DRG® PAPP-A 60 (EIA-4889)

Revised 24 Sept. 2009 (Vers. 4.0) **USA: RUO**

Please use only the valid version of the package insert provided with the kit.

INTRODUCTION

1.1 Intended Use

The **DRG PAPP-A 60 ELISA** is an enzyme immunoassay for the quantitative *in vitro diagnostic* measurement of Pregnancy associated plasma protein A (PAPP-A) in serum and plasma. In the United States, this kit is intended for Research Use Only.

1.2 Summary and Explanation

PAPP-A is a protein produced by the developing placenta. Its concentration in the maternal blood increases rapidly after the 7th week of pregnancy. The measurement of PAPP-A in the first trimester of pregnancy has been reported as a useful marker in antenatal screening for Down Syndrome and other fetal aneuploidies. Reduced PAPP-A values in combination with maternal age, the measurement of free ß-HCG and the ultrasonic determination of nuchal translucency (NT) in pregnancy weeks 11 to 14 may detect up to 90 % of pregnancies with Down syndrome (reference 7).

For the risk assessment of trisomy 21 and other fetal aneuploidies PAPP-A should be measured in combination with other analytes (for example free ß-HCG and NT, see above) and a special software for the risk assessment of trisomy 21.

PRINCIPLE OF THE TEST

The DRG PAPP-A 60 ELISA Kit is a solid phase enzyme-linked immunosorbent assay (ELISA) based on the sandwich principle.

The microtiter wells are coated with a polyclonal anti PAPP-A antibody. An aliquot of patient sample containing endogenous PAPP-A is incubated in the coated well with assay buffer. After incubation the unbound material is washed off. In the second incubation step a sandwich complex is formed with a polyclonal anti PAPP-A antibody peroxidase conjugate. Having added the substrate solution, the intensity of color developed is proportional to the concentration of PAPP-A in the patient sample.

WARNINGS AND PRECAUTIONS

1. This kit is for in vitro diagnostic use only. For professional use only. In the United States, this kit is intended for Research Use Only.
2. 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.
3. Before starting the assay, read the instructions completely and carefully. Use the valid version of the package insert provided with the kit. Be sure that everything is understood.
4. The microplate contains snap-off strips. Unused wells must be stored at 2 °C to 8 °C in the sealed foil pouch and used in the frame provided.

5. Pipetting of samples and reagents must be done as quickly as possible and in the same sequence for each step.
6. Use reservoirs only for single reagents. This especially applies to the substrate reservoirs. Using a reservoir for dispensing a substrate solution that had previously been used for the conjugate solution may turn solution colored. Do not pour reagents back into vials as reagent contamination may occur.
7. Mix the contents of the microplate wells thoroughly to ensure good test results. Do not reuse microwells.
8. Do not let wells dry during assay; add reagents immediately after completing the rinsing steps.
9. Allow the reagents to reach room temperature (21-26°C) before starting the test. Temperature will affect the absorbance readings of the assay. However, values for the patient samples will not be affected.
10. Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.
11. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.
12. Wear disposable latex gloves when handling specimens and reagents. Microbial contamination of reagents or specimens may give false results.
13. Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.
14. Do not use reagents beyond expiry date as shown on the kit labels.
15. All indicated volumes have to be performed according to the protocol. Optimal test results are only obtained when using calibrated pipettes and microtiterplate readers.
16. 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.
17. Avoid contact with *Stop Solution* containing 0.5 M H_2SO_4. It may cause skin irritation and burns.
18. Some reagents contain Proclin 300, BND and/or MIT as preservatives. In case of contact with eyes or skin, flush immediately with water.
19. TMB substrate has an irritant effect on skin and mucosa. In case of possible contact, wash eyes with an abundant volume of water and skin with soap and abundant water. Wash contaminated objects before reusing them. If inhaled, take the person to open air.
20. Chemicals and prepared or used reagents have to be treated as hazardous waste according to the national biohazard safety guideline or regulation.
21. For information on hazardous substances included in the kit please refer to Material Safety Data Sheets. Material Safety Data Sheets for this product are available upon request directly from DRG.

