96 tests
DSNOV20	Cortisol Saliva	96 tests
DNOV112	C-Peptide	96 tests
DNOV005	DHEA-S	96 tests
DSNOV24	DHEA-S Saliva	96 tests
DNOV100	Ferritin	96 tests
DNOV051	Free T3	96 tests
FT41050	Free T4	96 tests
DNOV009	Free Testosterone	96 tests
DNOV031	FSH	96 tests
DNOV101	HGH	96 tests
DNOV102	IgE	96 tests
DNOV111	Insulin	96 tests
DNOV030	LH	96 tests
DNOV006	Progesterone	96 tests
DNOV032	Prolactin	96 tests
RFM3010	Rheumatoid Factor IgM *(Fc fragments of human IgG for high specificity)*	96 tests
DNOV002	Testosterone	96 tests
DSNOV21	Testosterone Saliva	96 tests
DNOV057	Thyroglobulin	96 tests
DNOV064	Total PSA (RUO)	96 tests
DNOV053	Total T3	96 tests
DNOV054	Total T4	96 tests
TSH1030	TSH (*Quantitative assay adjusted to the WHO standard)*	96 tests
DNOV010	Urinary Cortisol	96 tests

ELISA • Additional Products

IgA Sets for Serology Diagnostics

Order No.	Product Description	Related Kit Order No.	Format
EC121.08	Adenovirus IgA Set	EC121.00	3 x 1.3 ml & 1 x 11 ml
EN215Q60	Bordetella pertussis IgG quantification	EC215G00	3 x 2 ml
EC101.08	Brucella IgA Set	EC101.00	3 x 1.3 ml & 1 x 11 ml
EC111.08	Candida albicans IgA Set	EC111.00	3 x 1.3 ml & 1 x 11 ml
EC114.08	Mycoplasma pneumoniae IgA Set	EC114.00	3 x 1.3 ml & 1 x 11 ml
EC148.08	ParaScreen Virus IgA Set	EC148.00	3 x 1.3 ml & 1 x 11 ml
EC107.08	Respiratory Syncytial Virus IgA Set	EC107.00	3 x 1.3 ml & 1 x 11 ml
EC110.08	Varicella-Zoster Virus IgA Set	EC110.00	3 x 1.3 ml & 1 x 11 ml

Standards and Controls for CSF Diagnostics

Order No.	Product Description	Related Kit Order No.	Format
EN022L65	Borrelia + VlsE IgG CSF AI Control Set	EC022G00/EC024G00	4 x 1 ml
EC022L60	Borrelia + VlsE IgG CSF Standards	EC022G00/EC024G00	4 x 1 ml
EC022L80	Borrelia afzelii IgM CSF Standards	EC022M00	4 x 1 ml
EC113L60	Cytomegalovirus IgG CSF Standards	EC113.00	4 x 1 ml
EN102L65	Epstein-Barr Virus IgG CSF AI Control Set	EC102.00	4 x 1 ml
EC102L60	Epstein-Barr Virus IgG CSF Standards	EC102.00	4 x 1 ml
EC130L60	Herpes Simplex Virus 1 (gG1) IgG CSF Standards	EC130.00	4 x 1 ml
EC131L60	Herpes Simplex Virus 2 (gG2) IgG CSF Standards	EC131.00	4 x 1 ml
EN108L65	Herpes Simplex Virus Screen IgG CSF AI Control Set	EC108.00	4 x 1 ml
EC108L60	Herpes Simplex Virus Screen IgG CSF Standards	EC108.00	4 x 1 ml
EN105L65	Measles Virus IgG CSF AI Control Set	EC105.00	4 x 1 ml
EC105L60	Measles Virus IgG CSF Standards	EC105.00	4 x 1 ml
EC106L60	Mumps Virus IgG CSF Standards	EC106.00	4 x 1 ml
EN109L65	Rubella Virus IgG CSF AI Control Set	EC109L00	4 x 1 ml
EC109L60	Rubella Virus IgG CSF Standards	EC109L00	4 x 1 ml
EN117L65	Tick-Borne Encephalitis IgG CSF AI Control Set	EC117.00	4 x 1 ml
EC117L60	Tick-Borne Encephalitis IgG CSF Standards	EC117.00	4 x 1 ml
EC117L80	Tick-Borne Encephalitis IgM CSF Standards	EC117.00	4 x 1 ml
EC110L40	Varicella-Zoster Virus IgA CSF Standards	EC117.00	4 x 1 ml
EN110L65	Varicella-Zoster Virus IgG CSF AI Control Set	EC110.00	4 x 1 ml
EC110L60	Varicella-Zoster Virus IgG CSF Standards	EC110.00	4 x 1 ml

