AFP-ELISA

KAPD1468

DIAsource ImmunoAssays S.A. - Rue de l'Industrie, 8 - B-1400 Nivelles - Belgium

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IN VITRO DIAGNOSTIC USE

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1 INTRODUCTION

1.1 Intended Use

The **DIAsource AFP ELISA** is an enzyme immunoassay for the quantitative *in vitro diagnostic* measurement of alpha fetoprotein (AFP) in serum. This kit is not intended to be used for the risk evaluation of trisomy 21.

1.2 Summary and Explanation

Alpha-fetoprotein (AFP) is a glycoprotein with a molecular weight of approximately 70 KD(1). AFP is normally produced during fetal and neonatal development by the liver, yolk sac, and in small concentrations by the gastrointestinal tract (2). After birth, serum AFP concentrations decrease rapidly, and by the second year of life and thereafter only trace amounts are normally detected in serum (3).
Elevation of serum AFP to abnormally high values occurs in several malignant diseases (4-7), most notably nonseminomatous testicular cancer and primary hepatocelluar carcinoma. In the case of nonseminomatous testicular cancer, a direct relationship has been observed between the incidence of elevated AFP levels and the stage of disease (8-9). Elevated AFP levels have also been observed in patients diagnosed with seminoma with nonseminomatous elements, but not in patients with pure seminoma (6,8,10-11).
In addition, elevated serum AFP concentrations have been measured in patients with other noncancerous diseases, including ataxia telangiectasia, hereditary tyrosinemia, neonatal hyperbilirubinemia, acute viral hepatitis, chronic active hepatitis and cirrhosis (12-15). Elevated serum AFP concentrations are also observed in pregnant women (16-17). Therefore, AFP measurements are not recommended for use as a screening procedure to detect the presence of cancer in the general population.

2 PRINCIPLE OF THE TEST

The DIAsource AFP ELISA Kit is a solid phase enzyme-linked immunosorbent assay (ELISA) based on the sandwich principle.
The microtiter wells are coated with a monoclonal [mouse] antibody directed towards a unique antigenic site on an AFP molecule. An aliquot of patient sample containing endogenous AFP is incubated in the coated well with enzyme conjugate, which is an anti- AFP antibody conjugated with horseradish peroxidase. After incubation the unbound conjugate is washed off.
The amount of bound peroxidase is proportional to the concentration of AFP in the sample.
Having added the substrate solution, the intensity of colour developed is proportional to the concentration of AFP in the patient sample.

3 PRECAUTIONS

- This kit is for in vitro diagnostic use only.
- For information on hazardous substances included in the kit please refer to Material Safety Data Sheets.
- All reagents of this test kit which contain human serum or plasma have been tested and confirmed negative for HIV I/II, HBsAg and HCV by FDA approved procedures. All reagents, however, should be treated as potential biohazards in use and for disposal.
- Avoid contact with *Stop Solution* containing 0.5 M H_2SO_4. It may cause skin irritation and burns.
- Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.
- Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.
- Wear disposable latex gloves when handling specimens and reagents. Microbial contamination of reagents or specimens may give false results.
- Handling should be in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.
- Do not use reagents beyond expiry date as shown on the kit labels.
- All indicated volumes have to be performed according to the protocol. Optimal test results are only obtained when using calibrated pipettes and microtiterplate readers.
- Do not mix or use components from kits with different lot numbers. It is advised not to exchange wells of different plates even of the same lot. The kits may have been shipped or stored under different conditions and the binding characteristics of the plates may result slightly different.
- Chemicals and prepared or used reagents have to be treated as hazardous waste according the national biohazard safety guideline or regulation.

4 KIT COMPONENTS

4.1 Contents of the Kit

1. 12x8 (break apart) strips, 96 wells;
   Wells coated with anti-AFP antibody (monoclonal).

2. CAL | N
   N=1 to 4, 4 vials (lyophilized), 0.5 mL;
   See exact values on the vial label
   Conversion: 1IU/mL = 1,21ng/mL
   The calibrators are calibrated against NIBSC 1st International Standard for Alphafoetoprotein AFP (AFP 1st IRP 72/225)
   See „Preparation of Reagents";
   * contain 0.03% Proclin 300, 0.015% BND and 0.010% MIT as a preservative.

3. CAL | 0
   Zero Calibrator, 1 vial (lyophilized), 0.5 ml
   * contain 0.03% Proclin 300, 0.015% BND and 0.010% MIT as a preservative.
   See „Preparation of Reagents"

4. Ab | HRP
   (Enzyme conjugate) 1 vial, 11 mL, ready to use,
   Anti-AFP antibody conjugated to horseradish peroxidase;
   contains 0.03% Proclin 300 as a preservative.

5. CHROM | TMB
   (Substrate solution) 1 vial, 14 mL, ready to use,
   Tetramethylbenzidine (TMB).

6. STOP | SOLN
   (Stop solution) 1 vial, 14 mL, ready to use,
   contains 0.5M H_2SO_4,
   Avoid contact with the stop solution. It may cause skin irritations and burns.

* BND = 5-bromo-5-nitro-1,3-dioxane
MIT = 2-methyl-2H-isothiazol-3-one

Note: Additional *Calibrator 0* for sample dilution is available upon request.

4.1.1 Equipment and material required but not provided

- A microtiter plate calibrated reader (450 ± 10 nm)
- Calibrated variable precision micropipettes.
- Absorbent paper.
- Bidistilled water

4.2 Storage and stability of the Kit

When stored at 2-8°C unopened reagents will retain reactivity until expiration date. Do not use reagents beyond this date.
Opened reagents must be stored at 2-8°C. Microtiter wells must be stored at 2-8°C. Once the foil bag has been opened, care should be taken to close it tightly again.
Opened kits retain activity for six weeks if stored as described above.