REAGENTS

1.3 Reagents provided

1. ***Microtiterwells***, 12x8 (break apart) strips, 96 wells;
   Wells coated with anti-PAPP-A antibody (polyclonal).
2. ***Standard (Standard 0-5)***, 6 vials (lyophilized), 0.80 mL;
   Concentrations: 0 – 2.5 – 5 – 15 – 30 – 60 µg/mL
   Conversion: 1 mU/mL = 4.5 mg/L
   The DRG PAPP-A Standards are comparable with NEQAS approved Reference material for Down Syndrome Screening (U/L, IRP 76/610)
   See „*Reagent Preparation*“;
   contain 0.015% BND and 0.010% MIT as a preservative.
3. ***Control (low and high)***, 2 vials (lyophilized), 0.80 mL,
   For control values and ranges please refer to vial label or QC-Datasheet.
   see „*Reagent Preparation*“
   Contain 0.015% BND and 0.010% MIT as a preservative.
4. ***Assay Buffer***, 1 vial, 25 mL, ready to use,
   contains 0.015% BND and 0.010% MIT as a preservative.
5. ***Enzyme Conjugate A***, 1 vial, 3 mL, ready to use
   contains steptavidin
   Contains 0.03% Proclin 300, 0.015% BND and 0.010% MIT as a preservative.
6. ***Enzyme Conjugate B***, 1 vial, 3 mL, ready to use
   complex containing horseradish peroxidase;
   Contains 0.03% Proclin 300, 0.015% BND and 0.010% MIT as a preservative.
7. ***Conjugate Diluent***, 1 vial, 6 mL, ready to use
   Contains 0.03% Proclin 300, 0.015% BND and 0.010% MIT as a preservative.
8. ***Substrate Solution***, 1 vial, 14 mL, ready to use,
   Tetramethylbenzidine (TMB).
9. ***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.
10. ***Wash Solution***, 1 vial, 30 mL (40X concentrated),
    see „*Reagent Preparation*“.

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

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

1.4 Materials required but not provided

- A microtiter plate calibrated reader (450 ± 10 nm) (e.g. the DRG Instruments Microtiter Plate Reader).
- Calibrated variable precision micropipettes.
- Absorbent paper.
- Distilled or deionized water
- Timer (60 min. range).
- Semi logarithmic graph paper or software for data reduction

1.5 Storage Conditions

When stored at 2 °C - 8 °C unopened reagents will retain reactivity until expiration date. Do not use reagents beyond this date.

Opened reagents must be stored at 2 °C - 8 °C. Microtiter wells must be stored at 2 °C - 8 °C. Once the foil bag has been opened, care should be taken to close it tightly again.
Opened kits retain activity for two months if stored as described above.

1.6 Reagent Preparation

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

Standards

Reconstitute the lyophilized contents of the standard vial with 800 µL Aqua dest.

Note: *The reconstituted standards are stable for 2 months at 2-8°C.*

Control

Reconstitute the lyophilized content with 800 µL Aqua dest. and let stand for 10 minutes in minimum. Mix the control several times before use.

Note: *The reconstituted control is stable for 2 months at 2-8°C*

Wash Solution

Add deionized water to the 40X concentrated Wash Solution.
Dilute 30 mL of concentrated *Wash Solution* with 1170 mL deionized water to a final volume of 1200 mL.

The diluted Wash Solution is stable for 2 weeks at room temperature.

1.7 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 (see chapter 13).

1.8 Damaged Test Kits

In case of any severe damage to the test kit or components, DRG has to be informed in writing, at the 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.

SPECIMEN COLLECTION AND PREPARATION

Serum or plasma (EDTA-, heparin- or citrate plasma) can be used in this assay.

Do not use haemolytic, icteric or lipaemic specimens.

Please note: Samples containing sodium azide should not be used in the assay.

1.9 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.

Plasma:

Whole blood should be collected into centrifuge tubes containing anti coagulant and centrifuged immediately after collection.

(E.g. for EDTA plasma Sarstedt Monovette – red cap - # 02.166.001;
for Heparin plasma Sarstedt Monovette – orange cap - # 02.165.001;
for Citrate plasma Sarstedt Monovette – green cap - # 02.167.001.)

1.10 Specimen Storage and Preparation

Specimens should be capped and may be stored for up to 5 days at 2-8°C prior to assaying.

If EDTA plasma is stored at 2-8°C, it must be assayed within 48 hours.

Specimens held for a longer time (up to two months) should be frozen only once at -20°C prior to assay. Thawed samples should be inverted several times prior to testing.

