

# Angiotensin I RIA KIT

Instruction for use in local language is available at [beckmancoulter.com/techdocs](http://beckmancoulter.com/techdocs).

## REVISION HISTORY

| Previous version: | Current version:                                   |
|-------------------|--|
| PI-IM3518-09      | IFU-IM3518-02                                      |
| —                 | Adding Bulgarian, Slovenian and French to the IFU. |

**REF** IM3518

## FOR PROFESSIONAL USE ONLY

## INTENDED PURPOSE

Angiotensin I RIA KIT is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of plasma renin activity (PRA) in human plasma. Measurement of plasma renin activity is intended to be used as an aid in diagnosis and differential diagnosis of primary and secondary hyperaldosteronism and hypoaldosteronism in general population [1, 2].

## PRINCIPLE

The Angiotensin I RIA KIT serves for the quantitative determination of plasma renin activity (PRA) by the radioimmunoassay of the product of the reaction, angiotensin I.

The generation of angiotensin I is the result of the enzymatic cleavage of the renin substrate, angiotensinogen, in plasma samples in the presence of ACE inhibitor (ACE - Angiotensin-Converting Enzyme), an enzymatic inhibitor that blocks the conversion of angiotensin I to angiotensin II.

The radioimmunoassay of angiotensin I is a competition assay. Samples and calibrators are incubated with <sup>125</sup>I-labeled angiotensin I, as a tracer, in polyclonal antibody-coated tubes. After incubation, the contents of the tubes are rinsed so as to remove unbound <sup>125</sup>I-labeled tracer. The bound radioactivity is then determined in a gamma counter. The angiotensin I concentrations in the samples are obtained by interpolation from the standard curve. The concentration of angiotensin I in the samples is indirectly proportional to the radioactivity.

## WARNING AND PRECAUTIONS

### General remarks:

- Enzymatic inhibitor solution, calibrators, control sample and analyzed samples must be cooled to 2-8°C before pipeting.
- The vials with calibrators and controls should be opened as shortly as possible to avoid excessive evaporation.
- Do not mix the reagents from kits of different lots.
- A standard curve must be established with each assay.
- It is recommended to perform the immunoassay in duplicate.
- Each tube must be used only once.

### Basic rules of radiation safety

The purchase, possession, utilization, and transfer of radioactive material is subject to the regulations of the country of use. Adherence to the basic rules of radiation safety should provide adequate protection:

- No eating, drinking, smoking or application of cosmetics should be carried out in the presence of radioactive materials.
- No pipetting of radioactive solutions by mouth.
- Avoid all contact with radioactive materials by using gloves and laboratory overalls.
- All manipulation of radioactive substances should be done in an appropriate place, distant from corridors and other busy places.
- Radioactive materials should be stored in the container provided in a designated area.
- A record of receipt and storage of all radioactive products should be kept up to date.
- Laboratory equipment and glassware which are subject to contamination should be segregated to prevent cross-contamination of different radioisotopes.
- Each case of radioactive contamination or loss of radioactive material should be resolved according to established procedures.
- Radioactive waste should be handled according to the rules established in the country of use.

### Sodium azide

Some reagents contain sodium azide as a preservative. Sodium azide can react with lead, copper or brass to form explosive metal azides. Sodium azide disposal must be in accordance with appropriate local regulations.

## Materials of human origin

The materials of human origin, contained in this kit, were found negative for the presence of antibodies to HIV 1 and HIV 2, antibodies to HCV, as well as of Hepatitis B surface antigen (HBsAg). However, they should be handled as if capable of transmitting disease. No known test method can offer total assurance that no virus is present. Handle this kit with all necessary precautions.

All patient specimens should be handled as potentially infectious and waste should be discarded according to the country rules.