Additional Components

Order No.	Product Description	Format
EN250K60	Pipetting Control Set *(For use with EC250.00)*	2.8 ml & 2 x 50 ml PBS buffer
161102 161101 B/300.00	RF-SorboTech *Pre-adsorbance for all IgM ELISA assays starting with "EC" as well as EC215A00.*	10 ml 2 ml 2 vials RF - 2 ml & buffer
EC250.00	Validation Kit	96 tests

ELISA • STOOL ANTIGEN DETECTION

Gold Standard Diagnostics Europe distributes the Serazym® ELISA kits from Seramun Diagnostica GmbH related to gastrointestinal infections. The external quality controls are offered twice a year; please contact us for further information.

Complete Kits

Order No.	Product Description	Format
HW/E-017 HW/E-017-A2	Serazym® Adenovirus	96 tests 2 x 96 tests
HW/E-045 HW/E-045-A2	Serazym® Astrovirus	96 tests 2 x 96 tests
HW/E-093 HW/E-093-A2	Serazym® Campylobacter	96 tests 2 x 96 tests
HW/E-107 HW/E-107-A2	Serazym® Clostridium difficile GDH	96 tests 2 x 96 tests
HW/E-040 HW/E-040-A2	Serazym® Clostridium difficile Toxin A+B	96 tests 2 x 96 tests
HW/E-039-A	Serazym® Cryptosporidium parvum	96 tests
HW/E-018-A	Serazym® Entamoeba histolytica	96 tests
HW/E-106-A	Serazym® Giardia	96 tests
HW/E-114-A	Serazym® Helicobacter pylori 2nd Generation	96 tests
HW/E-061 HW/E-061-A2	Serazym® Norovirus	96 tests 2 x 96 tests
HW/E-020 HW/E-020-A2	Serazym® Rotavirus	96 tests 2 x 96 tests
HW/E-030 HW/E-030-A2	Serazym® Verotoxin 1+2	96 tests 2 x 96 tests

External Controls

Order No.	Product Description	Format
HW/EK-017	Adenovirus	2 x 0.4 ml
HW/EK-045	Astrovirus	2 x 0.4 ml
HW/EK-093	Campylobacter	2 x 0.4 ml
HW/EK-107	Clostridium difficile GDH	2 x 0.4 ml
HW/EK-040	Clostridium difficile Toxin A&B	2 x 0.4 ml
HW/EK-039	Cryptosporidium parvum	2 x 0.4 ml
HW/EK-018	Entamoeba histolytica	2 x 0.4 ml
HW/EK-106	Giardia	2 x 0.4 ml
HW/EK-114	Helicobacter pylori 2nd Generation	2 x 0.4 ml
HW/EK-061	Norovirus	2 x 0.4 ml
HW/EK-020	Rotavirus	2 x 0.4 ml
HW/EK-030	Verotoxin 1+2	2 x 0.4 ml


marking
serum control
IgG-conjugate control
93 kDa
66 kDa

LINE IMMUNOBLOT

Line immunoassays for the detection of pathogen-specific IgG, IgM, and IgA antibodies in human serum.