1.11 Specimen Dilution

If in an initial assay, a specimen is found to contain more than the highest standard, the specimens can be diluted with *Standard 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 *Standard 0* (mix thoroughly)

b) dilution 1:100: 10 µL dilution a) 1:10 + 90 µL *Standard 0* (mix thoroughly).

ASSAY PROCEDURE

1.12 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 standard, 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.

1.13 Test Procedure

Each run must include a standard curve.All standards, samples, and controls should be run in duplicate. All standards, samples, and controls should be run concurrently so that all conditions of testing are the same.

1. Secure the desired number of Microtiter wells in the frame holder.
2. Dispense **20 µL** of each ***Standard, Control*** and **samples** with new disposable tips into appropriate wells.
3. Add **100 µl** ***Assay Buffer*** into each well.
4. Incubate for **30 minutes** at room temperature on a plate shaker at 500 rpm. It is important to have a complete mixing in this step.
5. Briskly shake out the contents of the wells.
   Rinse the wells 3 times with diluted *Wash Solution* (400 µl). Strike the wells sharply on absorbent paper to remove residual water droplets.
   Important note:
   The sensitivity and precision of this assay is markedly influenced by the correct performance of the washing procedure!
6. Dispense **25 µL** ***Enzyme Conjugate A*** into each well.
7. Dispense **25 µL** ***Enzyme Conjugate B*** into each well.
8. Incubate for **5 minutes** at room temperature on a plate shaker at 500 rpm.
9. Dispense **50 µL** ***Conjugate Diluent*** into each well.
10. Incubate for **30 minutes** at room temperature on a plate shaker at 500 rpm.
11. Briskly shake out the contents of the wells.
    Rinse the wells 3 times with diluted *Wash Solution* (400 µL per well). Strike the wells sharply on absorbent paper to remove residual droplets.
12. Add **100 µL** of ***Substrate Solution*** to each well.
13. Incubate for **15 minutes** at room temperature.
14. Stop the enzymatic reaction by adding **50 µL** of ***Stop Solution*** to each well.
15. 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*.

1.14 Calculation of Results

1. Calculate the average absorbance values for each set of standards, controls and patient samples.
2. Using semi-logarithmic graph paper, construct a standard curve by plotting the mean absorbance obtained from each standard 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 standard 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 standard curve. Samples with concentrations higher than that of the highest standard have to be further diluted or reported as > 60 µg/mL. For the calculation of the concentrations this dilution factor has to be taken into account.

1.14.1 Example of Typical Standard Curve

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

Standard	Optical Units (450 nm)
Standard 0 (0 µg/mL)	0.19
Standard 1 (2.5 µg/mL)	0.44
Standard 2 (5 µg/mL)	0.62
Standard 3 (15 µg/mL)	1.21
Standard 4 (30 µg/mL)	1.80
Standard 5 (60 µg/mL)	2.29

EXPECTED NORMAL VALUES

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

1.15 Pregnant women in the 1st trimester

238 samples of pregnant women in the 1st trimester have been measured with the DRG PAPP-A 60 ELISA.
The values are validated in comparison with a Gaussian distribution.

