

**1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY****1.1 Product identifier**Product Name: DIASpot Neptune Cytoplasm<sup>6</sup> IgG

Catalog #: KAPDTCY6N

Kit Components: Diluent Buffer  
Wash Buffer  
Conjugate  
Substrate  
Dot Strips  
Cartridge**1.2 Intended Use**

Immunodot kit (professional IVD use only, automated on the Neptune Instrument) for the detection of IgG antibodies to M2/nPDC, Jo-1, PL-7, PL-12, SRP-54 and Ribosomal P0 antigens in human serum.

**1.3 Company**DIAsource ImmunoAssays S.A.  
Rue du Bosquet, 2  
B-1348 Louvain-la-Neuve  
Belgium  
Tel. Nr. +32 (0)10/84.99.11  
E-mail: [tech.support@diasource.be](mailto:tech.support@diasource.be)**1.4 Emergency telephone**DIAsource (only office hours): +32 (0)10/84.99.23  
Centre Anti-Poisons (BE) 070 245 245  
Please refer to your local Anti-Poison Center!**2 HAZARDS IDENTIFICATION****2.1 Classification of the substance or mixture**According to *Regulation (EC) N° 1272/2008* the preparation is not classified as dangerous.**2.2 Label elements**According to *Regulation (EC) N° 1272/2008*: none**2.3 Other hazards**

The products / product components contain preservatives which may possess in their given concentration, skin-sensitizing and slightly polluting properties. As any chemicals contain specific hazards, the products / product components should only be handled by appropriately trained personnel and with the necessary precautions for chemicals.


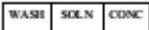



### 3 COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

N/A (see hereunder: mixture)

#### 3.2 Mixtures

| Abbreviation | Substance                          | Abbreviation | Substance            |
|--------------|------------------------------------|--------------|----------------------|
| AP           | Alkaline Phosphatase               | NBT          | NitroBlueTetrazolium |
| BCIP         | Bromo-Chloro-Indolyl-Phosphate     | TBS          | Tris Buffer Saline   |
| MIT          | MethylIsoThiazolone (preservative) |              |                      |

| Contents  | Quantity   | Ingredients  |
|---|--|--|
| <b>1. Cartridge</b>   |  |  |
| <b>24 units having each 7 compartments (Position I to VII); sealed, containing:</b>                   |  |  |
| Sample Buffer<br>    | Position I, 1 x 1,4 mL<br>(yellow)   | TBS, Sodium Chloride, Tween 20, Dye, MIT, antifoam emulsion  |
| Wash Buffer<br>      | Position II, III, IV, VI, 1 x<br>1,4 mL (colourless)                                       | TBS, Sodium Chloride, Tween 20, MIT, antifoam emulsion   |
| Conjugate<br>        | Position V, 1 x 1,4 mL<br>(red)  | TBS, Sodium Chloride, Potassium Chloride, Magnesium Chloride, Goat anti-human IgG/AP, Dye, MIT, antifoam emulsion  |
| Substrate<br>       | Position VII, 1 x 1,4 mL<br>(pale yellow)  | TBS, Magnesium Chloride, BCIP, NBT, NBT Stabilizer, Sodium Azide, antifoam emulsion  |
| <b>2. Strips</b>  |  |  |
| <b>3 x 8 units on plastic supports, breakable individually; sealed</b>                                |  |  |
| Membrane Strip<br> | <b>8 dots on each:</b><br>1 positive control (C+)<br>6 antigens<br>1 negative control (C-) | Membrane-coated with purified antigens:<br><b>M2/nPDC</b> (E1, E2, E3 subunits of Pyruvate Dehydrogenase Complex, purified from bovine heart),<br><b>Jo-1</b> (Histidyl-tRNA synthetase, recombinant, human),<br><b>PL-7</b> (Threonyl-tRNA synthetase, recombinant, human),<br><b>PL-12</b> (Alanyl-tRNA synthetase, recombinant, human),<br><b>SRP-54</b> (54 kD subunit of the Signal Recognition Particle, recombinant, human),<br><b>Ribosome P0 Protein</b> (P0-38 kDa, recombinant, human). |

**Hazardous Substances and their concentrations**

The Hazard Classification listed in this section refers to the chemical at *a pure concentration*. It has been determined that the remaining ingredient(s) of these components are not classified as hazardous chemicals due to their physical and/or chemical nature and/or concentration in solution (see concentration here in the table).