4.3 Preparation of Reagents

Allow all reagents and required number of strips to reach room temperature prior to use.

Calibrators
Reconstitute the lyophilized contents of the calibrator vial with 0.5 mL bidistilled water!
Note: *The reconstituted calibrators are stable for 2 months at 2-8°C. For longer storage freeze at -20°C.*

4.4 Disposal of the Kit

The disposal of the kit must be made according to the national regulations. Special information for this product is given in the Material Safety Data Sheets.

4.5 Damaged Test Kits

In case of any severe damage of the test kit or components, DIAsource ImmunoAssays S.A. have to be informed written, latest one week after receiving the kit. Severely damaged single components should not be used for a test run. They have to be stored until a final solution has been found. After this, they should be disposed according to the official regulations.

5 SPECIMEN

Serum should be used in this assay.
Do not use haemolytic, icteric or lipaemic specimens.
NOTE: Samples containing sodium azide should not be used in the assay.

NOTE: If an amniocentesis is necessary the specimen collection has to done before the puncture. After the amniotic puncture increased AFP values are determined.

5.1 Specimen Collection

Serum:
Collect blood by venipuncture (e.g. Sarstedt Monovette # 02.1388.001), allow to clot, and separate serum by centrifugation at room temperature. Do not centrifuge before complete clotting has occurred. Patients receiving anticoagulant therapy may require increased clotting time.

5.2 Specimen Storage

Specimens should be capped and may be stored for up to 5 days at 2-8°C prior to assaying.
Specimens held for a longer time should be frozen only once at -20°C prior to assay. Thawed samples should be inverted several times prior to testing.

5.3 Specimen Dilution

If in an initial assay, a specimen is found to contain more than the highest calibrator, the specimens can be diluted with *Calibrator 0* and reassayed as described in Assay Procedure.
For the calculation of the concentrations this dilution factor has to be taken into account.
Example:
a) dilution 1:10: 10 µL Serum + 90 µL *Calibrator 0* (mix thoroughly)
b) dilution 1:100: 10 µL dilution a) 1:10 + 90 µL *Calibrator 0* (mix thoroughly).

6 TEST PROCEDURE

6.1 General Remarks

- All reagents and specimens must be allowed to come to room temperature before use. All reagents must be mixed without foaming.
- Once the test has been started, all steps should be completed without interruption.
- Use new disposal plastic pipette tips for each calibrator, control or sample in order to avoid cross contamination
- Absorbance is a function of the incubation time and temperature. Before starting the assay, it is recommended that all reagents are ready, caps removed, all needed wells secured in holder, etc. This will ensure equal elapsed time for each pipetting step without interruption.
- As a general rule the enzymatic reaction is linearly proportional to time and temperature.

6.2 Assay Procedure

Each run must include a calibration curve.

1. Secure the desired number of Microtiter wells in the frame holder.
2. Dispense **25 µL** of each ***Calibrator, Control*** and **samples** with new disposable tips into appropriate wells.
3. Dispense **100 µL** ***Enzyme Conjugate*** into each well.
   Thoroughly mix for 10 seconds. It is important to have a complete mixing in this step.
4. Incubate for **30 minutes** at room temperature.
5. Briskly shake out the contents of the wells.
   Rinse the wells 5 times with distilled water (400 µL per well). Strike the wells sharply on absorbent paper to remove residual droplets.
   Important note:
   The sensitivity and precision of this assay is markedly influenced by the correct performance of the washing procedure!
6. Add **100 µL** of ***Substrate Solution*** to each well.
7. Incubate for **10 minutes** at room temperature.
8. Stop the enzymatic reaction by adding **50 µL** of ***Stop Solution*** to each well.
9. Determine the absorbance (OD) of each well at **450±10 nm** with a microtiter plate reader.
   It is recommended that the wells be read **within 10 minutes** after adding the *Stop Solution*.

6.3 Calculation of Results

1. Calculate the average absorbance values for each set of calibrators, controls and patient samples.
2. Construct a calibration curve by plotting the mean absorbance obtained from each calibrator against its concentration with absorbance value on the vertical(Y) axis and concentration on the horizontal (X) axis.
3. Using the mean absorbance value for each sample determine the corresponding concentration from the calibration curve.
4. Automated method: The results in the IFU have been calculated automatically using a 4 PL (4 Parameter Logistics) curve fit. 4 Parameter Logistics is the preferred method. Other data reduction functions may give slightly different results.
5. The concentration of the samples can be read directly from this calibration curve. Samples with concentrations higher than that of the highest calibrator have to be further diluted. For the calculation of the concentrations this dilution factor has to be taken into account.

6.3.1 Example of Typical Calibration curve

The following data is for demonstration only and cannot be used in place of data generations at the time of assay.

Calibrator	Optical Units (450 nm)
Calibrator 0 (0 IU/mL)	0.07
Calibrator 1 (10 IU/mL)	0.21
Calibrator 2 (40 IU/mL)	0.69
Calibrator 3 (80 IU/mL)	1.29
Calibrator 4 (160 IU/mL)	1.97

7 EXPECTED VALUES

It is strongly recommended that each laboratory should determine its own normal and abnormal values.

In a study conducted using the DIAsource AFP ELISA the following values are observed:

7.1 Normal healthy adults, non-pregnant

The lower limit of AFP concentration in normal serum is less than 1 IU/mL; the upper limit is about 10 IU/mL.

