MATERIAL SAFETY DATA SHEET

PRODUCT NAME:
DIALAB HBcIgM ELISA (IgM Antibody to Hepatitis B Virus Core Antigen ELISA Assay)
CATALOG NUMBER: Z01365

IVD **For In Vitro Use Only**
For Professional Use Only

Kit Storage +8℃ / +2℃

MANUFACTURER:
DIALAB GmbH
IZ-NÖ Süd, Hondastrasse
Objekt M55, A-2351 Wr. Neudorf
Austria
Phone: +43-2236-660910-0
Fax: +43-2236-660910-30
email: office@dialab.at

Emergency: +43 1 4064343-0

KIT COMPONENTS AND CHEMICAL TOXICITY

Components of the kit	Format	Hazardous Chemicals	CAS#	Pages	EU R&S-paragraphs
MICROWELL PLATE	1x96well	none			
POSITIVE/NEGATIVE CONTROLS	2x0.5ml	ProClin™ 300 (0.1%)	N/A	5-7	**R43, S28-37**
HRP-CONJUGATE REAGENT	1x6.5ml	ProClin™ 300 (0.1%)	N/A	5-7	**R43, S28-37**
STOCK WASH BUFFER	1x30ml	Tween 20™ (0.2%)	9005-64-5	8-10	**R1, S1**
SUBSTRATE SOLUTION A	1x7ml	TMB solution (0.1%)	54827-17-7	11-13	**R20/21/22 ,S 26-36/33/6/37/38/40**
SUBSTRATE SOLUTION B	1x7ml	Hydrogen peroxide (0.1%)	7722-84-1	11-13	**R34 ,S 3-28-36/39-45**
STOP SOLUTION	1x7ml	Sulfuric Acid	7664-93-9	2-4	**R34, S36-37, S39 S24, S25**

BIOLOGICAL SAFETY

Antigen: recombinant hepatitis B virus core antigen (HBcAg) **Infectivity:** none (commercially available preparation)
Antibody: monoclonal antibodies to human IgM antibodies (u-chain) have been used in the preparation of the HRP-Conjugate of the kit :
Infectivity: none (commercially available preparation)
Antibody: monoclonal antibodies HBcAg IgM antibodies have been used in the preparation of the positive control of the kit :
Infectivity: none (commercially available preparation)
Positive control: Materials from human origin may have been used in the preparation of the Positive Control of the kit. These materials have been tested and found negative for antibodies to HCV, TP and HIV 1+2 and HBsAg.
Negative control: Materials from human origin may have been used in the preparation of the Negative Control of the kit. These materials have been tested and found negative for antibodies to HCV, HIV ½, TP and HBsAg.
Bovine origin materials: for stabilization of standards and HRP-Conjugate reagent, sera bovine serum albumin (BSA) and fetal calf sera (FCS) are used; these products are derived from animals from geographical areas known to be BSE-free.

SECTION 1. IDENTIFICATION OF SUBSTANCES /PREPARATION

Component name: Stop solution
Catalog No.: N/A

Effective Date: July 14,2003

EMERGENCY TELEPHONE: +43 1 4064343-0

Digitally signed by Bolea Petru
Date: 2021.10.22 19:21:32 EEST
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Location: Moldova

MATERIAL SAFETY DATA SHEET

Application: Stopping solution in Dialab HBcIgM ELISA
Hazardous component: Sulfuric Acid (H_2SO_4) Water Solution

SECTION 2. COMPOSITION / INFORMATION ON INGREDIENTS

Aqueous solution C; 35
Hazardous ingredients:
CAS# 7664-93-9 2 Molar Sulfuric acid

SECTION 3. HAZARD IDENTIFICATION

C Corrosive **(not indicated on reagent label)**
R34 Cause burns

SECTION 4. FIRST AID MEASURES

- **After inhalation** In case of unconsciousness place patient stably in side position for transportation
- **After skin contact** Immediately wash with water and soap and rinse thoroughly
- **After eye contact** Rinse opened eye for several minutes under running water
- **After swallowing** Drink plenty of water and provide fresh air. Call for a doctor immediately