## GHS HAZARD CLASSIFICATION

Tracer

WARNING



H317  
H412  
P273  
P280

May cause an allergic skin reaction.  
Harmful to aquatic life with long lasting effects.  
Avoid release to the environment.  
Wear protective gloves, protective clothing and eye/face protection.  
If skin irritation or rash occurs: Get medical advice/attention.  
Take off contaminated clothing and wash it before use.  
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

P333+P313  
P362+P364

Inhibitor

DANGER



H317  
H360  
P201  
P280

May cause an allergic skin reaction.  
May damage fertility or the unborn child.  
Obtain special instructions before use.  
Wear protective gloves, protective clothing and eye/face protection.  
IF exposed or concerned: Get medical advice/attention.  
If skin irritation or rash occurs: Get medical advice/attention.  
Take off contaminated clothing and wash it before use.  
8-Hydroxyquinoline 0.1 - 0.2%

P308+P313  
P333+P313  
P362+P364

Wash solution U (20x)

DANGER



H360  
P201  
P280

May damage fertility or the unborn child.  
Obtain special instructions before use.  
Wear protective gloves, protective clothing and eye/face protection.  
IF exposed or concerned: Get medical advice/attention.  
Boric Acid 0.1 - 0.3%  
Sodium Borate Decahydrate 0.1 - 0.3%

P308+P313



Safety Data Sheet is available at [beckmancoulter.com/techdocs](http://beckmancoulter.com/techdocs)

## SPECIMEN COLLECTION, PROCESSING, STORAGE AND DILUTION

- Plasma samples have to be collected into cold EDTA tubes.
- Separate plasma from cells by centrifugation at 2-8°C.
- Keep plasma samples frozen (<-20°C, 1 year maximum) if determination is not to be performed immediately, after aliquoting in order to avoid repeated freezing and thawing.

Note: The temperature of plasma samples must be kept at 2-8°C in the course of sampling. Avoid further manipulation to prevent both formation and decomposition of angiotensin I.

- If samples have concentrations greater than the highest calibrator, they must be diluted into the zero calibrator.

## MATERIALS PROVIDED

All reagents of the kit are stable until the expiry date indicated on the kit label, if stored at 2-8°C. Expiry dates printed on vial labels apply to the long-term storage of components by the manufacturer only, prior to assembly of the kit. Do not take into account.

Storage conditions for reagents after reconstitution or dilution are indicated in paragraph Procedure.

**Tubes: 2 x 50** (ready-to-use)

**<sup>125</sup>I-Tracer: one 11 mL vial** (ready-to-use)

The vial contains 260 kBq, at the date of manufacture, of <sup>125</sup>I-labeled angiotensin I in buffer with bovine serum albumin and a dye.

**Calibrators: six 1 mL vials** (ready-to-use)

The calibrator vials contain from 0 to approximately 30 ng/mL of angiotensin I in buffer with bovine serum albumin and sodium azide (<0.1%). The exact concentration is indicated on each vial label. The calibrators are traceable to the international standard 86/536.

**Control sample: one 1 mL vial** (ready-to-use)

The vial contains angiotensin I in buffer with bovine serum albumin and sodium azide (<0.1%). The concentration range is indicated on a supplement. The control sample is traceable to the international standard 86/536.

**Inhibitor: one vial** (lyophilized)

Inhibitor contains sodium azide (<0.1%).

**Wash solution U (20X): one 50 mL vial**

Concentrated solution has to be diluted before use. It may be ordered separately, too (REF. A54825).

## **MATERIALS REQUIRED, BUT NOT PROVIDED**

In addition to standard laboratory equipment, the following items are required:

- Precision micropipette (75 µL).
- Semi-automatic pipette (100 µL, 200 µL, 2 mL).
- Water bath.
- Ice bath.
- Vortex type mixer.
- Horizontal or orbital shaker.
- Aspiration system.
- Gamma counter set for <sup>125</sup>I.

## **PROCEDURE**

### **Preparation of reagents**

#### **Preparation of enzymatic inhibitor solution**

The content of the vial is reconstituted with the volume of cold distilled water (4°C) indicated on the label and mixed. The reconstituted enzymatic inhibitor may be stored at 2-8°C until the expiry date of the kit.