| Name | CAS        | EINECS | Concentration in mixture | Classification (in concentrated form) according to Regulation |  |
|------|------------|--------|--------------------------|---|--|
|      |            |        |                          | 1999-45/EC Significance R Phrases                             | EC 1272/2008 Significance H Phrases  |
| MIT  | 55965-84-9 | -      | < 0,0015 %               | T<br>R23/24/25;<br>R34; R43<br><br>N<br>R50/53                | Acute tox. 3<br>H331, H311, H301<br><br>Skin Corr. 1B.<br>H314<br>Skin Sens. 1<br>H317<br><br>Aquatic acute 1 ;<br>Aquatic chronic 1<br>H410 |

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| Name | CAS      | EINECS    | Concentration in mixture | Classification (in concentrated form) according to Regulation |                                     |
|------|----------|-----------|--------------------------|---|-------------------------------------|
|      |          |           |                          | 1999-45/EC Significance R Phrases                             | EC 1272/2008 Significance H Phrases |
| NBT  | 298-83-9 | 206-067-4 | < 0,01%                  | Xn (Nocif)<br>R20/R22   | Acute tox. 4<br>H302                |

| Name         | CAS        | EINECS    | Concentration in mixture | Classification (in concentrated form) according to Regulation |   |
|--------------|------------|-----------|--------------------------|---|---|
|              |            |           |                          | 1999-45/EC Significance R Phrases                             | EC 1272/2008 Significance H Phrases                 |
| Sodium Azide | 26628-22-8 | 247-852-1 | < 0.1 %                  | T+<br>R28; R32<br><br>N<br>R50/53                             | Acute tox. 2<br>H300<br><br>Aquatic acute 1<br>H400 |

Annex VI to Regulation (EC) No 1272/2008: Index Number: 011-004-00-7

Abbreviations and significances:

CAS: Chemical Abstract Service (division of the American Chemical Society)

EINECS: European Inventory of Existing Commercial Chemical Substances

C: N:dangerous for the T:toxic T+:very Xn:harmful

Information on significance of R and H Phrases: see Section16

**4 FIRST AID MEASURES**

|                           | SYMPTOMS   | FIRST AID  |
|---------------------------|--|--|
| <b>Contact with eyes:</b> | Irritation. Tears  | Immediately flush eyes large volume of water.  |
| <b>Contact with skin:</b> | Irritation   | Immediately wash skin with soap and thoroughly with water.   |
| <b>Ingestion:</b>         | It is recommended to avoid ingestion and contact with food | If swallowed, wash out mouth with water provided the person is conscious; seek medical advice (showing this document when possible). Never give anything by mouth to an unconscious person; never try to make an unconscious person vomit. |

**5 FIRE FIGHTING MEASURES**

|  |  |
|--|--|
| <b>Flammability:</b>                     | Liquid reagents contained in the kit are not flammable.<br>Combustion of cardboard inserts inside the kit and the outer cardboard box of the kit may produce intense heat.   |
| <b>Extinguishing Media:</b>              | Water, carbon dioxide, dry chemical powder or polymer foam.<br>Use extinguishing media appropriate to surrounding fire conditions.   |
| <b>Special Fire Fighting Procedures:</b> | For fires involving this material, do not enter any enclosed or confined fire space without proper protective equipment. This may include self-contained breathing apparatus to protect against the hazardous effects of the normal products of combustion or oxygen deficiency. |

**6 ACCIDENTAL RELEASE MEASURES**
**6.1 Personal Precautions**

Always observe GLP (Good Laboratory Practice) safety lines. To avoid contact with skin and eyes wear appropriate protective clothing. Do not swallow, do not pipette by mouth.

**6.2 Environmental Precautions**

Avoid flushing away in drains; keep away from surface- and ground-water; keep away from soil.

**6.3 Methods and material for containment and cleaning up**

Sweep up and collect in appropriate containers for waste disposal; clean the floor and all other contaminated objects with water.

**6.4 Reference to other sections**

N/A

**7 HANDLING AND STORAGE**
**7.1 Precautions for safe handling**

Always observe GLP (Good Laboratory Practice) safety lines. Wear appropriate protective clothing (refer to point 8.2). Wash hands and any other exposed zones with water and mild soap before eating, drinking, smoking and leaving workplace. Check the local and general ventilation of the workplace. Take any measures to prevent aerosol and dust generation and fire. Dispose of the waste according to safety measures of GLP.

**7.2 Conditions for safe storage, including any incompatibilities**

Always store the product according to instructions given on the label.

Always observe given temperature and humidity limit/range.

**7.3 Specific end use(s)**

N/A

**8 EXPOSURE CONTROLS/PERSONAL PROTECTION**
**8.1 Control parameters**

| Name         | Comment  |
|--------------|--|
| MIT          | Contains no substances with occupational exposure limit values |
| NBT          | Contains no substances with occupational exposure limit values |
| Sodium Azide | TWA value 0,1 mg/m <sup>3</sup> (in EU)                        |

TWA: Time Weighted Average, i.e. the average exposure to a contaminant to which workers may be exposed without adverse effect over a period such as in an 8-hour day or 40-hour week (an average work shift). They are usually expressed in units of ppm (volume/volume) or mg/m<sup>3</sup>.