SECTION 5. FIRE FIGHTING MEASURES

Suitable extinguishing agents: CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Non-applicable extinguishing media: Undetermined
Special exposure hazards arising from the substance or preparation itself: Undetermined
Special protective equipment for fire fighters. Not required

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Wear protective equipment. Keep unprotected persons away.
Environmental precautions:
- Prevent seepage into sewage system, work pits and cellars. Dilute with plenty of water.
- Do not allow entering sewers/ surface or ground water.

Measures for cleaning
- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- Use neutralizing agent.
- Dispose contaminated material as waste according to item 13.
- Ensure adequate ventilation.

SECTION 7. HANDLING AND STORAGE

Handling: Cannot be stored indefinitely
Information for safe handling, fire, and explosion protection: No special measures required
Storage:
Requirements to be met by storerooms and receptacles: Store in cool, well-ventilated location, away from any area where fire hazard may be present.
Information about storage in one common storage facility: Store separately from incompatible materials.
Common storage facility: Not special requirements
Further information about storage conditions: Keep vials tightly closed. Protect against physical damage.
Storage class and class according to regulation on flammable liquids: Void

MATERIAL SAFETY DATA SHEET

SECTION 8. EXPOSURE CONTROL / PERSONAL PROTECTION

Additional information about design of technical facilities:
Ingredients with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace
Additional information: The lists valid during the making were used as basis
Personal protective equipment **S36, S37, S39**
General protective and hygienic measures
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work
Avoid contact with the eyes **S25** and skin **S24**
Respiratory protection: Not required
Hand protection: S37 required
Eye protection: S39 required

SECTION 9. IMPORTANT HEALTH, SAFETY AND ENVIRONMENTAL INFORMATION

Form: liquid	**Solvent content:** Organic solvents 0 %
Color: Colorless	**Odor:** Odourless
Flash point: N/A	**Vapor pressure:** N/A
Oxidizing properties:	**Evaporation rate:** N/A
Explosivity :N/A	**Melting point**: N/A
Boiling point: N/A	**Danger of explosion:** No explosion hazard.
Self-igniting: Not selfigniting.	**Solubility in Water:** Totally miscible
Relative density: N/A	**PH :** 0.5

SECTION 10. STABILITY AND REACTIVITY

Thermal decomposition: If used according to specifications the reagent will not decompose
Conditions to be avoided:
Dangerous reactions: No dangerous reactions known
Dangerous decomposition products: No dangerous decomposition products known

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity:
Primary irritant effect:
- **On the skin:** Caustic effect on skin and mucous membranes.
- **On the eye:** Strong caustic effect.

Sensitization: No sensitizing effects known.
Additional toxicological information:
The product shows the following dangers:
Corrosive - Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxisity: N/A
Mobility: N/A
Persistence and degradability:
Bioaccumulative potential
Others: Hazardous for water

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Danger to drinking water if even small quantities leak into the ground. Should not be allowed to reach ground water, water route or sewage system undiluted or unneutralized.

SECTION 13. DISPOSAL CONSIDERATIONS

Recommendation Smaller quantities can be disposed of with household waste.
Uncleaned packaging: N/A
Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14. TRANSPORT INFORMATION

Land Transport ADR/RID
Shipping name: Sulfuric Acid Water Solution as Stop solution in Dialab HBcAb ELISA
Packaging group: III
Classification: R34
Maritime Transport IMDG/GGVSee
Shipping name: Sulfuric Acid Water Solution as Stop solution in Dialab HBcAb ELISA
Packaging group: III
Classification: R34
EmS: 8-06
Marine pollutant: No
Air Transport ICAO/IATA
Shipping name: Sulfuric Acid Water Solution as Stop solution in Dialab HBcAb ELISA
Packaging group: III
Classification: R34

SECTION 15. REGULATIONS

Code letter and hazard designation of product: N/A
Risk phrases: R34 Causes burns.
Safety phrases:
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S60 This material and its container must be disposed of as hazardous waste.
National regulations: The current regulation 91/155/EC
Water hazard class: hazardous for water.

