DRG:HYBRiD•XL®

Instructions for Use

Procalcitonin

IVD

CE

REF HYC-6210

Σ 80 tests

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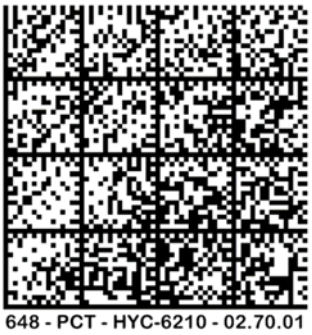
ASSAY PROTOCOL BARCODE (APB)

(Version 2.70 Software or later / ab Softwareversion 2.70 oder höher / Versione Software 2.70 o superiore / Versión de Software 2.70 o posterior / Version de logiciel 2.70 et supérieure / Wersja oprogramowania 2.6 lub późniejsza)



HYC-6210 – v2.70.1

The barcode must be used to install the assay protocol into the DRG:HYBRiD-XL software via the SCAN NEW LOT page.

Der Barcode muss in dem Menü „NEUES LOT SCANNEN“ eingelesen werden, um das Protokoll in der DRG:HYBRiD-XL-Software zu installieren.

Il codice a barre deve essere utilizzato per installare il protocollo del assay nel software DRG:Hybrid-XL tramite la pagina SCAN NUOVO LOTTO.

El código de barras debe utilizarse para instalar el protocolo de ensayo en el software del DRG:HYBRiD-XL a través del menú SCAN NEW LOT.

Le code barre doit être lu dans le menu SCAN NOUVEAU LOT afin d´installer le protocole DRG:HYBRiD-XL Software.

Kod kreskowy powinien być uzyty do instalacji protokołu oznaczenia w analizatorze DRG:HYBRiD-XL w zakładce SKANUJ NOWY LOT

Please refer to section **3**: **Routine Procedures: “Installing a new assay product”** of the User Manual v2.60 or later.

Bitte lesen Sie dazu auch Abschnitt **3 Routineprozeduren: “Installation eines neuen Assays/eines neuen Assay-Protokolls“** im Benutzerhandbuch v2.60 oder höher.

Si prega di fare riferimento alla sezione **3: Procedure ordinarie: "Installazione di un nuovo Assay"** del Manuale utente v2.60 o superiore.

Consulte la sección **3 Procesos Rutinarios: "Instalación de un nuevo ensayo"** en el Manual del usuario v2.60 o posterior.

Merci de vous référer au chapitre **3 : Procédure de routine: " Installation d´un nouvel assay/ un nouveau protocole d´assay"** dans le manuel d´utilisation à partir de la version v2.60.

Proszę zapoznać się z sekcją **3: Prcedury rutynowe: "Instalowanie nowego oznaczenia"** w Instrukcji Użytkownika, wersja 2.60 lub późniejsza

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1 INTENDED USE

The **DRG:HYBRiD-XL Procalcitonin** is an automated immunoturbidimetric assay for the **quantitative** measurement of Procalcitonin (PCT) in human serum and plasma (EDTA, lithium heparin or citrate plasma).

For *in vitro* diagnostic use.

For laboratory professional use, only with the DRG:HYBRiD-XL Analyzer.

1.1 Summary and Explanation

Procalcitonin (PCT) is a 116-amino acid polypeptide normally produced by the medullary C-glands of the thyroid. It is a pro-hormone and is metabolized to produce the 32-amino acid hormone calcitonin which has a role in calcium homeostasis via its actions on osteoclasts in bone. In systemic inflammation, specifically in bacterial infections, under the influence of inflammatory cytokines and bacterial endotoxin, PCT is secreted by various cell types and goes in circulation. (1,2)

Elevated PCT values are often found in patients suffering from bacterial sepsis, especially severe sepsis and septic shock. After an infectious bacterial insult with systemic consequences, PCT starts to rise at 4 hours and peaks between 8 and 24 hours. The magnitude of the increase in PCT concentration correlates with the severity of the bacterial infection. (3-5)

PCT as biomarker is used in a variety of settings, including primary care, emergency room and intensive care, where it can be used as a marker to monitor disease progression or to guide and observe antibiotic treatment. Studies have demonstrated a significant improvement in diagnostic accuracy when adding PCT and CRP to standard clinical signs and symptoms. (6-15)

2 PRINCIPLE OF THE TEST

The DRG:HYBRiD-XL Procalcitonin Kit is an **immunoturbidimetric assay**.

Sample reacts with a buffer and monoclonal (mouse) anti-PCT coated latex beads.

