

(According to regulation 91/155 EEC) Product name: DIASOURCE 250H Vitamin D total ELISA kit

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	DIASOURCE 250H Vitamin D total ELISA
	Catalog #	KAP1971
	Kit components	Microtiter plate Incubation Buffer Concentrated conjugate Concentrated HRP Conjugate Buffer Calibrators 0 to 5 Controls 1 and 2 Wash Solution Chromogen :TMB Stop Solution
1.2	Intended Use	In vitro diagnostic use
1.3	Company	DIAsource ImmunoAssays S.A. Rue du Bosquet, 2 B-1348 Louvain-la-Neuve Belgium e-mail: <u>tech.support@diasource.be</u>
1.4	In emergencies	Call your local emergency centre

2. COMPONENTS AND HAZARDOUS INGREDIENTS

Concentrated conjugate

Contains material considered hazardous by the OSHA Hazard Communication Standard (29CFR190.1200) that can cause respiratory tract, eye and skin irritation.

Concentrated HRP

Contains material considered hazardous by the OSHA Hazard Communication Standard (29CFR190.1200) that can cause respiratory tract, eye and skin irritation.

Incubation Buffer

Contains proteins from bovine , ovine and murine origin and material at a concentration of 10 g /liter , classified with H codes: H302 and H304 and with R phrases: R22,R34 and R52/53.

Conjugate Buffer

Contains proteins from bovine origin

Calibrators 0 to 5 and Controls 1 and 2.

Contain material from equine origin .

Contain material from human origin. Although these materials have been tested for HBsAg, anti-HCV and anti-HIV-1/2 and have been found not reactive, they should be considered as potentially infectious.

Stop Solution

3.65% (w:w) Hydrochloric acid (HCl) C,R34-37



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3. HAZARDS IDENTIFICATION

Calibrators 1 to 5 , Conjugate Buffer

Animal material is potentially infectious.

Calibrators 0 and Controls 1 and 2

Contains material of human origin . Although these materials have been tested for HBsAg, anti-HCV and anti-HIV-1/2 and have been found not reactive, they should be considered as potentially infectious.

Concentrated HRP and concentrated conjugate

Contains material considered hazardous by the OSHA Hazard Communication Standard (29CFR190.1200) that can cause respiratory tract, eye and skin irritation.

Incubation Buffer

Animal material is potentially infectious.

Contains material at a concentration of 10 g /liter classified with H codes: H302 and H304 and with R phrases: R22,R34 and R52/53.

4. FIRST AID MEASURES

Concentrated HRP and concentrated conjugate

After skin contact:	- Wash immediately with soap and plenty of water
After eye contact:	- Wash immediately with plenty of water for at least 15 minutes.
Incubation Buffer After skin contact:	- Wash immediately with soap and plenty of water
After eye contact:	- Wash immediately with plenty of water for at least 15 minutes.

5. FIRE FIGHTING MEASURES

All Kit Components

Suitable extinguishing media:	- All non combustible extinguishing media allowed
Unsuitable extinguishing media:	- No data available
Special exposure hazards:	 No generation of hazardous or toxic gases in dangerous quantities
Instructions: Special protective equipment for firefighters:	 Due to small quantities: no special instructions apply Wear a breathing apparatus and protective clothing to avoid all contact with the skin and eyes.



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6. ACCIDENTAL RELEASE MEASURES

All Kit Components

Personal protection: see 8

Environmental precautions:

- Prevent soil and water pollution
- Discharge according to local regulations

Clean-up:

- Take up liquid spill into absorbent material
- Discharge of absorbed material according to local regulations
- Clean contaminated surfaces with an excess of water
- Wash clothing and equipment after handling

7. HANDLING AND STORAGE

All Kit Components

Handling:

- Observe normal hygiene standards
- Discharge according to local regulations
- Remove and clean contaminated clothing
- Handle and open the container with care

Storage:

- Keep container tightly closed
- Meet the legal requirements
- Keep away from: heat sources, combustible materials, acids, metals
- Storage temperature: see component label
- Specific purposes:

- NA

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

All Kit Components

Hand Protection	- Gloves
Eye Protection	- Face shield
Skin Protection	- Protective Clothing

9. PHYSICAL AND CHEMICAL PROPERTIES

Microtiter Plate : plate Controls 1 and 2, Calibrators 0 to 5 : Lyophilized, soluble in water Washing Solution, concentrated conjugate, concentrated HRP, Incubation Buffer, Conjugate buffer, Stop solution, Chromogen(TMB) : Liquid



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10. STABILITY AND REACTIVITY

All Kit Components

Stability: All components are stable until expiry date if stored in specified conditions (see label) *Reactivity/Hazardous decomposition products:* No hazardous decomposition products are formed in high quantities

Conditions/Materials to avoid: None known

11. TOXICOLOGICAL INFORMATION

Components do not contain substances with a known chronic effect (e.g. carcinogenicity, mutagenicity, toxicity to reproduction).

12. ECOLOGICAL INFORMATION

- -WGK:1 (Classification based on the components as per Verwaltungsvorschrift wassergefährdender Stoffe (VwVwS) of 17may 1999)
- Effect on the ozone layer:
- Greenhouse effect:

Not dangerous for the ozone layer (1999/45/EC) No data available No data available

- Effect on waste water purification:

13. WASTE DISPOSAL CONSIDERATIONS

Provisions relating to waste: Hazardous waste (91/689/EEC).

Packaging/container: Waste material code packaging (91/689/EEC, Council Decision 2001/118/EC, O.J. L47 of 16/2/2001): 15 01 10 (packaging containing residues of or contaminated by dangerous substances)

Disposal methods:

- Patient samples, Calibrators 0 to 5 ,Controls 1 and 2 , incubation buffer and conjugate buffer are potentially infectious. They should be disposed of following established safety procedures and local regulations.
- All the kit components must be considered as hazardous waste. They should be disposed of following local regulations.

14. TRANSPORT INFORMATION

Not applicable



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15. REGULATORY INFORMATION

Not applicable

16. OTHER INFORMATION

This product is designed for use by professionals.

NOTE: The safety analysis of the lyophilized components in this kit has been performed on the reconstituted components. Therefore, the information in this MSDS and product labeling relates to the components as they will be used, i.e. after reconstitution.

The human blood components included in this kit have been tested by European approved and/or FDA approved methods and found negative for HBsAg, anti-HCV and anti-HIV-1 and 2. No known method can offer complete assurance that human blood derivatives will not transmit hepatitis, AIDS or other infections. Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

All animal products and derivatives have been collected from healthy animals. Bovine components originate from countries where BSE has not been reported.

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

It remains the user's own responsibility to make sure that the information is appropriate and complete for his specific use of this product. The user is also responsible for observing any laws and applicable guidelines.

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