SECTION 16. OTHERS

This information is based on our present state of knowledge and according to the internationally and domestically available literature. However, this MSDS shall not be used as a warranty for any specific product features.
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MATERIAL SAFETY DATA SHEET

SECTION 1. IDENTIFICATION OF SUBSTANCES /PREPARATION

Component name: 1. Positive/Negative controls , 2. HRP - Conjugate
Catalog No.: N/A **Application 1:** for determination of the successes of the assay in Dialab HBcAb ELISA
Catalog No.: N/A **Application 2:** HRP conjugate in Dialab HBcAb ELISA

Hazardous component: ProClin^{TM} 300

SECTION 2. COMPOSITION / INFORMATION ON INGREDIENTS

Aqueous solution Xi; 35 0.1%
Hazardous ingredients: CAS# N/A

SECTION 3. HAZARD IDENTIFICATION

Xi Irritant **(not indicated on reagent label)**
R43 May cause sensitization by skin contact

SECTION 4. FIRST AID MEASURES

- **After inhalation** In case of unconsciousness place patient stably in side position for transportation
- **After skin contact** Immediately wash with water and soap and rinse thoroughly
- **After eye contact** Rinse opened eye for several minutes under running water
- **After swallowing** Drink plenty of water and provide fresh air. Call for a doctor immediately

SECTION 5. FIRE FIGHTING MEASURES

Suitable extinguishing agents: CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Non-applicable extinguishing media: N/A
Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases, etc.: Emits toxic fumes under fire conditions
Special protective equipment for fire fighters. Wear self-contaminated breathing apparatus and protective clothing to prevent contact with skin and eyes

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Wear protective equipment. Keep unprotected persons away.
Environmental precautions:
- Prevent seepage into sewage system, work pits and cellars.
- Dilute with plenty of water.
- Do not allow entering sewers/ surface or ground water.

Measures for cleaning
- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- Dispose contaminated material as waste according to item 13.
- Ensure adequate ventilation.

SECTION 7. HANDLING AND STORAGE

Handling:
Information for safe handling: No special measures required
Information about fire - and explosion protection: No special measures required
Storage:
Requirements to be met by storerooms and receptacles: Store in cool, well-ventilated location, away from any area where fire hazard may be present.
Information about storage in one common storage facility: Store separately from incompatible materials.

MATERIAL SAFETY DATA SHEET

Common storage facility: Not special requirements
Further information about storage conditions: Keep vials tightly closed. Protect against physical damage.
Storage class and class according to regulation on flammable liquids: Void

SECTION 8. EXPOSURE CONTROL /PERSONAL PROTECTION

Additional information about design of technical facilities:
Ingredients with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace
May cause sensitization by skin contact **R 43**
In case of accident or if you feel unwell, seek medical advice immediately **S45**
Avoid release to the environment **S 61**
Additional information: The lists valid during the making were used as basis
Personal protective equipment S36, S37, S39
General protective and hygienic measures
Immediately remove all soiled and contaminated clothing. In case of contact with the eyes, rinse immediately with plenty of water and seek medical advice
Wash hands before breaks and at the end of work
Avoid contact with the eyes **S25** and skin **S24**
Respiratory protection: Not required
Hand protection: S37 required
Eye protection: S39 required

SECTION 9. IMPORTANT HEALTH, SAFETY AND ENVIRONMENTAL INFORMATION

Form: liquid	**PH :** 4.1
Color: Colorless	**Odour:** Odourless
Flash point: 66.11C	**Vapour pressure:** >1 G/L
Oxidising properties: N/A	**Evaporation rate:** <1
Explosivity: N/A	**Boiling point: 189C**
Melting point: -40C	**Danger of explosion:** No explosion hazard.
Self-igniting: Not selfigniting.	**Solubility in Water:** Fully miscible Z1076
Relative density: N/A	**Solvent content:** N/A