7.2 Values during pregnancy

Weeks of pregnancy	AFP [IU/mL]
10	9 - 24
11	10 - 27
12	10 - 30
13	10 - 34
14	11 - 45
15	14 - 60
16	16 - 69
17	17 - 78
18	22 - 93

Weeks of pregnancy	AFP [IU/mL]
19	32 - 103
20	42 - 121
21	48 - 139
22 - 24	56 - 224
25 - 27	95 - 357
28 - 30	135 - 435
31 - 33	141 - 423
34 - 36	121 - 380
37 - 40	93 - 321

CLINICAL IMPORTANCE

1. Maternal serum containing AFP above 2.5 times the normal median for weeks 16 to 18 of pregnancy was detected in 88% of cases of anencephaly and in 79% of cases of open spina bifida.
2. The concentration of AFP in hepatocellular carcinoma and germ cell tumor varies from the normal range up to several million IU/ml. After surgical resection, the serum AFP may drop to normal range or somewhat above it.
3. AFP may occur in serum of patients with diseases other than hepatocarcinoma or embryonal carcinoma of the testes, such as neonatal hepatitis and nonhepatic neoplasms.

8 QUALITY CONTROL

Good laboratory practice requires that controls be run with each calibration curve. A statistically significant number of controls should be assayed to establish mean values and acceptable ranges to assure proper performance.
It is recommended to use control samples according to state and federal regulations. The use of control samples is advised to assure the day to day validity of results. Use controls at both normal and pathological levels.
The controls and the corresponding results of the QC-Laboratory are stated in the QC certificate added to the kit. The values and ranges stated on the QC sheet always refer to the current kit lot and should be used for direct comparison of the results.
It is also recommended to make use of national or international Quality Assessment programs in order to ensure the accuracy of the results.
Employ appropriate statistical methods for analysing control values and trends. If the results of the assay do not fit to the established acceptable ranges of control materials patient results should be considered invalid.
In this case, please check the following technical areas: Pipetting and timing devices; photometer, expiration dates of reagents, storage and incubation conditions, aspiration and washing methods.

9 ASSAY CHARACTERISTICS

9.1 Assay Dynamic Range

The range of the assay is between 1.78 – 160 IU/mL.

9.2 Specificity of Antibodies (Cross Reactivity)

The following substances were tested for cross reactivity of the assay:

Protein		Produced Color Intensity Equivalent to AFP in serum (IU/mL)
HSA	20 mg/ml	2
Prolaktin	200 ng/ml	2
hCG	2000 ng/ml	2
SP- 1	2000 ng/ml	2
hPL	2011 µg/ml	2

9.3 Analytical Sensitivity

The analytical sensitivity was calculated from the mean plus two standard deviations of twenty (20) replicate analyses of *Calibrator 0* and was found to be 1.78 IU/mL.

9.4 Precision

9.4.1 Intra Assay Variation

The within assay variability is shown below:

Sample	n	Mean (IU/mL)	CV (%)
1	20	25.63	3.82
2	20	105.78	5.39
3	20	77.63	3.50

9.4.2 Inter Assay Variation

The inter assay variability (between run is shown below:

Sample	n	Mean (IU/mL)	CV (%)
1	16	25.31	3.64
2	16	109.34	6.54
3	16	84.10	6.74

9.5 Recovery

Recovery of the DIAsource ELISA was determined by adding increasing amounts of the analyte to three sera of pregnant women. The percentage recoveries were determined by comparing expected and measured values of the samples.

		Sample 1	Sample 2	Sample 3
Concentration [IU/mL]		30.86	115.20	69.02
Average Recovery		92.9	94.0	99.1
Range of Recovery [%]	from	86.7	93.4	92.6
	to	99.5	94.7	106.5

9.6 Linearity

Three samples (serum) containing different amounts of analyt were serially diluted (up to 1:16) with zero calibrator and assayed with the DIAsource ELISA. The percentage recovery was calculated by comparing the expected and measured values for the analyt.

		Sample 1	Sample 2	Sample 3
Concentration [IU/mL]		39.7	75.6	128.4
Average Recovery		102.0	95.5	96.8
Range of Recovery [%]	from	90.9	86.2	92.9
	to	115.0	109.3	101.3

10 LIMITATIONS OF USE

10.1 Interfering Substances

Any improper handling of samples or modification of this test might influence the results.
Haemoglobin (up to 4 mg/mL), Bilirubin (up to 0.5 mg/mL) and Triglyceride (up to 30 mg/mL) have no influence on the assay results.

10.2 Drug Interferences

Until today no substances (drugs) are known to us, which have an influence to the measurement of AFP in a sample.

10.3 High-Dose-Hook Effect

No hook effect was observed in this test up to 1600 IU/mL of AFP.

11 LEGAL ASPECTS

11.1 Reliability of Results

The test must be performed exactly as per the manufacturer's instructions for use. Moreover the user must strictly adhere to the rules of GLP (Good Laboratory Practice) or other applicable national standards and/or laws. This is especially relevant for the use of control reagents. It is important to always include, within the test procedure, a sufficient number of controls for validating the accuracy and precision of the test.
The test results are valid only if all controls are within the specified ranges and if all other test parameters are also within the given assay specifications. In case of any doubt or concern please contact DIAsource.