- Firm strips sorted in a booklet
- Additional control sets available for every kit (positive, negative and cut off controls)
- Standardized methods suitable for automated procedures
- Interpretation software available
- CE marked

VIROLOGY

Order No.	Product Description	Format
WE102G32 WE102G96	**Epstein-Barr Virus IgG** *Differentiates between primary and past infection and offers a special cut-off strategy for the EBNA1 interpretation.*	32 tests 96 tests
WE102M32 WE102M96	**Epstein-Barr Virus IgM** *Differentiates between primary and past infection and offers a special cut-off strategy for the EBNA1 interpretation.*	32 tests 96 tests
WE130G16 WE130G32	**Herpes Simplex Virus IgG** *Use of gG1-recombinant and gG2-purified as well as a native total antigen to differentiate between HSV 1 and 2.*	16 tests 32 tests

BACTERIOLOGY

Order No.	Product Description	Format
WE116A32 WE116A96	**Bordetella pertussis + CatACT IgA** *Differentiates between vaccination and infection, and gives notice of a parapertussis infection.*	32 tests 96 tests
WE116G32 WE116G96	**Bordetella pertussis + CatACT IgG** *Differentiates between vaccination and infection, and gives notice of a parapertussis infection.*	32 tests 96 tests
WE225G32 WE225G96	**Borrelia Europe + TpN17 IgG** *Includes the Treponema-band TpN17 as exclusion marker, validated for cerebrospinal fluid testing.*	32 tests 96 tests
WE224G32 WE224G96	**Borrelia Europe IgG** *Combination of purified lysate antigens (OspC, DbpA-PKo) and recombinant antigens (VlsE, p83, p58, p39, DbpA-mix), validated for cerebrospinal fluid testing.*	32 tests 96 tests
WE224M32 WE224M96	**Borrelia Europe IgM** *Combination of purified lysate antigens (OspC) and recombinant antigens (VlsE, p39, DbpA-mix), provides an additional EBV band as exclusion marker, validated for cerebrospinal fluid testing.*	32 tests 96 tests
WE223G32 WE223G96	**Borrelia in vivo + TpN17 IgG** *Includes the Treponema-band TpN17 as exclusion marker, validated for cerebrospinal fluid testing.*	32 tests 96 tests
WE222G32 WE222G96	**Borrelia in vivo IgG** *Combination of the most important common antigens (VlsE, p39, p83/100) with well-known "in-vivo" antigens. Validated for cerebrospinal fluid testing.*	32 tests 96 tests
WE222M32 WE222M96	**Borrelia in vivo IgM** *Combination of the most important common antigens (OspC, VlsE, p39) and EBV-band as exclusion marker. Validated for cerebrospinal fluid testing.*	32 tests 96 tests

Order No.	Product Description	Format
WE243A32 WE243A96	**Helicobacter pylori IgA** *Therapy-relevant differentiation of virulent and non-virulent strains with CagA and VacA.*	32 tests 96 tests
WE243G32 WE243G96	**Helicobacter pylori IgG** *Therapy-relevant differentiation of virulent and non-virulent strains with CagA and VacA.*	32 tests 96 tests
WE214A16	**Mycoplasma pneumoniae IgA** *Detection of acute or recent infection.*	16 tests
WE214G16	**Mycoplasma pneumoniae IgG** *Detection of acute or recent infection.*	16 tests
WE214M16	**Mycoplasma pneumoniae IgM** *Detection of acute or recent infection.*	16 tests
WE150G16 WE150G32	**Syphilis IgG** *Uses recombinant proteins.*	16 tests 32 tests
WE150M16 WE150M32	**Syphilis IgM** *Uses recombinant proteins.*	16 tests 32 tests
WE242A32 WE242A96	**Yersinia enterocolitica IgA** *Detection of reactive bands contributes towards the diagnosis of Yersinia-associated sequelae, as reactive arthritis.*	32 tests 96 tests
WE242G32 WE242G96	**Yersinia enterocolitica IgG** *Detection of reactive bands contributes towards the diagnosis of Yersinia-associated sequelae, as reactive arthritis.*	32 tests 96 tests

RAPID TEST

Rapid chromatographic immunoassays for the qualitative detection of SARS-CoV-2 Nucleocapsid (N) Protein antigens present in respiratory samples.