The formation of the antibody-antigen complex during the reaction results in an increase in turbidity and the absorbance is measured at 600 nm. The change in absorbance signal is proportional to the amount of PCT in the sample. PCT concentration in the sample is determined by comparison with a master curve.

3 WARNINGS AND PRECAUTIONS

1. This kit is for in vitro diagnostic use only.
   For professional use only.
2. This kit can only be used in combination with the DRG:HYBRiD-XL Analyzer
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 clear and understood.
4. **Do not remove, exchange, discard or damage any of the barcode labels provided with each kit and its components. All barcodes build an integral system for the kit lot.**
5. Respect the general safety measures for use of laboratory reagents.
6. 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.
7. Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.
8. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.
9. Wear appropriate disposable gloves when handling specimens and reagents. Microbial contamination of reagents or specimens may cause false results.
10. Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.
11. Do not use reagents beyond expiry date as shown on the kit labels.
12. Unused reagent cartridges must be stored at 2 °C to 8 °C in the sealed foil pouch with desiccant provided.
13. Optimal test results are only obtained when using calibrated pipettes.
14. Do not mix or use components from kits with different lot numbers. It is advised not to interchange reagent cartridges of different kits even of the same lot. The kits may have been shipped or stored under different conditions and the binding characteristics of the wells in the reagent cartridges may differ slightly.
15. Some reagents contain Proclin 300, BND and/or MIT as preservatives. In case of contact with eyes or skin, flush immediately with water.
16. Chemicals and prepared or used reagents have to be treated as hazardous waste according to the national biohazard safety guidelines or regulations.
17. For information on hazardous substances included in the kit please refer to Safety Data Sheets.
    For professional users the Safety Data Sheet for this product is available upon request directly from DRG.

4 REAGENTS

4.1 Reagents provided

4.1.1 Reagent Cartridges

80 pieces containing the following:

- ***Reagent 1***, 180 µL
  Tris buffer solution;
  Contains non-mercury preservative.
- ***Reagent 2***, 100 µL
  Suspension of latex particles (0.2%) coated with anti-human PCT antibody (monoclonal, mouse)
  Contains non-mercury preservative.

4.1.2 Re-Calibrator 1 & 2

2 vials, 0.5 mL each, ready to use;

For re-calibration of the quantitative DRG:HYBRiD-XL Procalcitonin test.

Concentrations are lot-specific.

Re-Calibrators are standardized against the following reference material: BioRad Lyphochek Specialty Immunoassay Control
Contain non-mercury preservative.

4.1.3 Control 1 & 2

2 vials, 1.0 mL each, ready to use;
For control values and ranges please refer to the bar code on vial label or to the Certificate of Analysis.
Contain non-mercury preservative.

4.2 Materials required but not provided

- General needed laboratory equipment
- Ultra-pure water
  DRG recommends to use Clinical Laboratory Reagent Water (CLRW) according to CLSI guideline 3C-A4 with the following specifications:
  Resistivity at 25 °C [MΩ·cm]: > 10
  Conductivity at 25 °C [µS·cm^{-1}]: < 0.1
  Total Organic Carbon/p.p.b.[µg/L] : < 50
  Colloids [µg/mL]: <0.05
- REF HYB-5252 DRG:HYBRiD-XL Analyzer
- REF HYI-5392: *System Solution 5L*, 5000 mL;
  (Instrument Feed Water according to CLSI guideline 3C-A4 with the following specification can also be used:
  Resistivity at 25 °C [MΩ·cm]: > 1
  Conductivity at 25 °C [µS·cm^{-1}]: < 1
  Total Organic Carbon/p.p.b.[µg/L] : < 200
  Colloids [µg/mL]: <0.1)
- REF HYI-5394: *Wash Buffer*, 40x concentrate, 25 mL
- REF HYI-5395: *Needle Cleaning Solution*, 30 mL. Cleaning solution for the pipetting needle (daily and weekly maintenance, see also user manual)
- REF HYI-5387: *Cuvettes*, (2 x 360 pieces)

For use of the *Secondary Sample Holder* for secondary tubes the following tubes are required:

- REF HYI-5391: *Sample Tubes (Secondary)*, 2500 pcs.

4.3 Storage Conditions

All kit components should be stored at 2 °C to 8 °C to ensure product performance until the defined expiry date.

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

- Cartridges (stored at 2 °C to 8 °C) in the supplied and unopened zip/foil bags will retain reactivity until expiration date.
- Unopened Re-Calibrators and Controls (stored at 2 °C to 8 °C) will retain reactivity until expiration date.