SECTION 10. STABILITY AND REACTIVITY

Thermal decomposition: If used according to specifications the reagent will not decompose
Conditions to be avoided:
Incompatibilities : OXIDIZING AGENTS, REDUCING AGENTS, AMINES , MERCAPTANS
Hazardous combustion or decomposition products : NITROGEN OXIDES, SULFUR OXIDES, HYDROGEN CHLORIDE GAS
Hazardous polymerization: Will not occur

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity:
Primary irritant effect:
- **On the skin:** Sensitization effect on skin and mucous membranes.
- **On the eye:** Strong caustic effect.

Additional toxicological information:
Acute effects – causes burns and sensitization (allergic effects) on the skin. Extremely destructive to the tissue of the mucous membranes and upper respiratory tract, the skin and the eyes. Maybe harmful if inhalated or swallowed .
INHALATION MAY RESULT IN SPASM, INFLAMMATION AND EDEMA OF THE LARYNX AND BRONCHI, CHEMICAL PNEUMONITIS AND PULMONARY EDEMA. SYMPTOMS OF EXPOSURE MAY INCLUDE BURNING SENSATION, COUGHING, WHEEZING, LARYNGITIS, SHORTNESS OF BREATH, HEADACHE, NAUSEA AND VOMITING. EXPOSURE CAN CAUSE: DERMATITIS

MATERIAL SAFETY DATA SHEET

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxisity: N/A
Mobility: N/A
Persistence and degradability: N/A
Bioaccumulative potential : N/A
Others: Hazardous for water; Very toxic to aquatic organisms **S 50;** Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground.

SECTION 13. DISPOSAL CONSIDERATIONS

To be disposed only by professional waste disposal service. Dissolve the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

SECTION 14. TRANSPORT INFORMATION

Land Transport ADR/RID
Shipping name: ProClin^{TM} 300 as a preservative reagent in Dialab HBcAb ELISA
Packaging group: III
Classification: R43
Maritime Transport IMDG/GGVSee
Shipping name: ProClin^{TM} 300 as a preservative reagent in Dialab HBcAb ELISA
Packaging group: III
Classification: R43
EmS: 8-06
Marine pollutant: Yes
Air Transport ICAO/IATA
Shipping name: ProClin^{TM} 300 as a preservative reagent in Dialab HBcAb ELISA
Packaging group: III
Classification: R43

SECTION 15. REGULATIONS

Code letter and hazard designation of product: N/A
Risk phrases: R43 May cause sensitization by skin contact
Safety phrases:
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S60 This material and its container must be disposed of as hazardous waste
S 45 In case of accident or if you feel unwell, seek medical advice immediately
S 61 Avoid release to the environment
National and international regulations: The current regulation 91/155/EC
Water hazard class: hazardous for water.

SECTION 16. OTHERS

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MATERIAL SAFETY DATA SHEET

SECTION 1. IDENTIFICATION OF SUBSTANCES /PREPARATION

Component name: 20 X Stock Wash Buffer
Catalog No.: N/A
Application: Washing solution in Dialab HBcAb ELISA
Hazardous component: Tween 20 (0.2%)
Synonyms: Polyoxyehtylene (**20**) sorbitan monolaurate

SECTION 2. COMPOSITION / INFORMATION ON INGREDIENTS

Aqueous solution **R1, S1 (As raw material)**
Hazardous ingredients:
CAS# 9005-64-5

SECTION 3. HAZARD IDENTIFICATION

- **Inhalation:** May cause mild irritation to respiratory tract.
- **Swallowing:** May cause gastrointestinal irritation.
- **Skin Contact:** Contact may cause irritation.
- **Eye Contact:** May cause irritation.