- Easy specimen collection
- High sensitivity and specificity
- Fast results in 15 minutes
- Intuitive visual interpretation
- CE marked

VIROLOGY

Order No.	Product Description	Format
CVAG4080A	**GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP swab)**	20 tests
CVAG4080B	**GSD NovaGen SARS-CoV-2 Ag Rapid Test (Nasal swab)**	20 tests
CVAG502H05	**GSD NovaGen SARS-CoV-2 Ag Rapid Test (Nasal swab) for self testing**	5 tests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MOLECULAR DIAGNOSTICS

NUCLEIC ACID EXTRACTION

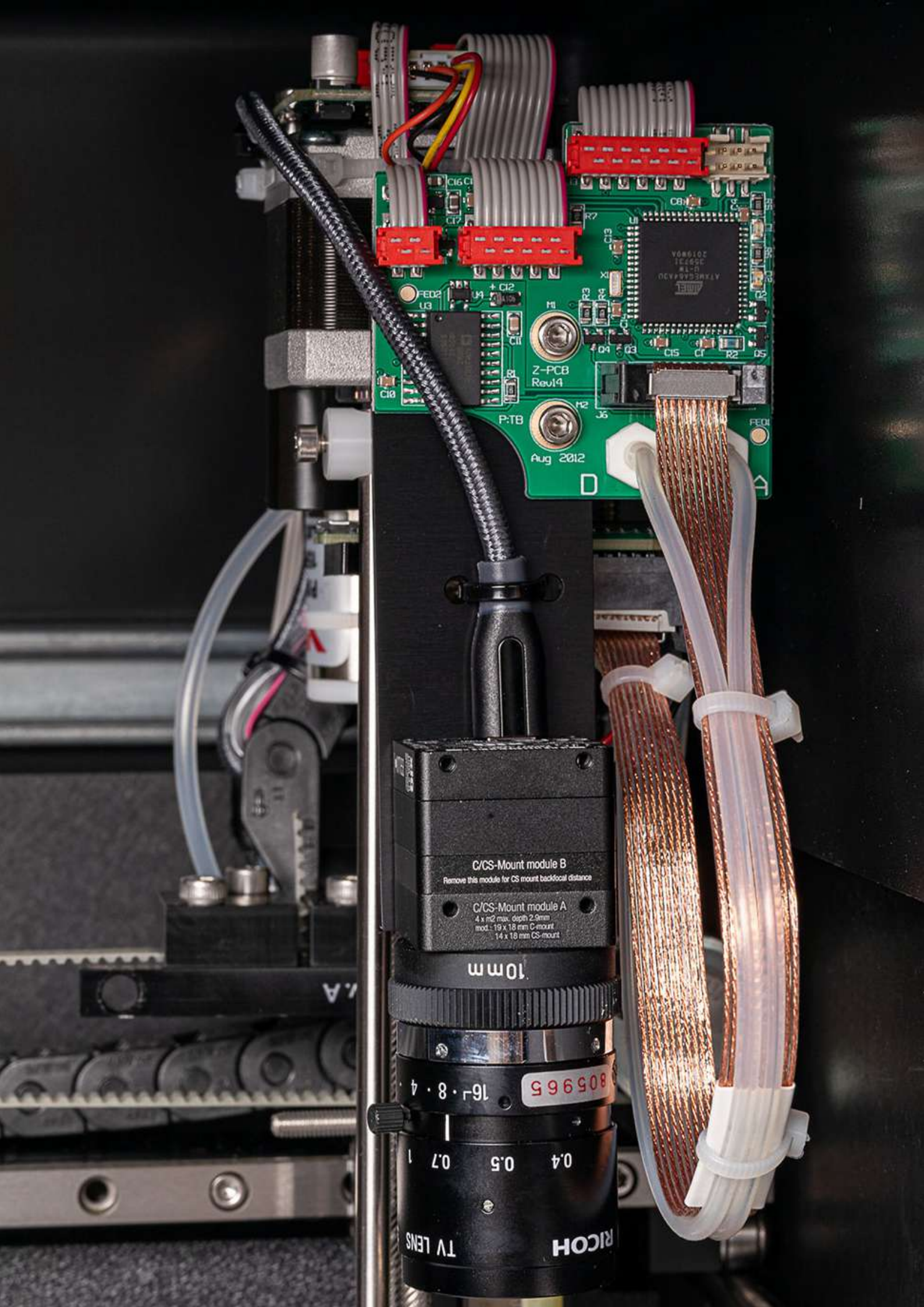
- Automated, magnetic bead extraction kits
- Efficient and reliable process which ensures the removal of potential inhibitors from sample matrices
- Perfect complement for virus detection assays