11.2 Therapeutic Consequences

Therapeutic consequences should never be based on laboratory results alone even if all test results are in agreement with the items as stated under point 11.1. Any laboratory result is only a part of the total clinical picture of a patient.
Only in cases where the laboratory results are in acceptable agreement with the overall clinical picture of the patient should therapeutic consequences be derived.
The test result itself should never be the sole determinant for deriving any therapeutic consequences.

11.3 Liability

Any modification of the test kit and/or exchange or mixture of any components of different lots from one test kit to another could negatively affect the intended results and validity of the overall test. Such modification and/or exchanges invalidate any claim for replacement.
Claims submitted due to customer misinterpretation of laboratory results subject to point 11.2. are also invalid. Regardless, in the event of any claim, the manufacturer's liability is not to exceed the value of the test kit. Any damage caused to the test kit during transportation is not subject to the liability of the manufacturer.

12 REFERENCES

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	Used symbols	**Symboles utilisés**
	Consult instructions for use	Consulter les instructions d'utilisation
	Storage temperature	Température de conservation
	Use by	Utiliser jusque
LOT	Batch code	Numéro de lot
REF	Catalogue number	Référence de catalogue
CONTROL	Control	Contrôle
IVD	In vitro diagnostic medical device	Dispositif médical de diagnostic in vitro
	Manufacturer	Fabricant
	Contains sufficient for <n> tests	Contenu suffisant pour <n> tests
WASH SOLN CONC	Wash solution concentrated	Solution de lavage concentrée
CAL 0	Zero calibrator	Calibrateur zéro
CAL N	Calibrator #	Calibrateur #
CONTROL N	Control #	Contrôle #
Ag 125I	Tracer	Traceur
Ab 125I	Tracer	Traceur
Ag 125I CONC	Tracer concentrated	Traceur concentré
Ab 125I CONC	Tracer concentrated	Traceur concentré
	Tubes	Tubes
INC BUF	Incubation buffer	Tampon d'incubation
ACETONITRILE	Acetonitrile	Acétonitrile
SERUM	Serum	Sérum
DIL SPE	Specimen diluent	Diluant du spécimen
DIL BUF	Dilution buffer	Tampon de dilution
ANTISERUM	Antiserum	Antisérum
IMMUNOADSORBENT	Immunoadsorbent	Immunoadsorbant
DIL CAL	Calibrator diluent	Diluant de calibrateur
REC SOLN	Reconstitution solution	Solution de reconstitution
PEG	Polyethylene glycol	Glycol Polyéthylène
EXTR SOLN	Extraction solution	Solution d'extraction
ELU SOLN	Elution solution	Solution d'elution
GEL	Bond Elut Silica cartridges	Cartouches Bond Elut Silica
PRE SOLN	Pre-treatment solution	Solution de pré-traitement
NEUTR SOLN	Neutralization solution	Solution de neutralisation
TRACEUR BUF	Tracer buffer	Tampon traceur
	Microtiterplate	Microplaque de titration
Ab HRP	HRP Conjugate	HRP Conjugué
Ag HRP	HRP Conjugate	HRP Conjugué
Ab HRP CONC	HRP Conjugate concentrate	HRP Conjugué concentré
Ag HRP CONC	HRP Conjugate concentrate	HRP Conjugué concentré
CONJ BUF	Conjugate buffer	Tampon conjugué
CHROM TMB CONC	Chromogenic TMB concentrate	Chromogène TMB concentré
CHROM TMB	Chromogenic TMB solution	Solution chromogène TMB
SUB BUF	Substrate buffer	Tampon substrat
STOP SOLN	Stop solution	Solution d'arrêt
INC SER	Incubation serum	Sérum d'incubation
BUF	Buffer	Tampon
Ab AP	AP Conjugate	AP Conjugué
SUB PNPP	Substrate PNPP	Tampon PNPP
BIOT CONJ CONC	Biotin conjugate concentrate	Biotine conjugué concentré
AVID HRP CONC	Avidine HRP concentrate	Avidine HRP concentré
ASS BUF	Assay buffer	Tampon de test
Ab BIOT	Biotin conjugate	Biotine conjugué
Ab	Specific Antibody	Anticorps spécifique
SAV HRP CONC	Streptavidin HRP concentrate	Concentré streptavidine HRP
NSB	Non-specific binding	Liant non spécifique
2nd Ab	2nd Antibody	Second anticorps
ACID BUF	Acidification Buffer	Tampon d'acidification