SECTION 4. FIRST AID MEASURES

- **After inhalation:** N/A
- **After swallowing:** Get medical attention immediately. Never give anything by mouth to an unconscious person. Call for a doctor immediately
- **After skin contact** Immediately wash with water and soap and rinse thoroughly. Get medical attention if irritation develops or persists.
- **After eye contact:** Rinse opened eye for several minutes under running water. Get medical attention immediately.

SECTION 5. FIRE FIGHTING MEASURES

Suitable extinguishing agents: N/A
Non-applicable extinguishing media: N/A
Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases, etc.: Explosive when dry **R1 (As raw material)**
Special protective equipment for fire fighters. Wear self-contaminated breathing apparatus and protective clothing to prevent contact with skin and eyes

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Wear protective equipment. Keep unprotected persons away.
Environmental precautions:
- Prevent seepage into sewage system, work pits and cellars.
- Do not allow entering sewers/ surface or ground water.

Measures for cleaning
- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- Dispose contaminated material as waste according to item 13.
- Ensure adequate ventilation.
- Use non-sparking tools

SECTION 7. HANDLING AND STORAGE

Handling:

MATERIAL SAFETY DATA SHEET

Information for safe handling: Avoid contact with skin and eyes. Wash hands before eating and after handling. Follow good hygienic practices, including no eating, drinking, or smoking in work areas.
Information about fire - and explosion protection: No special measures required
Storage:
Requirements to be met by storerooms and receptacles: Store in cool, well-ventilated location, away from any area where fire hazard may be present.
Information about storage in one common storage facility: Store separately from incompatible materials.
Common storage facility: Not special requirements
Further information about storage conditions: Keep vials tightly closed **S1** . Protect against physical damage.
Storage class and class according to regulation on flammable liquids: Void

SECTION 8. EXPOSURE CONTROL /PERSONAL PROTECTION

Additional information about design of technical facilities:
Ingredients with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace
Avoid release to the environment **S 61**
Keep locked up **S1**
Explosive when dry **R1 (As raw material)**
Additional information: The lists valid during the making were used as basis
Personal protective equipment S36, S37, S39
General protective and hygienic measures
Immediately remove all soiled and contaminated clothing. In case of contact with the eyes, rinse immediately with plenty of water. Wash hands before breaks and at the end of work
Avoid contact with the eyes **S25** and skin **S24**
Respiratory protection: Not required
Hand protection: S37 required
Eye protection: S39 required

SECTION 9. IMPORTANT HEALTH, SAFETY AND ENVIRONMENTAL INFORMATION

Form: liquid	**PH :** N/A
Color: Colorless	**Odour:** Odourless
Flash point: N/A	**Vapour pressure:** N/A
Oxidising properties: N/A	**Evaporation rate:** N/A
Explosivity: N/A	**Boiling point:** N/A
Melting point: N/A	**Danger of explosion:** Explosive when dry
Self-igniting: Not selfigniting.	**Solubility in Water:** Fully miscible
Relative density: N/A	**Solvent content:** N/A

SECTION 10. STABILITY AND REACTIVITY

Thermal decomposition: If used according to specifications the reagent will not decompose
Conditions to be avoided:
Incompatibilities : N/A
Hazardous combustion or decomposition products : N/A
Hazardous polymerization: Will not occur

SECTION 11. TOXICOLOGICAL INFORMATION

Skin, eye, and mucous membrane irritation, harmful by ingestion, inhalation or skin absorption.
Suspected carcinogen.

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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxisity: N/A
Mobility: N/A
Persistence and degradability: N/A
Bioaccumulative potential : N/A
Others:
Hazardous for water
Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground.

SECTION 13. DISPOSAL CONSIDERATIONS

To be disposed only by professional waste disposal service and according to the local regulations.