Occasional presence of turbidity in Inhibitor after reconstitution does not affect assay performance.

#### **Preparation of wash solution**

Pour the content of the vial into 950 mL of distilled water and homogenize. The diluted solution may be stored at 2-8°C until the expiry date of the kit.

### **Enzymatic step – generation of angiotensin I**

#### **Remarks and recommendations**

- The enzymatic inhibitor has to be cooled to 4°C before addition to the sample.
- Both incubation temperatures (4°C and 37°C) must be adhered to strictly, even slight variations may cause severe errors in determination.
- The enzymatic incubation time at 37°C should be determined as precisely as possible and kept within narrow limits for the whole set of tubes.
- The promptness of the temperature increase from 4°C to 37°C and the following reverse drop are critical. A circulating water bath is convenient for warming and, the use of an iced-cooled water bath is advisable for cooling.
- The promptness of the temperature increase and drop may be improved by using tubes made of material with good thermal conductivity (glass).
- If low plasma renin activity of the sample is expected, the incubation time of the enzymatic step may be prolonged for up to 3 hours.

#### **Enzymatic step – procedure**

**Attention: Do not treat the calibrators and the control sample.**

- Add 200 µL of pre-cooled enzymatic inhibitor to 200 µL of each plasma sample and mix.
- Split each sample into two 200 µL aliquots.
- Place the first aliquot into an ice-cold water bath in a refrigerator (intended for the determination of background angiotensin I at 4°C).
- Place the second one into the water bath set for 37°C (intended for the determination of generated angiotensin I at 37°C).

- Incubate all aliquots for 1 hour.
- After incubation, cool samples from 37°C to 4°C rapidly using ice water bath.

### Assay procedure

| Step 1<br>Additions*   | Step 2<br>Incubation                                  | Step 3<br>Counting   |
|--|---|--|
| To coated tubes add successively:<br><br>75 µL of calibrator, control or sample after enzymatic incubation at 37°C and at 4°C respectively and 100 µL of tracer.**<br><br>Vortex gently 1-2 seconds. | Incubate 2 hours at 18-25°C with shaking (≥ 280 rpm). | Aspirate carefully the contents of tubes (except the 2 tubes "total cpm").<br>Wash with 2 mL of wash solution.<br>Aspirate twice.<br><br>Count bound cpm (B) and total cpm (T) for 1 minute. |

\*. Calibrators, control sample and analyzed samples have to be cooled to 4°C before pipetting. Mix samples gently before they are added.

\*\*.. Add 100 µL of tracer to 2 additional tubes to obtain «total cpm».

## RESULTS

Results are obtained from the calibrator curve by interpolation. The curve serves for the determination of analyte concentrations in samples measured at the same time as the calibrators.

### Standard curve

The results in the quality control department were calculated using *cubic regression* curve fit with logit of  $B/T$  or  $B/B_0$  on the vertical axis and log of analyte concentration of the calibrators on the horizontal axis.

Other calculation methods may give slightly different results.

| Total activity: 68,511 cpm |                       |           |         |                      |
|----------------------------|-----------------------|-----------|---------|----------------------|
| Calibrators                | Angiotensin I (ng/mL) | cpm (n=3) | B/T (%) | B/B <sub>0</sub> (%) |
| 0                          | 0.00                  | 17,444    | 25.5    | 100.0                |
| 1                          | 0.30                  | 13,732    | 20.0    | 78.7                 |
| 2                          | 1.00                  | 9,390     | 13.7    | 53.8                 |
| 3                          | 3.00                  | 5,431     | 7.93    | 31.1                 |
| 4                          | 10.0                  | 2,746     | 4.01    | 15.7                 |
| 5                          | 30.0                  | 1,243     | 1.81    | 7.13                 |

(Example of standard curve, do not use for calculation)

### Samples

For the control and samples incubated at 4°C, or at 37°C, locate the B/T or the B/B<sub>0</sub> value on the vertical axis and read off the corresponding angiotensin I concentration in ng/mL on the horizontal axis.