Opened reagents and the reagent cartridges must be stored at 2 °C to 8 °C.

Once the plastic bag has been opened, care should be taken to tightly close it again along with the supplied desiccant bag.

Immediately after end of each run the Re-Calibrator and Control vials have to be removed from the instrument, tightly capped and stored at 2 °C to 8 °C.

- Unused cartridges in opened zip/foil bags (stored at 2 °C to 8 °C) will retain reactivity until expiration date, if stored as described above.
- Pierced or open cartridges must be disposed of immediately.
- Opened Re-Calibrators and Controls (stored at 2 °C to 8 °C) will retain reactivity for 8 weeks.

4.3.1 On-board Stability

For Re-Calibrators and Controls the on-board stability has been evaluated under controlled laboratory conditions at room temperature (20 °C to 25 °C).

Due to the differences in laboratory environmental conditions and reagent volumes, the on-board stability may deviate from the declared value.

On-board stability:	8 h

4.4 Reagent Preparation

Bring all reagents, such as controls and re-calibrators, to room temperature (20 °C to 25 °C) prior to use. Reagent Cartridges can be used directly after storage in the refrigerator.

***Wash Buffer* (not included in the kit)**

For Wash Buffer (1x) dilute 25 mL of *Wash Buffer* (40x) with 975 mL ultra-pure water to a final volume of 1000 mL.

The diluted Wash Buffer (1x) is stable for 2 weeks at room temperature.

4.5 Disposal of the Kit

The disposal of the kit and all used materials/reagents must be performed according to the national regulations. Special information for this product is given in the Safety Data Sheet.

4.6 Damaged Test Kits

In case of any damage to the test kit or components, DRG must be informed in writing, at the latest one week after receiving the kit. 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 of according to the official regulations.

5 SPECIMEN COLLECTION AND PREPARATION

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

A minimum of 72 µL of sample is needed for one determination.
This includes 12 µL sample and 60 µL dead volume.

Attention:

- This test was not verified with blood collection tubes of all available manufacturers.
- Sample Collection Systems of some manufacturers may contain different materials which in isolated cases could affect the test results.
- If primary tubes for sample collection are used, please follow the instructions of the manufacturer.
- Do not use haemolytic, icteric or lipaemic specimens.
- Samples containing precipitates have to be centrifuged prior to the test run.
- Do not use heat inactivated samples.
- Do not use standards or external controls stabilized with azide.

5.1 Specimen Collection

Serum:

Collect blood by venipuncture (e.g. Sarstedt Monovette for serum), 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 (e.g. Sarstedt Monovette with the appropriate plasma preparation) and centrifuged immediately after collection.

5.2 Specimen Storage

Specimens should be capped and may be stored for up to 24 hours at 2 °C to 8 °C prior to performing the assay.

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

5.3 Specimen Preparation

Samples can be assayed without additional preparation.

6 ASSAY PROCEDURE

6.1 General Remarks

- All reagents, such as controls and re-calibrators and specimens, must be allowed to come to room temperature (20 °C to 25 °C) before use.
  All reagents and samples must be mixed without foaming.
  Reagent Cartridges can be used directly after storage in the refrigerator.
- Samples, controls and re-calibrators should be measured within 2 hours in order to avoid possible evaporation effects.
- The *Secondary Sample Holder* (HYI-5437) for secondary tubes has the capacity for a maximum of 20 samples including controls and re-calibrators. They all have to be pipetted into the secondary tubes, and the respective barcodes of control/re-calibrator vials and, if available, the sample barcodes have to be read with the external barcode scanner.

6.2 Test Procedure

- **The total assay time for DRG:HYBRiD-XL Procalcitonin is 10 minutes.**
- To ensure proper operation of the test, the instructions in the user manual for the DRG:HYBRiD-XL should strictly be followed.
- All test specific information required for the correct operation is included in the respective barcodes of the reagents.
  Take care not to damage these bar codes!
- **It is recommended to tap the bottom of the Cartridge Segments containing the reagent cartridges once on the bench before placing them on the rotor. This is to avoid foam and adhering of the liquid on the sealing of the reagent cartridge.**
- Place reagent cartridges on the rotor of the unit. The heating to 37 °C incubation temperature is performed automatically in the unit.