	Gebruikte symbolen	**Gebrauchte Symbolen**
	Raadpleeg de gebruiksaanwijzing	Gebrauchsanweisung beachten
	Bewaartemperatuur	Lagern bei
	Houdbaar tot	Verwendbar bis
LOT	Lotnummer	Chargenbezeichnung
REF	Catalogusnummer	Bestellnummer
CONTROL	Controle	Kontrolle
IVD	Medisch hulpmiddel voor in-vitro diagnostiek	In Vitro Diagnostikum
	Fabrikant	Hersteller
	Inhoud voldoende voor <n> testen	Ausreichend für <n> Ansätze
WASH SOLN CONC	Wasoplossing, geconcentreerd	Waschlösung-Konzentrat
CAL 0	Nulkalibrator	Null kalibrator
CAL N	Kalibrator #	Kalibrator #
CONTROL N	Controle #	Kontrolle #
Ag 125I	Tracer	Tracer
Ab 125I	Tracer	Tracer
Ag 125I CONC	Tracer geconcentreerd	Tracer Konzentrat
Ab 125I CONC	Tracer geconcentreerd	Tracer Konzentrat
	Buisjes	Röhrchen
INC BUF	Incubatiebuffer	Inkubationspuffer
ACETONITRILE	Acetonitrile	Azetonitril
SERUM	Serum	Humanserum
DIL SPE	Specimen diluent	Probenverdünner
DIL BUF	Verdunningsbuffer	Verdünnungspuffer
ANTISERUM	Antiserum	Antiserum
IMMUNOADSORBENT	Immunoadsorbent	Immunadsorbens
DIL CAL	Kalibratorverdunner	Kalibratorverdünnung
REC SOLN	Reconstitutieoplossing	Rekonstitutionslösung
PEG	Polyethyleen glycol	Polyethylenglykol
EXTR SOLN	Extractieoplossing	Extraktionslösung
ELU SOLN	Elutieoplossing	Eluierungslösung
GEL	Bond Elut Silica kolom	Bond Elut Silikakartuschen
PRE SOLN	Pre-behandelingsoplossing	Vorbehandlungslösung
NEUTR SOLN	Neutralisatieoplossing	Neutralisierungslösung
TRACEUR BUF	Tracerbuffer	Tracer-Puffer
	Microtiterplaat	Mikrotiterplatte
Ab HRP	HRP Conjugaat	HRP Konjugat
Ag HRP	HRP Conjugaat	HRP Konjugat
Ab HRP CONC	HRP Conjugaat geconcentreerd	HRP Konjugat Konzentrat
Ag HRP CONC	HRP Conjugaat geconcentreerd	HRP Konjugat Konzentrat
CONJ BUF	Conjugaat buffer	Konjugatpuffer
CHROM TMB CONC	Chromogene TMB geconcentreerd	Chromogenes TMB Konzentrat
CHROM TMB	Chromogene Oplossing TMB	Farblösung TMB
SUB BUF	Substraatbuffer	Substratpuffer
STOP SOLN	Stopoplossing	Stopplösung
INC SER	Incubatieserum	Inkubationsserum
BUF	Buffer	Puffer
Ab AP	AP Conjugaat	AP Konjugat
SUB PNPP	Substraat PNPP	Substrat PNPP
BIOT CONJ CONC	Geconcentreerd Biotine conjugaat	Biotin-Konjugat-Konzentrat
AVID HRP CONC	Geconcentreerd Avidine-HRP conjugaat	Avidin-HRP-Konzentrat
ASS BUF	Assay buffer	Assaypuffer
Ab BIOT	Biotine conjugaat	Biotin-Konjugat
Ab	Specifiek antilichaam	Spezifischer Antikörper
SAV HRP CONC	Streptavidine-HRP concentraat	HRP Streptavidinkonzentrat
NSB	Aspecifieke binding	Unspezifische Bindung
2nd Ab	2de antilichaam	Sekundärer Antikörper
ACID BUF	Verzuringsbuffer	Ansäuerungspuffer

	Simboli utilizzati	**Símbolos utilisados**
	Consultare le istruzioni per l'uso	Consultar las instrucciones de uso
	Limitazioni di temperatura	Limitación de temperatura
	Utilizzare entro	Fecha de caducidad
LOT	Numero di lotto	Codigo de lote
REF	Numero di catalogo	Número de catálogo
CONTROL	Controllo	Control
IVD	Dispositivo medico-diagnostico in vitro	Producto sanitario para diagnóstico in vitro
	Fabbricante	Fabricante
	Contenuto sufficiente per <n> saggi	Contenido suficiente para <n> ensayos
WASH SOLN CONC	Tampone di lavaggio concentrato	Solución de lavado concentrada
CAL 0	Calibratore zero	Calibrador cero
CAL N	Standard #	Calibrador #
CONTROL N	Controllo #	Control #
Ag 125I	Marcato	Trazador
Ab 125I	Marcato	Trazador
Ag 125I CONC	Marcato concentrato	Trazador concentrada
Ab 125I CONC	Marcato concentrato	Trazador concentrada
	Provette	Tubos
INC BUF	Tampone incubazione	Tampón de incubación
ACETONITRILE	Acetonitrile	Acetonitrilo
SERUM	Siero	Suero
DIL SPE	Diluente campione	Diluyente de Muestra
DIL BUF	Tampone diluizione	Tampón de dilución
ANTISERUM	Antisiero	Antisuero
IMMUNOADSORBENT	Immunoassorbente	Inmunoadsorbente
DIL CAL	Diluente calibratore	Diluyente de calibrador
REC SOLN	Soluzione di ricostituzione	Solución de Reconstitución
PEG	Polietilenglicole	Glicol Polietileno
EXTR SOLN	Soluzione di estrazione	Solución de extracción
ELU SOLN	Soluzione di eluizione	Solución de elución
GEL	Cartucce di silice bond elut	Cartuchos Bond Elut Silica
PRE SOLN	Soluzione di pretrattamento	Solución de Pre-tratamiento
NEUTR SOLN	Soluzione di neutralizzazione	Solución de Neutralización
TRACEUR BUF	Tracer Buffer	Tampón de trazador
	Piastra di microtitolazione	Placa de microvaloración
Ab HRP	HRP Coniugato	HRP Conjugado
Ag HRP	HRP Coniugato	HRP Conjugado
Ab HRP CONC	HRP Coniugato concentrato	HRP Conjugado concentrada
Ag HRP CONC	HRP Coniugato concentrato	HRP Conjugado concentrada
CONJ BUF	Buffer coniugato	Tampón de Conjugado
CHROM TMB CONC	Cromogena TMB concentrato	Cromógena TMB concentrada
CHROM TMB	Soluzione cromogena TMB	Solución Cromógena TMB
SUB BUF	Tampone substrato	Tampón de sustrato
STOP SOLN	Soluzione di arresto	Solución de Parada
INC SER	Incubazione con siero	Suero de Incubación
BUF	Buffer	Tampón
Ab AP	AP Coniugato	AP Conjugado
SUB PNPP	Substrato PNPP	Sustrato PNPP
BIOT CONJ CONC	Concentrato coniugato con biotina	Concentrado de conjugado de biotina
AVID HRP CONC	Concentrato avidina HRP	Concentrado avidina-HRP
ASS BUF	Soluzione tampone per test	Tampón de ensayo
Ab BIOT	Coniugato con biotina	Conjugado de biotina
Ab	Anticorpo Specifico	Anticuerpo específico
SAV HRP CONC	Streptavidina-HRP concentrata	Estreptavidina-HRP Concentrado
NSB	Legame non-specifico	Unión no específica
2nd Ab	2° Anticorpo	Segundo anticuerpo
ACID BUF	Tampone Acidificante	Tampón de Acidificación