Calculation of plasma renin activity

The determination of plasma renin activity is performed indirectly by the measurement of the in vitro generation of angiotensin I (A-I) per hour. Background A-I, determined on plasma samples incubated at 4°C, is subtracted from the A-I generated at 37°C for the calculation of PRA using the following equation:

$$\text{PRA ng of A-I /mL/hr} = \frac{[ \text{A-I (37°C)} - \text{A-I (4°C)} ] \times 2}{\text{Enzymatic incubation time (hrs)}}$$

Where

A-I (37°C): angiotensin concentration in ng/mL of sample incubated at 37°C

A-I (4°C) : angiotensin concentration in ng/mL of sample incubated at 4°C

## EXPECTED VALUES

We recommend each laboratory to establish its own reference values. The following values obtained from healthy subjects are indicative only.

| N  | Normal adult          | 2.5 <sup>th</sup> - 97.5 <sup>th</sup> percentile (ng/mL/hr) | Median (ng/mL/hr) | Min - Max (ng/mL/hr) |
|----|-----------------------|--|-------------------|----------------------|
| 38 | Early Morning, Supine | 0.32 - 1.84  | 0.79              | 0.30 - 1.90          |
| 41 | Upright, 2 Hours      | 0.60 - 4.18  | 2.20              | 0.48 - 4.88          |

Detail information about expected values for children (sorted according to age) can be found in the data sheet "APPENDIX".

## QUALITY CONTROL

Good laboratory practices imply that control samples be used regularly to ensure the quality of the results obtained. These samples must be processed exactly in the same way as the assay samples, and it is recommended that their results be analyzed using appropriate statistical methods.

Failure to obtain the appropriate values for controls may indicate imprecise manipulations, improper sample handling or deterioration of reagents.

In case of packaging deterioration or if data obtained show some performance alteration, please contact your local distributor or use the following e-mail address: [imunochem@beckman.com](mailto:imunochem@beckman.com)

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of EU Member State in which the user and/or patient is located.

## PERFORMANCE CHARACTERISTICS

*(For more details, see the data sheet "APPENDIX")*

Representative data are provided for illustration only. Performance obtained in individual laboratories may vary.

### Sensitivity

**Analytical sensitivity:** 0.07 ng/mL

**Functional sensitivity:** 0.20 ng/mL

### Specificity

The antibody used in the immunoassay is highly specific for angiotensin I. Extremely low cross reactivity was obtained against several molecules.

Moreover, the influence of possible interferences on PRA result is eliminated by subtraction of background.

### Precision

#### Intra-assay

Samples were assayed in 25 replicates in the same series. The coefficients of variation were found below or equal to 11.3%.

#### Inter-assay

Samples were assayed in duplicate in 10 different series. Coefficients of variation were found below or equal to 20.9%.

### Accuracy

#### Dependence on time of enzymatic incubation

The samples were incubated with enzymatic inhibitor for 60, 120, and 180 minutes. No significant effect on PRA results was found.

#### Dilution test

High-concentration plasma samples were serially diluted in the zero calibrator. The recovery percentages obtained were between 78.2% and 98.8%.

#### Recovery test

Low-concentration plasma samples were spiked with known quantities of angiotensin I. The recovery percentages obtained were between 104% and 123%.

**Measurement range** (from analytical sensitivity to the highest calibrator): 0.07 to approximately 30 ng/mL.

## LIMITATIONS

Failure to follow these instructions for use (IFU) may significantly affect results.

Results should be interpreted in the light of the total clinical presentation of the patient, including clinical history, data from additional tests and other appropriate information.

Do not use hemolyzed, lipemic or icteric samples. For more details, see Appendix, § Interference.

