

Material Safety Data Sheet

1. Product Identification

1.1. Identification of the products:

OLIGOBIND® Thrombin activity assay

Product no.: ADG844

For detection of active thrombin in stabilized plasma samples.

1.2. Manufacturer:

American Diagnostica GmbH

Kaplaneigasse 35

D-64319 Pfungstadt

Tel: (0)6157- 99 08 99

Fax: (0)6157- 99 08 08

1.3 Date of last revision: 04.04.2013

1.4 Changed information

2. Possible Hazards

The single components do not contain hazardous substances above the limit as per REACH – Regulation 1907/2006/EC and do thus not need special labelling.

Those components that contain preservatives (WASH, DILB, SBUF) have an irritating effect to skin, eyes and mucous. Toxic if breathed in or swallowed, or after contact with the skin. Sensitisation by skin contact is possible. Toxic to water organisms, can have a long-term harmful effect in water. Refer to package insert. Comply with general laboratory guidelines.

The source material for the plasma/serum-based reagent (STD) has been found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus Type 1 and Type 2 (HIV-1, HIV-2) using registered methods. As no known test method can provide complete assurance that products derived from human blood will not transmit HBsAg, HCV, HIV-1, HIV-2 or other blood-borne pathogens, this reagent should be handled as recommended for any potentially infectious human specimen.

3. Composition and Information on Ingredients

	COMPOSITION	SPECIFICATION OF HAZARDOUS MATERIAL
MTP	Aptamer Coated Microtiter Plate, 12 break-apart microtiter strips, each with 8 coated single wells, lyophilised, and 1 frame	--
WASH	Wash Buffer , (20x concentrate), PBS with preservatives	Contains: ProClin® 300 (trade name) 5-chloro-2-methyl-4-isothiazolin-3-one CAS Nr.: 26172-55-4 and 2-methyl-4-isothiazolin-3-one CAS Nr.: 2682-20-4
DILB	Dilution Buffer , PBS, 0.1% BSA, 0.1% Argatroban with preservatives, ready to use	Contains: ProClin® 300 (trade name) 5-chloro-2-methyl-4-isothiazolin-3-one CAS Nr.: 26172-55-4
STD	Standard Plasma , with 0.1% Argatroban, lyophilised	Contains: 100 % human plasma CAS Nr.: 9001-26-7
SBUF	Substrate Buffer , TBS with preservative, ready to use	Contains: ProClin® 300 (trade name) 5-chloro-2-methyl-4-isothiazolin-3-one CAS Nr.: 26172-55-4
TSUB	Thrombin substrate , lyophilised	Contains: p-nitroanaline, < 0.1% CAS-Nr.: 100-01-6

4. First-aid Measures

After inhalation:

After inhalation, bring affected person into the fresh air at once. After respiratory arrest, perform artificial respiration and give oxygen.

Skin contact:

If body parts are contacted, please wash them under flowing water for at least 15 minutes and possibly consult a doctor. Change contaminated clothing and shoes.

Eye contact:

After eye contact, rinse thoroughly with adequate amount of water for at least 15 minutes. Keep the eye lids open during rinsing. Call a doctor.

After swallowing:

After swallowing, rinse the mouth with adequate amount of water, assuming the person is conscious. Call a doctor. Do not trigger vomiting.

5. Fire-fighting Measures

Extinguishing agents:

The following are suitable: water jet, foam, dry extinguishing powder or carbon dioxide.

Specific hazards:

Releases toxic fumes in flames.

Special protective equipment:

Wear safety clothing.

6. Accidental Release Measures

Release of standard plasma, dilution and washing buffer, conjugate, substrate or citrate stopping-solution: Take up spill with spill absorbance materials / chemical absorbance fleece and dispose. The standard plasma have been tested and found negative for HIV1-AK, HIV2-AK, HCV-AK and hepatitis B surface antigen. Still, the plasma should be treated as potentially infectious material. Wear disposable gloves (as per DIN EN 455) and laboratory clothing to prevent contact with skin and eyes. Please handle material in accordance with laboratory directions.

7. Handling and Storage

7.1. Storage:

Store the reagents under dry and cool conditions at 2–8°C.
Do not use beyond the expiration date.

7.2. Handling:

Doors and windows must be kept closed during work (avoid drafts). Do not inhale fumes. Avoid contact with eyes, skin or clothing. If contact does take place, see first aid procedures under point 4. Avoid protracted or repeated exposure. After completing work with (potentially) infectious material or after spilling (potentially) infectious material, disinfect the workplaces and equipment with a surface disinfectant. Comply with the appropriate guidelines for laboratory work.

8. Exposure Controls and Personal Protection

Breathing mask:

It is not necessary to wear a mask for respiratory protection.

Gloves:

To prevent skin contact, disposable gloves in accordance with DIN EN 455 shall be worn. (Use powder free gloves to avoid allergic reactions.)

Safety glasses:

It is not necessary to wear glasses for eye protection.

Lab clothing:

To prevent skin and body contact, wear laboratory clothing.

9. Physical and Chemical Properties

	Appearance	Colour	Odour	Volatility	pH	Concentration of preservative
MTP	no data	colourless	odourless	non volatile	no data	-
WASH	liquid	colourless	odourless	non volatile	7,0 - 7,5	ProClin® (<0,01%)
DILB	liquid	colourless	odourless	non volatile	7,0 - 7,4	ProClin® (<0,01%)
STD	lyophilisate	colourless / pale yellow	odourless	non volatile	7,0 - 7,4	-
SBUF	liquid	colourless	odourless	non volatile	8,0 - 7,5	ProClin® (<0,01%)
TSUB	lyophilisate	colourless	odourless	non volatile	7,0 - 7,4	-

10. Stability and Reactivity

Chemical stability

Stable

Stability

If stored at the temperatures prescribed in the test instructions, the reagents will be stable until the expiration date.

Conditions to avoid

- Greater than normal room temperature
- Exposure to ultraviolet light; Sources of strong light.

11. Toxicological Information

Sensitisation:

Skin: Can cause allergic reactions.

Signs and symptoms after exposure:

Immediate effect: Possibly irritation to the skin, eyes and mucous membranes, chemical burns. Inhalation can lead to paralysis, inflammation and oedema of the larynx and bronchi and chemical inflammation of the lung and pulmonary oedema. The following symptoms can occur after contact: sensation of heat, cough, shortness of breath, headache, nausea and vomiting.

Swallowing: Can be harmful to the health if swallowed.

12. Ecological Information

None of the possible effects are known to have negative impact on the environment.

13. Disposal Considerations

After use, discard these materials in compliance with relevant local, regional and national regulations.

14. Transportation Information

No specific precautionary measures are required for the transportation of these products.

15. Regulatory Information

None given

16. Other information

Only for Research use.

The information compiled and given above is to the best of our knowledge correct, but does not purport to be all inclusive and should only be understood by the user as a set of guidelines. These data do not represent a guarantee of product properties and do not constitute a legal contract. The products should be handled by qualified and experienced professionals only.

American Diagnostica GmbH rejects all liability for consequential, special or indirect damage resulting from the handling, storage or use of this product. We refer to our general terms of trade.

This Material Safety Data Sheet corresponds to the REACH regulation EC No. 1907/2006.