**8.2 Exposure controls**

|                                |                                    |
|--------------------------------|------------------------------------|
| <b>Respiratory protection:</b> | None                               |
| <b>Gloves:</b>                 | Laboratory nitrile or latex gloves |
| <b>Eye protection:</b>         | Goggles                            |
| <b>Skin protection</b>         | Laboratory coat                    |

**9 PHYSICAL AND CHEMICAL PROPERTIES**
**9.1 Information on basic physical and chemical properties**

|  | Kit Reagent   |   |   |                                       |
|--|---|---|---|---------------------------------------|
|  | <input type="checkbox"/> DIL <input type="checkbox"/> BUF | <input type="checkbox"/> WASH <input type="checkbox"/> SOLN <input type="checkbox"/> CONC | <input type="checkbox"/> Ab <input type="checkbox"/> AP | <input type="checkbox"/> SUB          |
| <b>Appearance:</b>                                   | Liquid reagent<br>Colour: yellow                          | Liquid reagent<br>Colour: colourless  | Liquid reagent<br>Colour: red                           | Liquid reagent<br>Colour: pale yellow |
| <b>Odour:</b>  | Negligible  | Negligible  | Negligible  | Negligible                            |
| <b>Odour threshold:</b>                              | Not given   | Not given   | Not given   | Not given                             |
| <b>pH value:</b>                                     | Not given   | Not given   | Not given   | Not given                             |
| <b>Melting point/freezing point:</b>                 | Not given   | Not given   | Not given   | Not given                             |
| <b>Initial boiling point and boiling range:</b>      | Not given   | Not given   | Not given   | Not given                             |
| <b>Flash point:</b>                                  | N/A   | N/A   | N/A   | N/A                                   |
| <b>Evaporation rate:</b>                             | N/A   | N/A   | N/A   | N/A                                   |
| <b>Flammability :</b>                                | N/A   | N/A   | N/A   | N/A                                   |
| <b>Upper/lower flammability or explosive limits:</b> | Not explosive   | Not explosive   | Not explosive   | Not explosive                         |
| <b>Vapour pressure:</b>                              | Not given   | Not given   | Not given   | Not given                             |
| <b>Vapour density:</b>                               | Not given   | Not given   | Not given   | Not given                             |
| <b>Relative density:</b>                             | Not given   | Not given   | Not given   | Not given                             |
| <b>Solubility:</b>                                   | Completely soluble  | Completely soluble  | Completely soluble                                      | Completely soluble                    |
| <b>Partition coefficient n-octanol/water :</b>       | Not given   | Not given   | Not given   | Not given                             |
| <b>Auto-ignition temperature :</b>                   | Not given   | Not given   | Not given   | Not given                             |
| <b>Decomposition temperature :</b>                   | Not given   | Not given   | Not given   | Not given                             |
| <b>Viscosity :</b>                                   | Not given   | Not given   | Not given   | Not given                             |
| <b>Explosive properties :</b>                        | Not explosive   | Not explosive   | Not explosive   | Not explosive                         |

|                        | Kit Reagent |     |           |      |           |    |           |     |
|------------------------|-------------|-----|-----------|------|-----------|----|-----------|-----|
|                        | DIL         | BUF | WASH      | SOLN | CONC      | Ab | AP        | SUB |
| Oxidizing properties : | Not given   |     | Not given |      | Not given |    | Not given |     |

## 9.2 Other information

N/A

## 10 STABILITY AND REACTIVITY

### 10.1 Reactivity

Particular dangerous reactions not known

### 10.2 Chemical stability

Materials to avoid: None.

Chemical stability: If storage conditions and expiry date are correctly observed, the mixture / product components are chemically stable.

### 10.3 Possibility of hazardous reactions

Sodium Azide (in high concentrations) reacts with heavy metals such as copper or lead and forms explosive compounds.

### 10.4 Conditions to avoid

Avoid inappropriate storage (temperature, humidity, light, etc).

Avoid inappropriate use.

### 10.5 Incompatible materials

Acids, alkalis and solvents may adversely affect the functionality of the mixtures / product components.

### 10.6 Hazardous decomposition products

Under appropriate storage conditions and correct handling of the mixtures / product components, hazardous decomposition products are not known.

Combustion of cardboard inserts inside the kit and of the outer cardboard box of the kit does not liberate toxic gas (only carbon dioxide and water vapour).