In immunoassays, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interfere with immunoassays. Immunoassays may be also affected by presence of anti-avidin or anti-streptavidin antibodies, as well as by the presence of autoantibodies directed against the determined analyte. Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies [3, 4, 5].

## APPENDIX

### PERFORMANCE CHARACTERISTICS

Representative data are provided for illustration only. Performance obtained in individual laboratories may vary.

#### Interference

Plasma samples containing angiotensin I concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using Angiotensin I RIA KIT. Values were calculated as described in CLSI EP07, 3<sup>rd</sup> ed. [6]. Interference was determined by testing controls (no interfering substance added) and matched test samples (with interfering substance added). No interference (defined as a shift in dose > 15 %) was found for addition of interferent up to concentration stated in the table below.

| Interferent            | Test concentration |
|------------------------|--------------------|
| Biotin                 | 1,631 ng/mL        |
| Conjugated bilirubin   | 474.4 µg/mL        |
| Hemoglobin             | 10,044 µg/mL       |
| Triglycerides          | 15.20 mg/mL        |
| Unconjugated bilirubin | 384.3 µg/mL        |

In spite of hemoglobin, bilirubin (conjugated, unconjugated) and triglyceride interference data in the table, we advise to avoid using hemolyzed, lipemic or icteric samples.

#### Specificity

| Analogue         | Cross-reactivity (%) |
|------------------|----------------------|
| Angiotensin I    | 100                  |
| Angiotensin II   | ND                   |
| Angiotensin III  | ND                   |
| Tetradecapeptide | ND                   |
| Angiotensinogen  | ND                   |

ND = Non-detectable

#### Precision

##### Intra-assay

| Sample                   | P1    | P2    |
|--------------------------|-------|-------|
| Number of determinations | 25    | 25    |
| PRA, ng/mL/hour          | 1.49  | 2.94  |
| CV (%)                   | 11.25 | 11.25 |

##### Inter-assay

After generation of Angiotensin I, samples were determined in duplicates in 10 different series according to the procedure of the kit. Plasma renin activity was obtained and used for the calculation of inter-assay precision.

| Sample                   | P1   | P2   | P3   | P4    | P5    |
|--------------------------|------|------|------|-------|-------|
| Number of determinations | 10   | 10   | 10   | 10    | 10    |
| PRA, ng/mL/hour          | 0.69 | 3.37 | 7.08 | 15.09 | 24.15 |
| CV (%)                   | 20.9 | 9.57 | 8.72 | 9.74  | 11.8  |

#### Accuracy

##### Dependence on time of enzymatic incubation

No dependence of PRA on time was observed.

| Time, minutes     |          | 60   | 120  | 180  |
|-------------------|----------|------|------|------|
| PRA<br>ng/mL/hour | Sample 1 | 0.30 | 0.32 | 0.33 |
|                   | Sample 2 | 0.56 | 0.48 | 0.53 |
|                   | Sample 3 | 1.04 | 1.15 | 1.19 |
|                   | Sample 4 | 1.64 | 1.56 | 1.65 |
|                   | Sample 5 | 5.12 | 5.19 | 4.93 |

### Dilution test

Samples were diluted in zero calibrator and assayed according to the assay procedure of the kit.

| Sample | Dilution factor | Theoretical conc. | Observed conc. | Recovery (%) |
|--------|-----------------|-------------------|----------------|--------------|
|        |                 | (ng/mL)           |                |              |
| P1     | -               | -                 | 2.45           | -            |
|        | 1:2             | 1.23              | 1.21           | 98.78        |
|        | 1:4             | 0.61              | 0.56           | 91.43        |
|        | 1:8             | 0.31              | 0.27           | 88.16        |
| P2     | -               | -                 | 3.05           | -            |
|        | 1:2             | 1.53              | 1.46           | 95.74        |
|        | 1:4             | 0.76              | 0.64           | 83.93        |
|        | 1:8             | 0.38              | 0.34           | 89.18        |
| P3     | -               | -                 | 9.21           | -            |
|        | 1:2             | 4.61              | 4.30           | 93.38        |
|        | 1:4             | 2.30              | 1.82           | 79.04        |
|        | 1:8             | 1.15              | 0.90           | 78.18        |
|        | 1:16            | 0.58              | 0.45           | 78.18        |