6.3 Calibration

Traceability:

This method was standardized against the following commercially available test method:

BRAHMS PCT (Procalcitonin) sensitive KRYPTOR

Each DRG:HYBRiD-XL reagent contains a barcode with the specific information for recalibration of the reagent lot. The Master Curve is printed as a 2-D barcode on the outer label of the kit package and on the QC-Datasheet and has to be scanned with the external barcode scanner prior to the first use of the respective kit lot.

Recalibration is recommended:

- if a new kit lot is used. Each new lot should be verified by running the kit internal re-calibrators and controls before routine use.
- if one or both assay controls are found outside the specified range.
- after 4 weeks of use of the same reagent kit on the unit.

6.4 Calculation of Results

The analyte concentrations are calculated automatically by the DRG:HYBRiD-XL's system software.

7 QUALITY CONTROL

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.

It is also recommended to participate in national or international Quality Assessment programs in order to ensure the accuracy of the results.

Apply appropriate statistical methods for analysing control values and trends. If the results of the assay do not agree with the established acceptable ranges of control materials, patient results should be considered invalid. In this case, please check the following: expiration dates and storage conditions of reagents, operational reliability of the analyser. In addition, it is indicated to perform a Recalibration.

In case of further questions please contact your local distributor or DRG directly.

7.1 Internal Controls

For Quality Control it is necessary to use the two internal controls provided with each kit.

Acceptance ranges for both internal controls (*Control 1 & 2*) were established by the manufacturer and are summarized in the QC-Datasheet added to the kit. Note that the expected values and acceptance ranges stated in the QC-Datasheet always refer to the current kit lot.

Internal controls should be run in single determination:

- on a routine basis (e.g. once per 24 h)
- if re-calibration is required (if one or both internal controls are out of range)
- if a new kit lot is used (in order to avoid any negative impact on the kit performance by improper transport or to detect improper storage during transport).

7.2 External Controls

Use controls at both normal and pathological levels.

The control intervals and control ranges for external controls should be adapted to the individual requirements of each laboratory. All results must be within the defined limits.

Each laboratory should establish corrective measures to be taken if values of external controls are not found in the acceptance range.

8 EXPECTED NORMAL VALUES

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

In a study conducted with apparently healthy adults, using the DRG:HYBRiD-XL Procalcitonin the following data were observed:

Population	Total
n	40
Range (ng/mL)	< 0.309 – 0.356
Mean (ng/mL)	< 0.309
2.5th - 97.5th Percentile (ng/mL)	< 0.309 – 0.350
Median (ng/mL)	< 0.309

The results alone should not be the only reason for any therapeutic consequences. The results should be correlated with other clinical observations and diagnostic tests.

9 LIMITATIONS OF USE

Reliable and reproducible results will be obtained, when the assay procedure is performed with a complete understanding of the instructions for use and with adherence to good laboratory practice.

Any improper handling of samples or modification of this test might influence the results.

10 PERFORMANCE CHARACTERISTICS

10.1 Assay Dynamic Range

The dynamic range of the assay is defined by the limit of detection and the maximum value of the Master Curve.

Values found below the measuring range are indicated as "< 0.309 ng/mL".

Values found above the measuring range are indicated as "> 20 ng/mL".

The measuring range of the assay is between 0.309 ng/mL – 20 ng/mL.

10.2 Specificity of Antibodies (Cross-Reactivity)

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

Substance	Conc. Range of Spiked Substance ng/mL	Mean Cross-Reactivity %
Calcitonin (human)	1 – 100	-0.6
Katacalcin	3 – 300	-0.8
alpha-CGRP	3 – 300	-0.3
beta-CGRP	3 – 300	-0.6

10.3 Sensitivity

The sensitivity study was designed according to CLSI guideline EP17-A2.

The Limit of Blank (LoB) is 0.221 ng/mL.

The Limit of Detection (LoD) is 0.309 ng/mL.

The Limit of Quantification (LoQ) is 0.312 ng/mL.

10.4 Precision Performance

The precision study was designed according to CLSI guideline EP5-A2.

10.4.1 Within-run precision

Calculated from the mean value of 5 replicates on 5 days with 1 device.

Sample	n	Mean (ng/mL)	CV (%)
1	5	0.41	8.2
2	5	1.18	5.1
3	5	5.16	4.0
4	5	10.03	7.5

10.4.2 Between-run precision

Calculated by 5 replicates each on 5 days with 1 device.

Sample	n	Mean (ng/mL)	CV (%)
1	25	0.41	12.7
2	25	1.18	7.4
3	25	5.16	4.9
4	25	10.03	10.2

10.4.3 Between-device precision

Calculated by 5 replicates each on 5 days with 3 devices.