	Símbolos utilizados	**Använda symboler**
	Consulte instruções de utilização	Läs instruktionerna före användning
	Temperatura de conservação	Förvaringstemperatur
	Utilizar antes de	Används av
LOT	Código de lote	Lotnummer
REF	Número de catálogo	Katalognummer
CONTROL	Controlo	Kontroll
IVD	Dispositivo médico de diagnóstico in vitro	In vitro diagnostiskt kit
	Fabricante	Tillverkare
	Conteúdo suficiente para <n> testes	Innehållet räcker till <n> prover
WASH SOLN CONC	Solução de lavagem concentrada	Tvättlösning, koncentrerad
CAL 0	Calibrador zero	Nollkalibrerare
CAL N	Calibrador #	Kalibrator #
CONTROL N	Controlo #	Kontroll #
Ag 125I	Marcador	Radioisotop, antigen
Ab 125I	Marcador	Radioisotop, antikropp
Ag 125I CONC	Marcador concentrada	Radioisotop, antigen koncentrerad
Ab 125I CONC	Marcador concentrada	Radioisotop, antikropp koncentrerad
	Tubos	Rör
INC BUF	Tampão de incubação	Inkuberingsbuffert
ACETONITRILE	Acetonitrilo	Acetonitril
SERUM	Soro	Serum
DIL SPE	Diluidor de espécimes	Spädningsbuffert för prover
DIL BUF	Tampão de diluição	Spädningsbuffert
ANTISERUM	Anti-soro	Antiserum
IMMUNOADSORBENT	Imunoadsorvente	Immunoadsorberare
DIL CAL	Diluente do calibrador	Kalibratordiluent
REC SOLN	Solução de Reconstituição	Rekonstitutionslösning
PEG	Polietileno-glicol	Polyetylenglykol
EXTR SOLN	Solução de Extracção	Extraktionslösning
ELU SOLN	Solução de Eluição	Elueringslösning
GEL	Cartuchos de silica Bond Elut	Silikonpatroner för elueringsbindning
PRE SOLN	Solução de pré-tratamento	Förbehandlingslösning
NEUTR SOLN	Solução de neutralização	Neutraliseringslösning
TRACEUR BUF	Tampão Marcador	Tracerbuffert
	Placa de micro titulação	Microtiterplatta
Ab HRP	HRP Conjugação	HRP-konjugat
Ag HRP	HRP Conjugação	HRP-konjugat
Ab HRP CONC	HRP Conjugação concentrada	HRP-konjugat-koncentrat
Ag HRP CONC	HRP Conjugação concentrada	HRP-konjugat-koncentrat
CONJ BUF	Conjugue o tampão	Konjugatbuffert
CHROM TMB CONC	Cromogénica TMB concentrada	Kromogeniskt TMB-koncentrat
CHROM TMB	Solução Cromogénica TMB	Kromogenisk TMB-lösning
SUB BUF	Tampão de substrato	Substratbuffert
STOP SOLN	Solução de Paragem	Stoplösning
INC SER	Soro de incubação	Inkubationsserum
BUF	Tampão	Buffert
Ab AP	AP Conjugação	AP-konjugat
SUB PNPP	Substrato PNPP	Substrat-PNPP
BIOT CONJ CONC	Concentrado conjugado de biotina	Biotinkonjugat koncentrat
AVID HRP CONC	Concentrado HRP de avidina	Avidin HRP-koncentrat
ASS BUF	Tampão de ensaio	Provbuffert
Ab BIOT	Conjugado de biotina	Biotinkonjugat
Ab	Anticorpo específico	-
SAV HRP CONC	Estreptavidina HRP concentrado	-
NSB	Ligações não especificas	-
2nd Ab	Anticorpo secundário	-
ACID BUF	Tampão de acidificação	-