### Recovery test

Plasma samples were spiked with known quantities of angiotensin I and assayed according to the procedure of the kit.

| Initial conc. (ng/mL) | Added angiotensin (ng/mL) | Observed conc. (ng/mL) | Observed addition (ng/mL) | Recovery (%) |
|-----------------------|---------------------------|------------------------|---------------------------|--------------|
| 0.88                  | 1.01                      | 1.89                   | 2.09                      | 110.7        |
|                       | 1.30                      | 2.18                   | 2.68                      | 122.9        |
|                       | 1.93                      | 2.81                   | 3.20                      | 113.9        |
| 1.39                  | 1.01                      | 2.40                   | 2.64                      | 110.2        |
|                       | 1.30                      | 2.69                   | 2.98                      | 110.8        |
|                       | 1.93                      | 3.32                   | 3.59                      | 108.2        |
| 1.54                  | 1.01                      | 2.54                   | 2.84                      | 111.7        |
|                       | 1.30                      | 2.84                   | 3.31                      | 116.7        |
|                       | 1.93                      | 3.46                   | 4.03                      | 116.4        |
| 2.60                  | 1.01                      | 3.61                   | 3.83                      | 106.2        |
|                       | 1.30                      | 3.90                   | 4.59                      | 117.7        |
|                       | 1.93                      | 4.53                   | 5.20                      | 114.9        |
| 2.62                  | 1.01                      | 3.62                   | 3.75                      | 103.5        |
|                       | 1.30                      | 3.92                   | 4.19                      | 107.0        |
|                       | 1.93                      | 4.55                   | 4.82                      | 106.0        |

### Expected data for children

Results are sorted according to age.

| Children    |    | Angiotensin (ng/mL/hr) |      |        |                              |                               |
|-------------|----|------------------------|------|--------|------------------------------|-------------------------------|
| Upright     | N  | Min                    | Max  | Median | 2.5 <sup>th</sup> percentile | 97.5 <sup>th</sup> percentile |
| 2-9 years   | 27 | 0.60                   | 7.38 | 3.20   | 0.76                         | 6.64                          |
| 10-15 years | 16 | 0.58                   | 3.98 | 1.52   | 0.64                         | 3.93                          |

### <sup>125</sup>I Characteristics

$T_{1/2} (^{125}\text{I}) = 1443 \text{ h} = 60.14 \text{ d}$

| <sup>125</sup> I   | E (MeV) | %     |
|--------------------|---------|-------|
| $\gamma$           | 0.035   | 6.5   |
| $K_{\alpha}$ X-ray | 0.027   | 112.5 |
| $K_{\beta}$ X-ray  | 0.031   | 25.4  |

## Symbols Key

### **DANGER**

Danger / Danger / Gefahr / Pericolo / Peligro / Perigo / Fara / Κίνδυνος / 危險 / Pavojus / Veszély! / Niebezpieczeństwo / Nebezpečí / Nebezpečnostvo / 위험 / Tehlike / Опасно! / Опасност / 危險

### **REF**

Product Reference / Référence du produit / Produktreferenz / Riferimento prodotto / Número de referencia del producto / Referência do produto / Produktreferens / Κωδικός αναφοράς προϊόντος / 产品参考 / Gaminio nuoroda / Termékszám / Dane referencyjne produktu / Reference k produktu / Referenčné označenie výrobku / 제품 참조 자료 / Ürün Referansı / Ссылка на продукт / Референца за производ / 產品參考