Sample	n	Mean (ng/mL)	CV (%)
1	75	0.46	14.4
2	75	0.85	8.9
3	75	1.71	9.4
4	75	4.95	7.1

10.4.4 Between-lot precision

Determined with 3 different kit lots.

Sample	n	Mean (ng/mL)	CV (%)
1	18	0.40	7.25
2	18	1.24	2.52
3	18	5.18	6.98
4	18	11.06	6.96

10.5 Recovery

Recovery was determined by adding four increasing concentrations of the analyte to four different patient samples containing different amounts of endogenous analyte. Each sample (non-spiked and spiked) was assayed and analyte concentrations of the samples were calculated from the Master Curve. The percentage recoveries were determined by comparing expected and measured values of the samples.

Sample		1	2	3	4
Concentration (ng/mL)		0.74	1.06	1.22	4.50
Average Recovery (%)		89.5	95.6	88.2	107.6
Range of Recovery (%)	from	86.5	92.2	85.4	102.7
	to	96.2	99.0	91.8	114.7

10.6 Linearity

Four samples containing different amounts of analyte were serially diluted with *Sample Diluent*. The percentage recovery was calculated by comparing the expected and measured values for the analyte.

Sample		1	2	3	4
Concentration (ng/mL)		8.59	11.29	13.04	13.69
Average Recovery (%)		96.7	97.0	94.9	110.11
Range of Recovery (%)	from	86.8	87.9	87.9	105.6
	to	112.2	114.5	112.9	114.4

10.7 Interfering Substances

Haemoglobin (up to 4 mg/mL), Bilirubin (up to 0.5 mg/mL) and Triglyceride (up to 7.5 mg/mL) have no influence on the assay results.

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

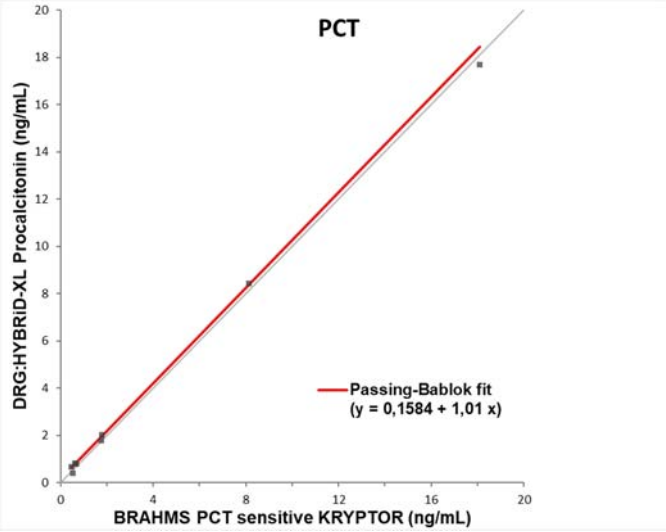
10.8 High-Dose-Hook Effect

Hook effect was detected in the range above 20 ng/mL for this assay. However, it could be demonstrated that at concentrations up to 6400 ng/mL, the results remain clearly above the decision point of 2 ng/mL and therefore a false negative result can be excluded.

11 METHOD COMPARISON

A comparison of DRG:HYBRiD-XL Procalcitonin Test HYC-6210 (y) and BRAHMS PCT sensitive KRYPTOR (x) using clinical samples gave the following correlation:

n = 8
r = 1.00
y = 0.1584 + 1.01x



12 LEGAL ASPECTS

12.1 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 DRG.

12.2 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 12.1. 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.

12.3 Liability

Any modification of the test kit and/or exchange or mixture of any components of different kit lots 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 12.2 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.

For further information please refer to the User Manual of the DRG:HYBRiD-XL, analyser-specific application sheets, product information and package inserts of all necessary components.