	Επεξήγηση συμβόλων	**Anvendte symboler**
	Συμβουλευτείτε τις οδηγίες χρήσης	Læs brugsvejledningen
	Θερμοκρασία αποθήκευσης	Opbevaringstemperatur
	Ημερομηνία λήξης	Anvend inden
LOT	Αριθμός παρτίδας	Batchkode
REF	Αριθμός καταλόγου	Katalognummer
CONTROL	Πρότυπο ελέγχου	Kontrol
IVD	In Vitro Διαγνωστικό Ιατροτεχνολιγικό προιόν	Medicinsk udstyr til in vitro-diagnosticering
	Κατασκευαστής	Fabrikant
	Περιεχόμενο επαρκές για «ν» εξετάσεις	Indeholder nok til <n> test
WASH SOLN CONC	Συμπυκνωμένο διάλυμα έκπλυσης	Koncentreret vaskeopløsning
CAL 0	Μηδενικός βαθμονομητής	Nul-kalibrator
CAL N	Βαθμονομητής #	Kalibrator nr.
CONTROL N	Ορός ελέγχου #	Kontrol nr.
Ag 125I	Ιχνηθέτης	Markør
Ab 125I	Ιχνηθέτης	Markør
Ag 125I CONC	Χρωμογόνος Ιχνηθέτης	Koncentreret markør
Ab 125I CONC	Χρωμογόνος Ιχνηθέτης	Koncentreret markør
	Σωληνάρια	Tuber
INC BUF	Ρυθμιστικό διάλυμα επώασης	Inkubationsbuffer
ACETONITRILE	Ακετονιτρίλιο	Acetonitril
SERUM	Ορός	Serum
DIL SPE	Διάλυμα αραίωσης δειγμάτων	Prøvediluent
DIL BUF	Ρυθμιστικό διάλυμα αραίωσης	Fortyndingsbuffer
ANTISERUM	Αντιορός	Antiserum
IMMUNOADSORBENT	Ανοσοπροσροφητικό	Immonoadsorbent
DIL CAL	Αραιωτικό βαθμονομητών	Kalibratordiluent
REC SOLN	Διάλυμα ανασύστασης	Rekonstitueringsopløsning
PEG	Πολυαιθυλενογλυκόλη	Polyetylenglykol
EXTR SOLN	Διάλυμα εκχύλισης	Ekstraktionsopløsning
ELU SOLN	Διάλυμα έκλουσης	Elueringsopløsning
GEL	Φύσιγγες πυριτίου Bond Elut	Patroner med bindingselueringssilica
PRE SOLN	Διάλυμα προεπεξεργασίας	Forbehandlingsopløsning
NEUTR SOLN	Διάλυμα εξουδετέρωσης	Neutraliseringsopløsning
TRACEUR BUF	Ρυθμιστικό διάλυμα	Markørbuffer
	Πλάκα μικροτιτλοδότησης	Mikrotiterplade
Ab HRP	HRP Σύζευγμα	HRP-konjugat
Ag HRP	HRP Σύζευγμα	HRP-konjugat
Ab HRP CONC	Χρωμογόνος HRP Σύζευγμα	HRP-konjugat-koncentreret
Ag HRP CONC	Χρωμογόνος HRP Σύζευγμα	HRP-konjugat-koncentreret
CONJ BUF	Ρυθμιστικό διάλυμα συζεύγματος	Konjugatbuffer
CHROM TMB CONC	Χρωμογόνος TMB	Kromogen TMB-koncentreret
CHROM TMB	Διάλυμα χρωμογόνου TMB	Kromogen TMB-opløsning
SUB BUF	Ρυθμιστικό διάλυμα υποστρώματος	Substratbuffer
STOP SOLN	Ανασχετικό αντιδραστήριο	Stopopløsning
INC SER	Ορός επώασης	Inkubationsserum
BUF	Ρυθμιστικό διάλυμα	Buffer
Ab AP	AP Σύζευγμα	AP-konjugat
SUB PNPP	PNPP υποστρώματος	Substrat PNPP
BIOT CONJ CONC	Συμπυκνωμένο αντιδραστήριο συζευγμένο με βιοτίνη	Biotin konjugat koncentrat
AVID HRP CONC	Συμπυκνωμένο διάλυμα αβιδίνης-HRP	Avidin HRP koncentrat
ASS BUF	Ρυθμιστικό διάλυμα προσδιορισμού	Prøvebuffer
Ab BIOT	αντιδραστήριο συζευγμένο με βιοτίνη	Biotin konjugat
Ab	Ειδικό Αντίσωμα	-
SAV HRP CONC	Συμπυκνωμένη στρεπταβιδίνη συνεξευγμένη με HRP	-
NSB	μη-ειδική δέσμευση	-
2nd Ab	2ο Αντίσωμα	-
ACID BUF	Ρυθμιστικό Διάλυμα όξινο	-