SECTION 14. TRANSPORT INFORMATION

Land Transport ADR/RID
Shipping name: Tween 20 as detergent reagent in Dialab HBcAb ELISA
Packaging group: N/A
Classification: R1 **(As raw material)**
Maritime Transport IMDG/GGVSee
Shipping name: Tween 20 as detergent reagent in Dialab HBcAb ELISA
Packaging group: N/A
Classification: R1 **(As raw material)**
Marine pollutant: not studied
Air Transport ICAO/IATA
Shipping name: Shipping name: Tween 20 as detergent reagent in Dialab HBcAb ELISA
Packaging group: N/A
Classification: R1 **(As raw material)**

SECTION 15. REGULATIONS

Code letter and hazard designation of product: N/A
Risk phrases: Explosive when dry **R1 (As raw material)**
Safety phrases:
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S60 This material and its container must be disposed of as hazardous waste
S 45 In case of accident or if you feel unwell, seek medical advice immediately
S 61 Avoid release to the environment
S1 Keep locked up
National and international regulations:
The current regulation 91/155/EC
Water hazard class: Not studied.

SECTION 16. OTHERS

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SECTION 1. IDENTIFICATION OF SUBSTANCES /PREPARATION

Component name: Substrate Solution B and Substrate Solution A Solutions
Catalog No.: N/A **Application:** Substrate Solution B – for color development in Dialab HBcAb ELISA
Catalog No.: N/A **Application:** Substrate Solution A - for color development in Dialab HBcAb ELISA
Hazardous component: Substrate B – urea hydrogen peroxide solution
Hazardous component: Substrate A – 3,3',5,5'-tetramethylbenzidine (TMB)

SECTION 2. COMPOSITION / INFORMATION ON INGREDIENTS

Substrate Solution A; Aqueous solution; T ; Xn  ;  **(As raw material)** Concentration < 0.1% CAS# 54827-17-7
R20/21/22: harmful by inhalation, in contact with skin and if swallowed.
R36/37/38: irritating to eyes, respiratory system and skin. **R40:** possible risk of irreversible effects. **S 26-36/37**

Substrate Solution B; Aqueous solution; C ; O ;  ;  **(As raw material)** Concentration < 0.1% CAS# 7722-84-1
R34 Causes burns; **S 3-28-36/39-45**

SECTION 3. HAZARD IDENTIFICATION

See section 2

SECTION 4. FIRST AID MEASURES

- **After inhalation** In case of unconsciousness place patient stably in side position for transportation
- **After skin contact** Immediately wash with water and soap and rinse thoroughly
- **After eye contact** Rinse opened eye for several minutes under running water
- **After swallowing** Drink plenty of water and provide fresh air. Call for a doctor immediately

SECTION 5. FIRE FIGHTING MEASURES

Suitable extinguishing agents: CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Non-applicable extinguishing media: N/A
Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases, etc.: Due to the nature and volume of this product, the type and amount of combustion products are negligible.
Special protective equipment for fire fighters. Not required

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Not required
Environmental precautions: No special considerations
Measures for cleaning

- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- Dispose contaminated material as waste according to item 13.

SECTION 7. HANDLING AND STORAGE

Handling:
Information for safe handling: No special measures required
Information about fire - and explosion protection: No special measures required
Storage:
Requirements to be met by storerooms and receptacles: Store in cool, well-ventilated location, away from any area where fire hazard may be present.

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Information about storage in one common storage facility: Store separately from incompatible materials.
Common storage facility: Not special requirements
Further information about storage conditions: Keep vials tightly closed. Protect against physical damage.
Storage class and class according to regulation on flammable liquids: Void

SECTION 8. EXPOSURE CONTROL /PERSONAL PROTECTION

Additional information about design of technical facilities:
Ingredients with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace
In case of accident or if you feel unwell, seek medical advice immediately **S45**
Additional information: The lists valid during the making were used as basis
Personal protective equipment S36, S37, S39
General protective and hygienic measures
In case of contact with the eyes, rinse immediately with plenty of water and seek medical advice
Wash hands before breaks and at the end of work
Avoid contact with the eyes **S25** and skin **S24**
Respiratory protection: Not required
Hand protection: S37 required
Eye protection: S39 required
S45 In case of accident or if you feel unwell, seek medical advice immediately