### **IVD**

In Vitro Diagnostic / Diagnostic in vitro / In-vitro-Diagnostikum / Diagnostica in vitro / Para diagnóstico in vitro / Diagnóstico in vitro / InVitro-diagnostik / Για διάγνωση in vitro / 体外诊断 / In vitro diagnostika / In vitro diagnosztikai felhasználásra / Diagnostyka in vitro / Diagnostika in vitro / 체외 진단 / In Vitro Diagnostik / Диагностика in vitro / За ин витро диагностика / 體外診斷

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### **SDS**

Safety Data Sheet / Fiche technique santé-sécurité / Sicherheitsdatenblatt / Scheda dati di sicurezza / Hoja de datos de seguridad / Ficha de Dados de Segurança / Säkerhetsdatablad / Φύλλο Δεδομένων Ασφάλειας / 安全数据单 / Saugos duomenų lapas / Biztonsági adatlap / Karta Charakterystyki Bezpieczeństwa / Bezpečnostní list / Bezpečnostný list / 안전보건자료 / Güvenlik Bilgi Formu / Паспорт безопасности / Информационен Лист За Безопасност / 安全性資料表



Consult Instructions for Use / Consultez le mode d'emploi / Siehe Gebrauchsanweisung / Consultare le istruzioni per l'uso / Consulte las Instrucciones de uso / Instruções de utilização / Konsultera bruksanvisning / Συμβουλευτείτε τις οδηγίες χρήσης / 请参阅使用说明 / Skaitykite naudojimo instrukciją / Olvassa el a használati utasítást / Zapoznać się z instrukcją użycia / Postupujte podle návodu k použití / Prečítajte si návod na použitie / 사용 안내 문의 / Kullanma Talimatına Başvurun / Обратитесь к инструкциям / Вижте Инструкциите за употреба / 請參閱使用說明



Temperature range(s) / Plage(s) de température / Temperaturbereich(e) / Intervallo/i di temperatura / Intervalo(s) de temperatura / Intervalo(s) de temperatura / Temperaturintervall / Εύρος(-η) θερμοκρασίας / 溫度範圍 / Temperatūros diapazonas (-ai) / Hőmérséklet-tartomány(ok) / Zakres(y) temperatury / Rozsahy teplot / Rozsah(y) teploty / 온도 범위 / Sicaklik araliklari / Диапазон(-ы) температуры / Температурен(ни) диапазон(и) / 溫度範圍 請參閱使用說明



Caution / Précaution / Achtung / Attenzione / Precaución / Atenção / Försiktighet / Προσοχή / 注意事項 / [spéjimas / Figyelem / Uwaga / Upozornění / Upozornenie / 주의 / Dikkat / Внимание / 注意



Expiration Date / Date D'expiration / Verfallsdatum, Verw. bis: / Data Di Scadenza / Fecha De Caducidad / Data de validade / Utgångsdatum / Ημερομηνία λήξης / 失效日期 / Galiojimo data / Lejárati idő / Data ważności / Datum expirace / Dátum expirácie / 만료 날짜 / Son Kullanma Tarihi / Срок годности / Срок на годност / 到期日

### **LOT**

Lot Number / Numéro de lot / Chargennummer / Numero di lotto / Lote número / Número de lote / Satsnummer / Αριθ. παρτίδας / 批次号 / partijos numeris / Tételszám / Numer serii / Číslo šarže / 로트 번호 / Lot Numarası / Номер партии / Номер на партида / 批號



Date of Manufacture / Date de Fabrication / Herstellungsdatum / Data di Fabbricazione / Fecha de Fabricación / Data de fabrico / Produktionsdatum / Ημερομηνία Παραγωγής / 生产日期 / Pagaminimo Data / Gyártás Dátuma / Data Produkcji / Datum Výroby / Dátum Výroby / 제조 일자 / Üretim Tarihi / Дата Производства / Дата на Производство / 製造日期