Order No.	Product Description	Format
5524401101 5524401201 55244011100	GSD NovaPrime® IVD RNA Extraction AE1	1 x 96 reactions 20 x 96 reactions 100 x 96 reactions
5524411020 5524411100	GSD NovaPrime® IVD RNA Extraction AE1 RTU	20 x 96 reactions 100 x 96 reactions
5524401301 5524401401	GSD NovaPrime® IVD RNA Extraction AE2	1 x 96 reactions 20 x 96 reactions

REAL-TIME PCR

- Fast and reliable results in approximately 1 hour
- Validated for a variety of specimen types
- Excellent performance with high sensitivity and specificity
- Suitable for most PCR platforms

Order No.	Product Description	Format
PCOV6111 PCOV6113	GSD NovaPrime® TSP SARS-CoV-2 *Contains specific primers and probes for the detection of SARS-CoV-2 genetic material and a heterologous amplification target to identify possible RT-PCR inhibition.*	1 x 96 reactions 3 x 96 reactions
PCOV6181 PCOV6184	GSD NovaType Detect + Select K417N SARS-CoV-2 (RUO) *Identifies N gene (N1/N2) and K417N mutation in one reaction.*	1 x 96 reactions 4 x 96 reactions
PCOV6191T PCOV6194T	GSD NovaType IV SARS-CoV-2 *Identifies S gene mutations K417N, E484K, and L452R.*	1 x 96 reactions 4 x 96 reactions
PRES6131 PRES6134	Mplex SARS-CoV-2+, Flu A, Flu B (C1) *Differentiates in a single reaction between Influenza A and B, and detects two SARS-CoV-2 targets (N-gene & RdRP-gene) in different channels.*	1 x 96 reactions 4 x 96 reactions
PPOX6201	Mplex Monkeypox, Orthopox (RUO) *Detects the monkeypox virus and differentiates it from other orthopox viruses.*	1 x 96 reactions
PRSV6161 PRSV6164	RSV A, RSV B *Differentiates in a single reaction between RSV A and RSV B.*	1 x 96 reactions 4 x 96 reactions


Z-PCB
Rev14
P:TB
Aug 2012
C/CS-Mount module B
Remove this module for CS mount backfocal distance
C/CS-Mount module A
4 x m2 max. depth 2.9mm
mod.: 19 x 18 mm C-mount
14 x 18 mm CS-mount
10mm
RICOH
TV LENS

INSTRUMENTATION

The Bolt™

Order No.	Product Description
00500-CL	The Bolt™ EIA/CLIA
00500	The Bolt™ EIA

Main Features

1-plate, fully automated, open platform, that can run ELISA and Chemiluminescence (CLIA) assays. This walk-away instrument offers a modular design so that it can be configured according to your laboratory's needs in a cost-effective manner.