SECTION 9. IMPORTANT HEALTH, SAFETY AND ENVIRONMENTAL INFORMATION

Form: liquid
Color: Substrate Solution B-Colorless
Color: Substrate Solution A-Colorless
Flash point: N/A
Oxidising properties: N/A
Explosivity: N/A
Melting point: N/A
Self-igniting: Not selfigniting.
Relative density: N/A
PH : Substrate Solution A 11.8
Odour: Odourless
Solubility in Water: Fully miscible Z1076
Vapour pressure: N/A
Evaporation rate: N/A
Boiling point: N/A
Danger of explosion: No explosion hazard.
Solvent content: N/A

SECTION 10. STABILITY AND REACTIVITY

Thermal decomposition: If used according to specifications the reagent will not decompose
Conditions to be avoided: Strong oxidizers, Strong acids, Strong bases
Incompatibilities : N/A
Hazardous combustion or decomposition products : N/A
Hazardous polymerization: Will not occur

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity:
Primary irritant or sensitization effects:
- **On the skin:** no irritation or sensitization effects
- **On the eye:** no irritation or sensitization effects

Additional toxicological information:
When used and handled according to specifications, the products will not show any harmful effects

SECTION 12. ECOLOGICAL INFORMATION

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Ecotoxisity: N/A
Mobility: N/A
Persistence and degradability: N/A
Bioaccumulative potential : N/A
Others: Not hazardous for water. Substrate Solution A -Toxic to fish and other water organisms **(As a raw material)**

SECTION 13. DISPOSAL CONSIDERATIONS

Can be disposed as normal waste
Clean with water and cleaning reagent

SECTION 14. TRANSPORT INFORMATION

Land Transport ADR/RID
Shipping name: Substrate Solution B and Substrate Solution A Solutions as coloring reagents in Dialab HBcAb ELISA
Maritime Transport IMDG/GGVSee
Shipping name: Substrate Solution B and Substrate Solution A Solutions as coloring reagents in Dialab HBcAb ELISA
Marine pollutant: No
Air Transport ICAO/IATA
Shipping name: Substrate Solution B and Substrate Solution A Solutions as coloring reagents in Dialab HBcAb ELISA

SECTION 15. REGULATIONS

Code letter and hazard designation of product: N/A

Substrate Solution A
R20/21/22: harmful by inhalation, in contact with skin and if swallowed. **(As raw material)**
R36/37/38: irritating to eyes, respiratory system and skin. **R40:** possible risk of irreversible effects. **(As raw material)**
S 26-36/3 (As raw material)

Substrate Solution B
R34 Causes burns **(As raw material)**
S 3-28-36/39-45 (As raw material)
National and international regulations:
The current regulation 91/155/EC
Water hazard class: Not hazardous for water

SECTION 16. OTHERS

This information is based on our present state of knowledge and according to the internationally and domestically available literature. However, this MSDS shall not be used as a warranty for any specific product features.
The MSDS is not a legally valid contractual relationship.

Department issuing the MSDS: Quality Control

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ELISA **E**NZYME **L**INKED **I**MMUNO**S**ORBENT **A**SSAY

Microwell Method

HBc IgM capture

REF: Z01365

For in vitro Diagnostic Use

P r o d u c t I n s e r t

Enzyme Linked Immunosorbent Assay for the **cut - off** determination of HBc IgM (IgM class antibodies to hepatitis B virus core antigen) in human serum or plasma.

Microwell Method - 96 wells

(12 x 8-well Antigen coated Strips)

Individual breakaway

GENERAL INFORMATION

- ❑ Wavelength Measurement Filter: 450 nm
  Optional Reference Filter: 630 nm
- ❑ Enzyme Conjugate
  HRP (Horseradish Peroxidase)
- ❑ Substrate
  TMB (3,3´,5,5´-Tetramethyl-benzidine)
- ❑ Sample
  Serum or Plasma
- ❑ Incubation Time
  75 minutes at 37°C (30/30/15)
- ❑ Shelf life and Stability of Kit Components

Kit:	see expiration date on the label
Kit Components:	see expiration date on the label

INTENDED USE

This anti-HBc IgM kit is an enzyme-linked immunosorbent assay (ELISA) for qualitative determination of IgM class antibodies to hepatitis B virus core antigen in human serum or plasma. It is intended for use in clinical laboratories for diagnosis and management of patients related to infection with hepatitis B.