Biohazard / Risque biologique / Biogefährdung / Rischio biologico / Riesgo biológico / Risco biológico / Biologisk fara / Βιολογικός κίνδυνος / 生物危害 / Biologisk fara / Veszélyes biológiai anyag / Zagrożenie biologiczne / Biologické riziko / Biologické riziko / 생물학적 위험 / Biolojik tehlike / Биологическая опасность / Биологична опасност / 生物危害



Radioactive / Radioactif / Radioaktiv / Radioattivo / Radiactivo / Radioactivo / Radioaktivt / Ραδιενεργό / 放射性 / Radioaktyvioji medžiaga / Radioaktiv / Radioaktywny / Radioaktívni / Rádioaktívny / 방사성 / Radyoaktif / Радиоактивный / Радиоактивен / 具放射性

Ag <sup>125</sup>I

Ab <sup>125</sup>I

Tracer / Tracéur / Tracer / Marcato / Trazador / Marcador / Tracer / Ανιχνευτής / 追踪剂 / Ateksamoi medžiaga / Nyomjelző / Znacznik / Radioindikátor / Indikátor (tracer) / 트레이서 / Tracer'lar / метка / Индикатор / 追踪剂

CAL

CAL 0

Calibrator / Calibrateur / Kalibrator / Calibratore / Calibrador / Calibrador / Kalibrator / Βοηθουομητής / 校准品 / Kalibravimo medžiaga / Kalibrátor / Kalibrator / kalibrátor / Kalibrátor / 보정 물질 / Kalibratör / Калибратор / Калибратор / 校正液

CTRL

Control / Contrôle / Kontrolle / Controllo / Control / Controllo / Kontrolle / Μάρτυρας / 质控品 / Kontrolliné / Kontroll / Kontrola / Kontrola / Kontrola / 정도관리 / Kontrol / Контроль / Контролна / 质控品

TUBE

Tubes / tubes / Röhrchen / provette / tubos / Tubos de amostra / Provrör / σωληνάρια / 试管 / Mégintüveliai / Csövek / Probówki / Zkumavky / Skúmavky / 튜브 / Tüpler / пробирки / Епруветки / 試管

IFU

Instruction for Use / Mode d'emploi / Gebrauchsanweisung / Istruzioni per l'uso / Instrucciones de uso / Instruções de utilização / Bruksanvisning / Οδηγίες χρήσης / 使用说明 / Naudojimo instrukcija / Használati utasítás / Instrukcja użycia / Návod k použití / Návod na použitie / 사용 안내 / Kullanma Talimatı / Инструкции / Инструкции за употреба / 使用说明

SOLN WASH 20X

Wash Solution Concentrate 20X / Solution de lavage concentrée 20X / Waschlösungskonzentrat 20X / Concentrato di soluzione di lavaggio 20X / Solución de lavado concentrada 20X / Concentrado de solução de lavagem 20X / Tvättlösingskoncentrat 20X / Συμπυκνωμένο διάλυμα πλύσης 20X / 浓缩清洗液 20X / Plovimo tirpalo koncentratas 20X / 20X mosóoldat-koncentrátum / Koncentrat 20X roztworu płuczącego / Koncentrát mycího roztoku 20X / Koncentrát premývacieho roztoku 20X / 농축 세척액(20배) / Yıkama Çözültisi Konsantresi 20X / Концентрат промывочного раствора 20X / Концентрат на разтвор за промиване 20X / 清洗溶液濃縮 20X

INH

Inhibitor / Inhibiteur / Inhibitor / Ihibitore / Inhibidor / Hämmare / Αναστολέας / 抑制剂 / Inhibitorius / Inhibitor / Inhibitor / Inhibitor / Inhibitor / 억제인자 / Inhibitor / ингибитор / Инхибитор / 抑制劑

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IMMUNOTECH s.r.o., Radiova 1122/1, 102 00 Prague 10, Czech Republic  
www.beckmancoulter.com