- Shaker, incubator, and reader are configurable options
- High sample loading capacity: 96 primary sample tubes
- Capable of running different protocols in a single batch
- LIS Connectivity
- Minimal consumables
- Dimensions: W: 48.3 cm, D: 53.3 cm, H: 55.8 cm
- Weight: 27 kg

AIX1000®

Order No.	Product Description
00400	AIX1000®

Main Features

The AIX1000® is an FDA cleared, CE marked, fully automated system for nontreponemal, rapid plasma reagin (RPR) testing designed to simplify the processing, analysis, and results interpretation for RPR screens and titers. With the new universal slide-in rack system accommodating a variety of tube sizes, sample loading has become even easier and faster.

- Runs screens and titers – up to 192 samples in 90 minutes
- Full sample traceability: integrated barcode reading compatible with 1D and 2D barcodes
- Proprietary image recognition algorithm gives objective results
- Reduced labor overhead: reduced TAT and hands on
- Easy access to test results: save data and review on demand
- Improved Database Management cutting in half the time to perform backups/restore
- Remote data archiving capabilities and an expandable status log
- For use with AIX1000® RPR Reagent kit (order no. # GSD01-1600)
- Dimensions: W: 64 cm, D: 57 cm, H: 45 cm
- Weight: 30 kg

ThunderBolt®

Order No.	Product Description
00300-CL	ThunderBolt® EIA/CLIA
00300	ThunderBolt® EIA

Main Features

2-plate, fully automated, open platform, that can run ELISA and Chemiluminescence (CLIA) assays.

- Program any EIA or CLIA protocol
- High sample loading capacity: 192 primary sample tubes
- Slide-in racks with positive sample identification
- Capable of running many different protocols in a single batch
- LIS Connectivity
- On-board camera allows remote troubleshooting
- Minimal consumables
- Dimensions: W: 64 cm, D: 57 cm, H: 45 cm
- Weight: 30 kg

Dynablot

Order No.	Product Description
T/D2144-CZC-DRY	**Dynablot Automatic with camera**

Main Features

Fully automated instrument for Line Immunoblot testing.

- Automatic sample pipetting from primary tubes
- 44 samples per run
- Strip image capture by camera
- Drying of strips
- Walk-away operation
- User friendly software for easy and comprehensible operation
- Primary tubes bar code reader
- Dimensions: W: 80 cm, D: 50 cm, H: 54 cm
- Weight: 35 kg

AriaDx & AriaMx

AriaMx

AriaDx

Order No.	Product Description
K893064001	AriaDx
G8830A	AriaMx (RUO)

Main Features

Modular and precise real time PCR instruments.

- Standardized methods suitable for automated procedures
- 96 samples
- Scan all channels in less than three seconds
- Factory calibrated
- Intuitive touch screen interface
- Modular optical cartridges: 1-6 filter capability
- On board self-diagnostics
- Dimensions: W: 50 cm, D: 46 cm, H: 42 cm
- Weight: 35 kg

GSD Auto-Pure 96

Order No.	Product Description
AS-17060-00	GSD Auto-Pure 96 - Nucleic Acid Purification System

Main Features

Automatic extraction and purification system for DNA/RNA, proteins, and cells.

- Automatic, fast, and simple
- Magnetic bead separation technology
- It can process 96 x 1 ml samples simultaneously and rapidly
- 8-plate position automatic identification design
- Intelligent operation with self-inspection
- Dimensions: W: 56 cm x D: 62 cm x H: 50 cm
- Weight: 54 kg