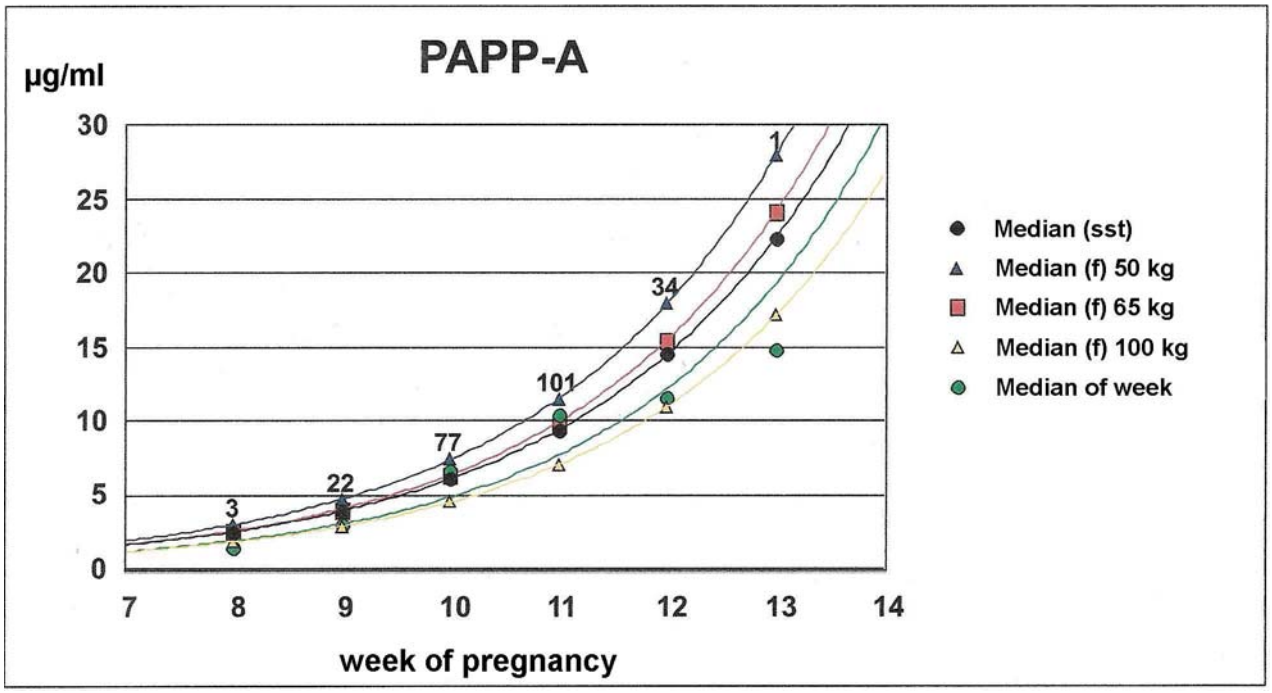
Consideration of body weight and day of gestation results in the following regression equation:

Median (f) PAPP-A = EXP (-2.12268 + 0.06324 * gestation day – 0.00979 * body weight).

If the values of the same 238 pregnant women are compared with the gestation day only (body weight not considered) the following weight independent regression equation is found:

Median (sst) PAPP-A = EXP (-2.705444 + 0.0618725 * gestation day).

In the following diagram and table the medians of function (median (f)) for **completed pregnancy weeks** 8 to 13 have been calculated for three body weights (50 kg, 65 kg (mean body weight), and 100 kg). For comparison the medians were also determined manually (Median of week) and by using the weight independent regression equation (Median (sst)).



Completed week of gestation	day of gestation	Median(sst) [µg/mL] weight independent	Median (f) [µg/mL] weight 50 kg	Median (f) [µg/mL] weight 65 kg	Median (f) [µg/mL] weight 100 kg	Median of week [µg/mL]
8	59	2.57	3.06	2.6	1.88	1.5
9	66	3.97	4.77	4.1	2.92	3.0
10	73	6.12	7.42	6.4	4.55	6.7
11	80	9.43	11.55	10.0	7.08	10.5
12	87	14.55	17.99	15.5	11.03	11.6
13	94	22.43	28.00	24.2	17.17	14.9

Population and laboratory differences may lead to slightly different medians. Each laboratory should therefore determine and continuously update its own medians from its own patient collective. The regression equations and values in the table should be used as a guideline only. The calculation of medians and/or regression functions for the calculation of medians from own patient data bases should be performed with the applied trisomy 21 risk calculation software. Medians determined for the DRG PAPP-A 60 ELISA can not be used with assays of other manufacturers. Medians determined for PAPP-A assays of other manufacturers can not be used with the DRG PAPP-A 60 ELISA.

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1.15.1 Use for Down Syndrom Screening

For risk calculation in prenatal screening PAPP-A concentrations are indicated as MOM (multiple of medians, MOM = Measured Concentration (PAPP-A) / Median PAPP-A).

In Down syndrome pregnancies the median of MOMs for PAPP-A are increasing during the first trimester and are not distinguishable anymore from normal pregnancies during the second trimester (reference 6, details see table). PAPP-A must therefore be measured in the first trimester of pregnancy (completed weeks 10–13).

Completed week of pregnancy	10	11	12	13	14-20
Median of MOM in pregnancies with Down Syndrom	0,34	0,42	0,50	0,58	1,11

Data from reference 6

For risk calculation of trisomy 21 not only PAPP-A but also other parameters like free ßHCG and nuchal translucency (NT) for the 1st trimester and/or AFP, free Estriol and HCG for the 2nd trimester have to be determined.