	Stosowane symbole	**Használt szimbólumok**
	Przed zastosowaniem zapoznać się z instrukcją	Olvassa el a használati útmutatót
	Temperatura przechowywania	Tárolási hőmérséklet
	Zużyć przed	Lejárati idő
LOT	Kod serii	Gyártási kód
REF	Numer katalogowy	Katalógus szám
CONTROL	Kontrola	Kontrol
IVD	Urządzenie medyczne do diagnostyki in vitro	In vitro diagnosztikai eszköz
	Producent	Gyártó
	Zawartość wystarczająca do <n> testów	Tartalma <n> teszt elvégzésére elegendő
WASH SOLN CONC	Roztwór płuczący stężony	Mosó folyadék koncentrátum
CAL 0	Kalibrator zerowy	Zero kalibrátor
CAL N	Kalibrator nr	Kalibrátor #
CONTROL N	Kontrola nr	Kontrol #
Ag 125I	Znacznik izotopowy	Nyomjelző izotóp
Ab 125I	Znacznik izotopowy	Nyomjelző izotóp
Ag 125I CONC	Znacznik izotopowy stężony	Nyomjelző izotóp koncentrátum
Ab 125I CONC	Znacznik izotopowy stężony	Nyomjelző izotóp koncentrátum
	Probówki	Csövek
INC BUF	Wymagana inkubacja buforu	Inkubáló puffer
ACETONITRILE	Acetonitryl	Acetonitril
SERUM	Surowica	Szérum
DIL SPE	Rozcieńczalnik próbki	Mintahigító
DIL BUF	Bufor do rozcieńczania	Higító puffer
ANTISERUM	Antysurowica	Antiszérum
IMMUNOADSORBENT	Immunoadsorbent	Immunadszorbens
DIL CAL	Rozcieńczalnik kalibratora	Kalibrátor higító
REC SOLN	Roztwór do rozcieńczania	Mintaelőkészítő oldat
PEG	Glikol poli(oksy)etylenowy	Polietilén glikol
EXTR SOLN	Roztwór ekstrakcyjny	Extrakciós oldat
ELU SOLN	Roztwór elucyjny	Eluáló oldat
GEL	Kolumny krzemionkowe Bond Elut	Bond Elut Silica szilikagél patronok
PRE SOLN	Roztwór do przygotowania wstępnego	Előkezelő oldat
NEUTR SOLN	Roztwór neutralizujący	Semlegesítő oldat
TRACEUR BUF	Bufor znacznika	Nyomjelző izotóp higító puffer
	mikropłytka	Mikrotiter lemez
Ab HRP	Koniugat peroksydazy chrzanowej	HRP konjugátum
Ag HRP	Koniugat peroksydazy chrzanowej	HRP konjugátum
Ab HRP CONC	Koncentrat koniugatu peroksydazy chrzanowej	HRP konjugátum koncentrátum
Ag HRP CONC	Koncentrat koniugatu peroksydazy chrzanowej	HRP konjugátum koncentrátum
CONJ BUF	Bufor do koniugacji	Konjugátum puffer
CHROM TMB CONC	Koncentrat chromogenu TMB (czterometylobenzydyny)	Kromogén TMB koncentrátum
CHROM TMB	Roztwór chromogenu TMB (czterometylobenzydyny)	Kromogén TMB oldat
SUB BUF	Bufor substratu	Szubsztrát puffer
STOP SOLN	Roztwór zatrzymujący reakcję	Stop oldat
INC SER	Wymagana inkubacja surowicy	Inkubációs szérum
BUF	Bufor	Puffer
Ab AP	Koniugat AP (fosfatazy alkalicznej)	AP konjugátum
SUB PNPP	p-nitrofenylofosforan substratowy	Szubsztrát PNPP
BIOT CONJ CONC	Koncentrat koniugatu biotyny	Biotin konjugátum koncentrátum
AVID HRP CONC	Koncentrat peroksydazy chrzanowej z awidyną	Avidin HRP koncentrátum
ASS BUF	Bufor do oznaczania	Vizsgálati puffer
Ab BIOT	Koniugatu biotyny	Biotin konjugátum
Ab	Przeciwciało swoiste	Specifikus ellenanyag
SAV HRP CONC	Koncentrat streptawidyny HRP	Sztreptavidin HRP koncentrátum
NSB	Wiązanie nieswoiste	Nem-specifikus kötődés
2nd Ab	Drugie przeciwciało	Másodlagos ellenanyag
ACID BUF	Bufor zakwaszający	Savas puffer

	Използвани символи
	Вижте инструкцията за работа
	Температура на съхранение
	Използвайте с
LOT	Партиден код
REF	Каталожен номер
CONTROL	Контрол
IVD	Ин витро диагностично медицинско изделие
	Производител
	Съдържание достатъчно за <n> теста
WASH SOLN CONC	Концентриран измиващ разтвор
CAL 0	Нулев калибратор
CAL N	Калибратор #
CONTROL N	Контрол #
Ag 125I	Трейсър
Ab 125I	Трейсър
Ag 125I CONC	Концентриран маркер
Ab 125I CONC	Концентриран маркер
	Епруветки
INC BUF	Инкубационен буфер
ACETONITRILE	Ацетонитрил
SERUM	Серум
DIL SPE	Разредител за пробите
DIL BUF	Буфер за разреждане
ANTISERUM	Антисерум
IMMUNOADSORBENT	Имуноабсорбент
DIL CAL	Разредител за калибратора
REC SOLN	Пресъздаващ разтвор
PEG	Полиетилен гликол
EXTR SOLN	Екстрактов разтвор
ELU SOLN	Разтвор за елюиране
GEL	Силикагелни пълнители
PRE SOLN	Пред-лечебен разтвор
NEUTR SOLN	Неутрализиращ ратвор
TRACEUR BUF	Маркерен буфер
	Микротитърна пластина
Ab HRP	HRP конюгат / Конюгат на хрянова пероксидаза
Ag HRP	HRP конюгат / Конюгат на хрянова пероксидаза
Ab HRP CONC	HRP конюгиран концентрат
Ag HRP CONC	HRP конюгиран концентрат
CONJ BUF	Буфер за конюгата
CHROM TMB CONC	Хромогенен TMB концентрат
CHROM TMB	Хромогенен TMB разтвор
SUB BUF	Субстратен буфер
STOP SOLN	Стоп разтвор
INC SER	Инкубационен серум
BUF	Буфер
Ab AP	AP конюгат / конюгат на алкална фосфатаза
SUB PNPP	Субстрат PNPP / пара нитрофенил фосфат
BIOT CONJ CONC	Биотин конюгиран концентрат
AVID HRP CONC	Авидин HRP концентрат
ASS BUF	Буфер за пробите
Ab BIOT	Биотин конюгат
Ab	специфично антитяло
SAV HRP CONC	стрептавидин HRP концентрат
NSB	не специфично свързване
2nd Ab	второ антитяло
ACID BUF	киселинизиращ буфер