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SYMBOLS USED

Symbol	English	Deutsch	Italiano	Español	Français	Polski
CE	European Conformity	CE-Konformitäts-kennzeichnung	Conformità europea	Conformidad europea	Conforme aux normes européennes	Zgodność z normami europejskimi
	Consult instructions for use*	Gebrauchsanweisung beachten*	Consultare le istruzioni per l'uso	Consulte las Instrucciones	Consulter les instructions d'utilisation	Zapoznać się z instrukcją użytkowania
IVD	*In vitro* diagnostic medical device*	*In-vitro*-Diagnostikum*	Per uso Diagnostica in vitro	Para uso Diagnóstico in vitro	Usage Diagnostic in vitro	Wyrób medyczny do diagnostyki in vitro
RUO	For research use only	Nur für Forschungszwecke	Solo a scopo di ricerca	Sólo para uso en investigación	Seulement dans le cadre de recherches	Tylko do użytku w badaniach
REF	Catalogue number*	Artikelnummer*	No. di Cat.	Número de catálogo	Référence	Numer katalogowy
LOT	Batch code*	Chargencode*	Lotto no	Número de lote	No. de lot	Numer LOT
	Contains sufficient for <n> tests *	Ausreichend für <n> Prüfungen *	Contenuto sufficiente per "n" saggi	Contenido suficiente para <n> ensayos	Contenu suffisant pour "n" tests	Zawartość przeznaczona na <n> testów
	Temperature limit*	Temperatur-begrenzung*	Temperatura di conservazione	Temperatura de conservacion	Température de conservation	Przechowywać w temperaturze
	Use-by date*	Verwendbar bis*	Data di scadenza	Fecha de caducidad	Date limite d'utilisation	Data przydatności
	Manufacturer*	Hersteller*	Fabbricante	Fabricante	Fabricant	Producent
	Caution*	Achtung*				UWAGA
Distributed by	Distributor	Vertreiber	Distributore	Distribuidor	Distributeur	Dystrybutor
Content	Content	Inhalt	Contenuto	Contenido	Contenu	Zawartość
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantità	Volumen/Número	Volume/Numéro	Objętość / Numer
Reagent Cartridge	Reagent Cartridge	Reagenzien-Cartridge	Cartucce di reagente	Cartucho de reactivo	Cartouche de réactif	Kartridż z odczynnikami
Re-Calibrator	Re-Calibrator	Re-Kalibrator	Re-Calibratore	Re-Calibrador	Re-calibrateurs	Re-kalibrator
Control	Control	Kontrolle	Controllo	Control	Contrôle	Kontrola
Enzyme Conjugate	Enzyme Conjugate	Enzymkonjugat	Tracciante enzimatico	Conjugado enzimático	Conjugué enzymatique	Koniugat enzymatyczny
Enzyme Complex	Enzyme Complex	Enzymkomplex	Complesso enzimatico	Complex enzimático		Enzymu kompleks
Substrate Solution	Substrate Solution	Substratlösung	Soluzione di substrato	Solución de sustrato	Solution substrat	Roztwór Substratu
Sample Diluent	Sample Diluent	Probenverdünnungs-medium	Diluente dei campioni	Solución para dilución de la muestra	Diluant d'échantillon	Rozcieńczalnik Próbki
Reagent 1	Reagent 1	Reagenz 1	Reagente 1	Reactivo 1	Réactif 1	Reagent 1
Reagent 2	Reagent 2	Reagenz 2	Reagente 2	Reactivo 2	Réactif 2	Reagent 2
Wash Buffer	Wash Buffer	Waschpuffer	Tampone di lavaggio	Tampón de lavado	Tampon de lavage	Bufor Płuczący
System Solution	System Solution	Systemlösung		Solución de sistema	Solution système	Roztwór systemowy
Needle Cleaning Solution	Needle Cleaning Solution	Nadel-Reinigungslösung	Soluzione lavaggio ago	Solución de lavado de la aguja	Solution de nettoyage des aiguilles	Roztwór Czyszczący Igły
Denaturation Buffer	Denaturation Buffer	Denaturierungspuffer	Tampone die denaturazione	Tampón de denaturalización	Tampon de dénaturation	
Neutralization Buffer	Neutralization Buffer	Neutralisierungspuffer	Tampone di neutralizzazione	Tampón de neutralización	Tampon de neutralisation	
Assay Buffer	Assay Buffer	Assaypuffer	Tampone del test	Tampón de ensayo	Tampon d'essai	
Secondary Sample Holder	Secondary Sample Holder	Sekundärprobenhalter	Sostegno secondario dei campioni	Soporte de muestras para tubos secundarios	Support d'échantillons secondaires	Statyw na probówki drugorzędowe
Sample Tubes (Secondary)	Sample Tubes (Secondary)	Sekundärproben-röhrchen	Tubetti di campioni secondari	Tubos de muestra secundarios	Tubes échantillon secondaires	Probówki drugorzędowe
Dilution Cartridge	Dilution Cartridge				Cartouches de dilution	Kartridż do rozcieńczeń
Vial Adapter	Vial Adapter	Fläschchen-Adapter	l'adattatore dei tubetti	Adaptador de tubos	l'Adaptateur de flacons	Nakładki na butelki dla kontroli i kalibratorów