The use of these parameters for risk calculation of trisomy 21 requires a special software. **The software must allow the calculation of medians from own patient measurements.**

It is imperative to take into consideration additional factors, e.g. age of the woman, weight, ethnic group and smoker/non-smoker. **An underestimation of the gestation age can lead to a falsely high calculated risk (false positive).** To reduce this source of error, it is important to **determine the gestation age as precisely as possible. Gestation age calculation from the last menstrual cycle inheres a high risk of variation. Sonographic determination of the crown-rump length (CRL) or biparietal diameter (BIP)** is recommended for the proper determination of the gestation age.

PAPP-A measurement in the course of a prenatal screening determines only a risk for trisomy 21.

For proof of trisomy 21 genetic determinations are required.

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.

After checking the above mentioned items without finding any error contact your distributor or DRG directly.

PERFORMANCE CHARACTERISTICS

1.16 Assay Dynamic Range

The range of the assay is between 0.1 – 60 µg/mL.

1.17 Specificity of Antibodies (Cross Reactivity)

The antibody used for the DRG PAPP-A 60 ELISA is specific for human PAPP-A. There is no cross-reactivity to other species.

No reaction is seen with normal human plasma.

1.18 Sensitivity

The analytical sensitivity was calculated from the mean plus two standard deviations of twenty (20) replicate analyses of *Standard 0* and was found to be 0.1 µg/mL.

LIMITATIONS OF USE

1.19 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.

1.20 Drug Interferences

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

1.21 High-Dose-Hook Effect

No hook effect was observed in this test up to 300 µg/mL of PAPP-A.

LEGAL ASPECTS

1.22 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 DRG.

1.23 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.

1.24 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.

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   a prospective study of 15 030 pregnancies.

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SYMBOLS USED WITH DRG ELISAS

Symbol	English	Deutsch	Français	Español	Italiano
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conforme aux normes européennes	Conformidad europea	Conformità europea
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las Instrucciones	Consultare le istruzioni per l'uso
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Référence	Número de catálogo	No. di Cat.
LOT	Lot. No. / Batch code	Chargen-Nr.	No. de lot	Número de lote	Lotto no
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungstemperatur	Température de conservation	Temperatura de conservacion	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributore
Content	Content	Inhalt	Contenu	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Numéro	Volumen/Número	Volume/Quantità
Microtiterwells	Microtiterwells	Mikrotiterwells	Plaques de micro-titration	Placas multipocillo	Micropozzetti
Antiserum	Antiserum	Antiserum	Antisérum	Antisuero	Antisiero
Enzyme Conjugate	Enzyme Conjugate	Enzymkonjugat	Conjugué enzymatique	Conjugado enzimático	Tracciante enzimatico
Enzyme Complex	Enzyme Complex	Enzymkomplex	Complexe enzymatique	Complex enzimático	Complesso enzimatico
Substrate Solution	Substrate Solution	Substratlösung	Solution substrat	Solución de sustrato	Soluzione di substrato
Stop Solution	Stop Solution	Stopplösung	Solution d'arrêt	Solución de parada	Soluzione d´arresto
Zero Standard	Zero Standard	Nullstandard	Zero Standard	Estándar cero	Standard zero
Standard	Standard	Standard	Standard	Estándar	Standard
Control	Control	Kontrolle	Contrôle	Control	Controllo
Assay Buffer	Assay Buffer	Assaypuffer	Tampon d'essai	Tampón de ensayo	Tampone del test
Wash Solution	Wash Solution	Waschlösung	Solution de lavage	Solución de lavado	Soluzione di lavaggio
1N NaOH	1N NaOH	1N NaOH	1N NaOH	1N NaOH	1N NaOH (idrossido di sodio 1N)
1 N HCl	1 N HCl	1 N HCl	1N HCl	1 N HCl	
Sample Diluent	Sample Diluent	Probenverdünnungs-medium	Solution pour dilution de l'échantillon	Solución para dilución de la muestra	Diluente dei campioni
Conjugate Diluent	Conjugate Diluent	Konjugatverdünnungs-medium	Solution pour dilution du conjugué	Solución para dilución del conjugado	Diluente del tracciante

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