

I. Identification

Chemical name and synonyms:	not applicable
Trade name and synonyms:	Anti-TPO kit (Ref: 24-06)
Chemical family:	In Vitro Diagnostic Test Kit (Reagents)
Formula:	not applicable
Proper DOT shipping name:	not applicable
DOT hazard classification:	not applicable
Manufacturer:	Astra Biotech GmbH
Manufacturer's Address:	Rudower Chaussee 29, 12489 Berlin, Germany
Manufacturer's phone/fax:	+49 (0)30 746 96 509/ +49 (0)30 367 405 135

II. Hazards Identification

Chemicals always may cause some special hazards. Therefore they should be handled by trained personnel with the necessary care.

III. Composition, Information on Ingredients

Product: Anti-TPO kit

Component	Preservative	Concentration of the hazardous substance	Stability at +4 °C
Microplate	Gentamicin sulphate	-	12 months
Wash solution, concentrated	none	-	12 months
Assay Buffer	Gentamicin sulphate; Thimerosal	Thimerosal – 0.01 %	12 months
Sample Diluent	Kathon MW	Kathon MW - 0.1 %, active ingredients – 0.015 %	12 months
Conjugate	Kathon MW	Kathon MW - 0.1 %, active ingredients – 0.015 %	12 months
Substrate	-	3,3',5,5'-tetramethylbenzidine - 1.2 mM; Hydrogen superoxide – 3.0 mM	12 months
Stop solution	none	1 M solution	18 months
Calibrators, Control	Kathon MW	Kathon MW - 0.1 %, active ingredients – 0.015 %	12 months (liquid); no more than 1 month after opening (reconstituted)

Information on substances derived from tissues of human origin

Substance	Description	Source (blood, serum, plasma, tissue, cells etc.)	Hazard/Biohazard
hTPOc-thyroid peroxidase	Human Thyroid peroxydase hTPO	Human Thyroid	Starting material is tested and found negative for HIV I and II antibodies, Hepatitis B surface antigen and HCV antibodies
Human serum anti-TPO	Human serum	Human blood	Serum from donors has been tested and found to be negative for HIV, HBC antigen, HCV, Syphilis and HBsAg

IV. First Aid Measures

Symptoms of exposure:

CORROSIVE: Stop solution (1 M hydrochloric acid solution);

POSSIBLE MUTAGEN: TMB Substrate solution:

POSSIBLE SENSITISATION BY INHALATION OR SKIN CONTACT: Assay Buffer (Thimerosal 0.01 %)

POSSIBLE SYSTEMIC EFFECTS: Assay Buffer (Thimerosal 0.01 %)

POSSIBLE IRRITANT: TMB, Assay Buffer (Thimerosal 0.01 %, Substrate solution Conjugate, Calibrators 0-5, Control, Sample diluent (Kathon MW - 0.1 %, active ingredients – 0.015 %)

In case of exposure to reagent solutions, we recommend the following emergency first-aid procedures:

1. Skin or Eye Contact: wash with tap water for at least 15 minutes. Remove any contaminated clothing. Obtain medical attention.
2. Inhalation: remove the affected individual to the fresh air. If breathing is difficult, give oxygen and call a physician.
3. Ingestion: rinse the mouth with copious amounts of tap water and call a physician.

V. Fire-fighting measures

Not applicable.

Usage of the reagents according to protocol should not incur a fire or explosion hazard. In case of fire, use water, foam, carbon dioxide or dry chemical, as suitable for surrounding fire and materials.

VI. Accidental Release Measures

Use standard laboratory absorbent materials for cleanup. Clean by enough water.

VII. Handling and storage

Hygienic Practice in Storage: store in a cool (+2...+8 °C) and dry area away from direct sunlight and incompatible substances.

Hygienic Practice in Handling: handle all the samples and materials in contact with samples according to NCCLS guidelines for preventing transmission of blood-borne infections.

VIII. Exposure control and personnel protection

Eye Protection: recommended

Skin Protection: recommended

Respiratory Equipment: not applicable

Good laboratory practices should be followed when handling all the reagents.

IX. Physical data

pH: Conjugate: 7.4
Substrate: 3.65
Stop solution: <1.0
Calibrators 0-5, Control, Sample diluents 7.3±0.1

X. Stability and reactivity

TMB Substrate solution contains hydrogen peroxide which is an oxidizing agent. TMB and Kathon MW are irritants.

XI. Toxicological information

Hydrochloric acid: LD₅₀ (rat) 900 mg/kg body weight

XII. Ecological information:

Biological effects:

Hydrochloric acid is toxic for water organisms by shift of PH value. LD₅₀ 25 mg/L up.

XIII. Disposal consideration


Dispose in accordance with Local, State and Federal Regulations.

XIV. Transport Information

This product can be transported without any limitations. No regulations are to be applied.

XV. Regulatory Information

European Labeling according to Regulation (EC) No 1272/2008.

Name	Percent	CAS-No	hazard Symbols	Risk Phrases
Kathon MW	0.0015%<=C<0.06%	55965-84-9	 Warning	H 317 May cause an allergic skin reaction

The following precautions should be observed:

- P261 - Avoid breathing spray;
- P272 - Contaminated work clothing should not be allowed out of the workplace;
- P280 - Wear protective gloves/protective clothing/eye protection;
- P302+P352 - IF ON SKIN: Wash with plenty of soap and water;
- P333+P313 - If skin irritation or rash occurs: Get medical advice/attention;
- P363 - Wash contaminated clothing before reuse;
- P501 - Dispose of contents/container in accordance with national regulation.

XVI. Other information

This product is designed and evaluated for the professional use by qualified laboratory staff. It has to be used only as *in vitro* diagnostic medical device.

XVII. Disclaimer

The information above is believed to be accurate and represents the best information currently available to us. However we make no warranty of merchantability or any other warranty expressed or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purpose. In no way shall the company be liable for any claims, losses or damages of any third party or for lost profits of any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.