Ordering Information

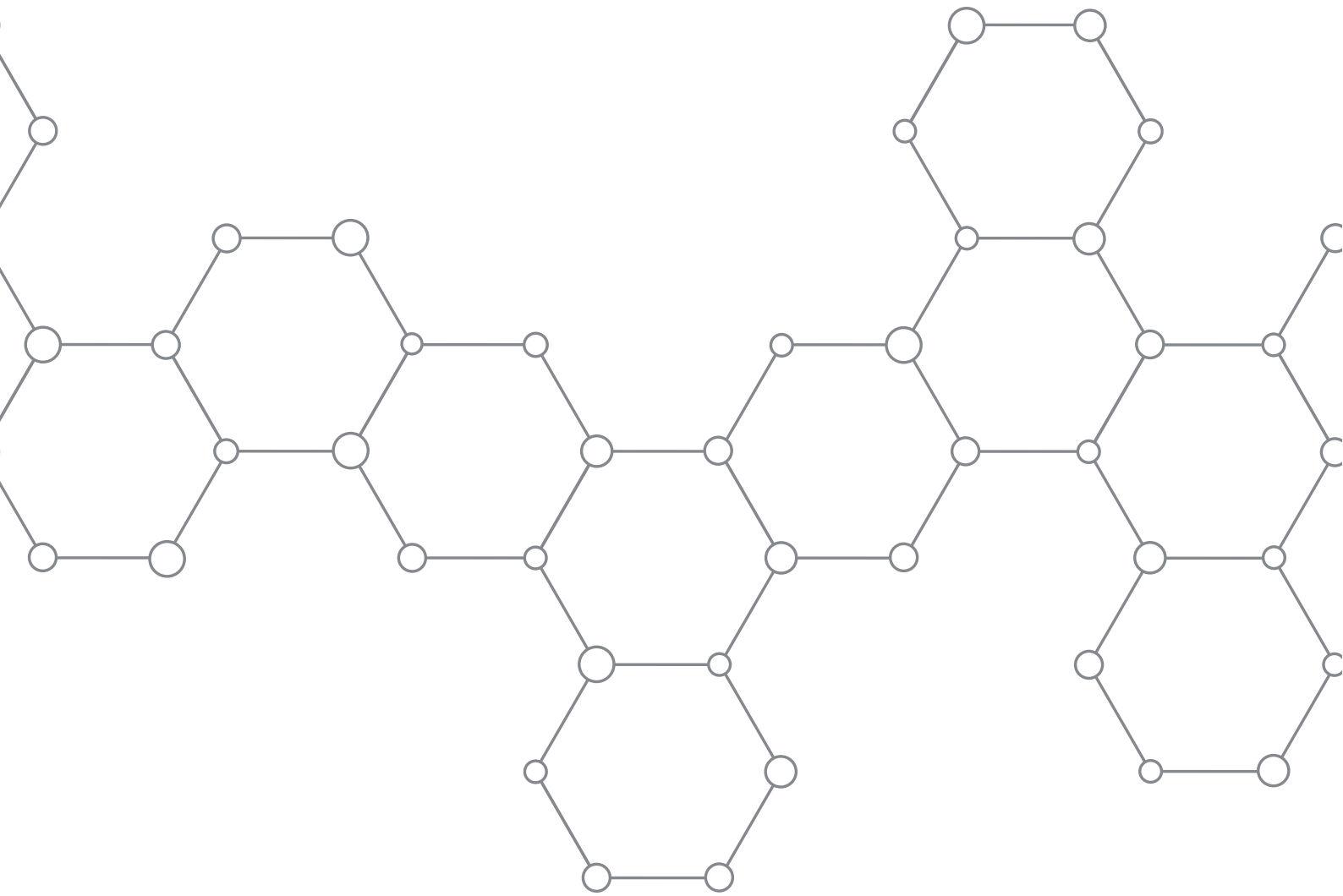
Please place your orders at order@golstandarddiagnostics.eu including the following:

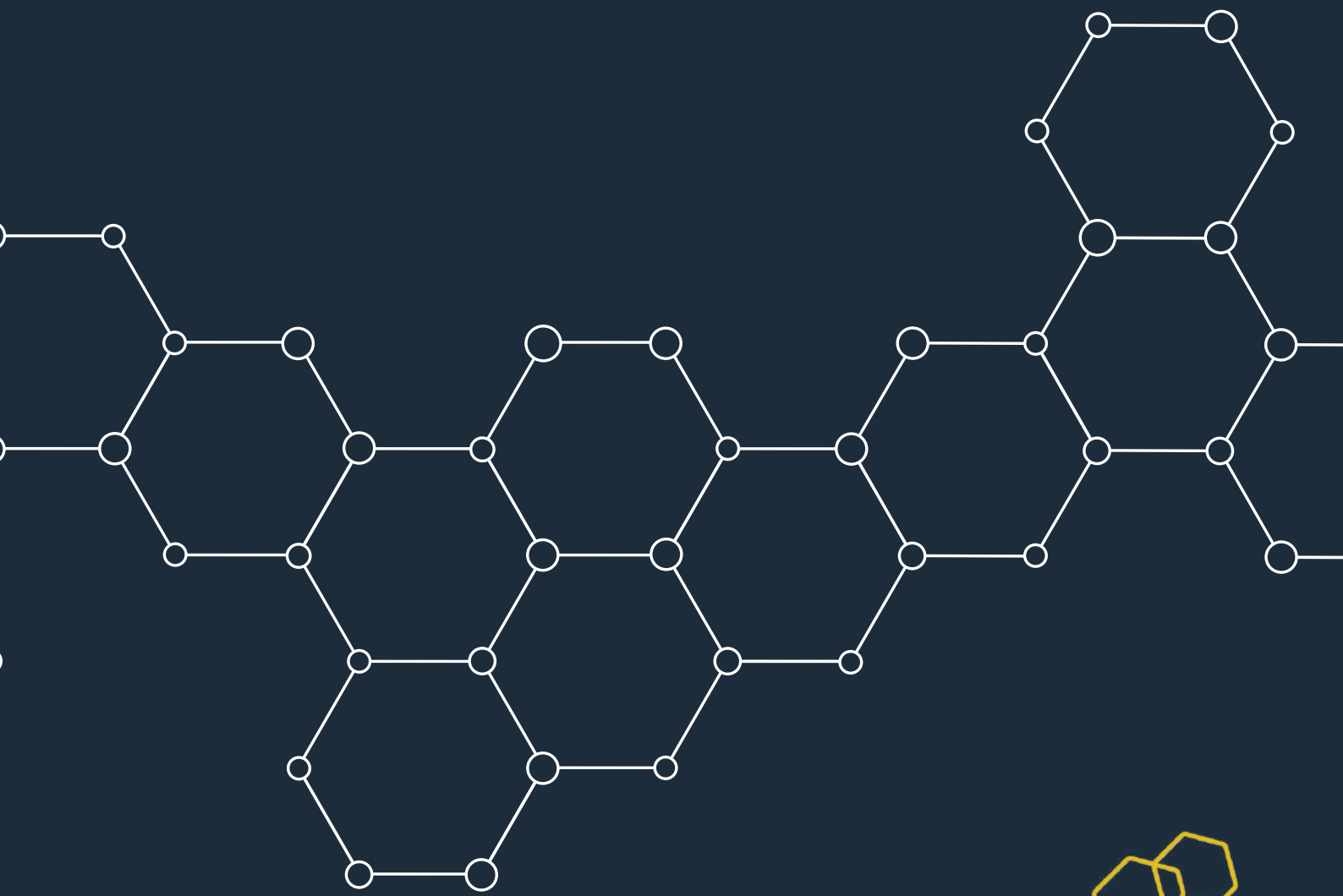
- Company's name
- VAT No. (only for EU-countries)
- Ship to and bill to address
- Purchase order number
- Article number, description, quantity, and price
- Special shipping conditions, courier account number, and expected delivery date if necessary

Orders are regulated by our General Terms and Conditions for Supply that can be consulted on www.goldstandarddiagnostics.com

Product Support

For assistance and information regarding our products and instruments, please contact productsupport@goldstandarddiagnostics.eu





GOLD STANDARD DIAGNOSTICS

Gold Standard Diagnostics Europe
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Not available in the U.S. with the exception of the AIX1000®, ThunderBolt®, and Bolt™.
Contact your local representative for more details.
GSDB007.1222-EN