## 11 TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute toxicity

| Ingredient   | Measured quantity       | Value      | Species |
|--------------|-------------------------|------------|---------|
| MIT          | LD <sub>50</sub> (oral) | -          | -       |
| NBT          | LD <sub>50</sub> (oral) | 2000 mg/kg | Mouse   |
| Sodium Azide | LD <sub>50</sub> (oral) | 27 mg/kg   | Rat     |

*LD<sub>50</sub> test: Lethal dose for 50% of the population of test animals*

**Other health effects**

| Ingredient   | Irritation and corrosivity | Sensitization     | CMR               |
|--------------|----------------------------|-------------------|-------------------|
| MIT          | No data available          | No data available | No data available |
| NBT          | No data available          | No data available | No data available |
| Sodium Azide | No data available          | No data available | No data available |

CMR: carcinogenic, mutagenic or toxic for reproduction

**12 ECOLOGICAL INFORMATION**
**12.1 Toxicity**

| Ingredient   | Toxicity for algae | Toxicity for daphnia | Toxicity for fish  | Toxicity for microorganisms |
|--------------|--------------------|----------------------|--|-----------------------------|
| MIT          | -                  | -                    | -  | -                           |
| NBT          | -                  | -                    | -  | -                           |
| Sodium Azide | -                  | -                    | LC50= 0.8 mg/L<br><i>Oncorhynchus mykiss</i> 96 h<br>LC50= 0.7 mg/L<br><i>Lepomis macrochirus</i> 96 h<br>LC50=5.46 mg/L<br><i>Pimephalespromelas</i> 96 h | -                           |

LC50 test: (Lethal Concentration 50) Standard measure of the toxicity of the surrounding medium that will kill 50 % of the sample population in a specified period through exposure via inhalation (respiration). LC50 is measured in micrograms (or milligrams) of the material per liter, or parts per million (ppm), of air or water.

**12.2 Persistence and degradability**

| Ingredient   | Measured quantity | Value | Comment |
|--------------|-------------------|-------|---------|
| MIT          | No data available | -     | -       |
| NBT          | No data available | -     | -       |
| Sodium Azide | No data available | -     | -       |

**12.3 Bioaccumulative potential**

No data available

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPVB assessment**

N/A

**12.6 Other adverse effects**

| Ingredient   | Effect   |
|--------------|--|
| MIT          | Very toxic to aquatic organisms, may cause long-term adverse effects |
| NBT          | No data available  |
| Sodium Azide | Very toxic to aquatic organisms                                      |

Due to the very low concentration of the toxic substance in the mixture / product ingredients, the handling and use of it do not lead to ecological problems.



**13 DISPOSAL CONSIDERATIONS****13.1 Waste treatment methods**

Emptied cartridges and used strips may retain product residues: always handle as if they were full. Chemical waste cannot be disposed of with household garbage: please contact a licensed professional waste disposal service to dispose of this material.

The waste generated by chemical preparations has generally to be regarded as special waste material, and is in most countries regulated by federal or state government laws and ordinances. Please contact the authority in the matter.

**13.2 Disposal of the packaging**

Used cartridges must be treated as chemical waste (see above). Disposal always according to official regulations: please contact the authority in the matter.

**14 TRANSPORT INFORMATION**

N/A: The products are not subject to transport regulations.

**15 REGULATORY INFORMATION****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

The user has to observe the applicable regulations.

***Directive 1999/45/EC of the European Parliament and of the Council*** concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

***Regulation (EC) N° 1907/2006 of the European Parliament and of the Council*** concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC (classification, packaging and labelling of dangerous preparations) and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

***Commission Regulation (EU) N° 453/2010*** amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

***Regulation (EC) N° 1272/2008 of the European Parliament and of the Council*** on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

**15.2 Chemical safety assessment**

No chemical safety assessment has been carried out.



**16 OTHER INFORMATION****Hazard phrases**

| Code | Phrase   |
|------|--|
| H300 | Fatal if swallowed                                   |
| H301 | Toxic if swallowed                                   |
| H302 | Harmful if swallowed                                 |
| H311 | Toxic in contact with skin                           |
| H314 | Causes severe skin burns and eye damage              |
| H317 | May cause an allergic skin reaction                  |
| H331 | Toxic if inhaled                                     |
| H400 | Very toxic to aquatic life                           |
| H410 | Very toxic to aquatic life with long lasting effects |

Full text of hazard and risk phrases mentioned in this document:

**Risk phrases**

| Code      | Phrase  |
|-----------|---|
| R20/22    | Harmful by inhalation and if swallowed  |
| R23/24/25 | Toxic by inhalation, in contact with skin and if swallowed                          |
| R28       | Very toxic if swallowed   |
| R32       | Contact with acids liberates very toxic gas   |
| R34       | Causes burns  |
| R43       | May cause sensitisation by skin contact   |
| R50/53    | Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic |

**MSDS established** : 2015-07-08

**Revision number** : 1