KIT COMPONENTS

MICROWELL PLATE	1	The plate is sealed in aluminium pouch with desiccant. **12×8-well strips per plate. Each well contains anti-IgM antibodies (anti-µ chain).** The microwell strips can be broken to be used separately. Place unused wells in the plastic sealable storage bag together with the desiccant and return to 2-8°C.
POSITIVE CONTROL	1	0.5 mL per vial. anti-HBc IgM antibodies diluted in Protein-stabilized buffer. Preservatives: 0.1% ProClin 300. Ready to use as supplied. Once open, stable for one month at 2-8°C.
NEGATIVE CONTROL	1	0.5 mL per vial. Protein-stabilized buffer tested non reactive for anti-HBc IgM. Preservatives: 0.1% ProClin 300. Ready to use as supplied. Once open, stable for one month at 2-8°C.
ENZYME CONJUGATE	1	12 mL per vial. Horseradish peroxidase-conjugated purified HBcAg, labeled with monoclonal anti-HBc. Ready to use as supplied. Once open, stable for one month at 2-8°C.

SUBSTRATE SOLUTION A	1	7 mL per vial. Urea peroxide solution. Ready to use as supplied. Once open, stable for one month at 2-8°C.
SUBSTRATE SOLUTION B	1	7 mL per vial. TMB solution. Tetramethylbenzidine dissolved in citric acid. Ready to use as supplied. Once open, stable for one month at 2-8°C.
STOP SOLUTION	1	7 mL per vial. Diluted sulfuric acid solution (0.5 M H_2SO_4).
WASH BUFFER	1	50 mL per bottle. pH 7.4, 20x PBS (Containing Tween-20 as a detergent).
CARDBOARD PLATE COVER SHEETS	2	

MATERIALS REQUIRED BUT NOT PROVIDED

1. Freshly distilled or deionized water.
2. Disposable gloves and timer.
3. Appropriate waste containers for potentially contaminated materials.
4. Disposable V-shaped troughs.
5. Dispensing system and/or pipette (single or multichannel), disposable pipette tips.
6. Absorbent tissue or clean towel.
7. Dry incubator or water bath, 37±0.5°C.
8. Microshaker for dissolving and mixing conjugate with samples.
9. Microwell plate reader, single wavelength 450nm or dual wavelength 450nm and 630nm.
10. Microwell aspiration/wash system.
11. Normal saline solution for dilution of the samples.

SUMMARY AND EXPLANATION

Hepatitis B virus (HBV) is an enveloped, double-stranded DNA virus belonging to the Hepadnaviridae family and is recognized as the major cause of blood transmitted hepatitis together with hepatitis C virus (HCV). Infection with HBV induces a spectrum of clinical manifestations ranging from mild, inapparent disease to fulminant hepatitis, severe chronic liver diseases, which in some cases can lead to cirrhosis and carcinoma of the liver. Classification of a hepatitis B infection requires the identification of a number of serological markers expressed during three phases (incubation, acute and convalescent) of the infection. Now several diagnostic test are used for screening, clinical diagnosis and management of the disease. Hepatitis B “core” antigen (HBcAg) is a major component of the viral structure. HBcAg is composed of a single polypeptide of about 17 kD that is released upon disaggregation of the core particles; the antigen contains at least one immunological determinant. Antibodies to HBcAg (anti-HBc total antibody and IgM) appear shortly after the appearance of HBsAg and persist for life both in persons who have recovered from a hepatitis B infection and in those who develop HBsAg-carrier status but in rare cases, an HBV infection can also run its course without the appearance of immunologically detectable anti-HBc (usually in immunosuppressed patients).
In chronic hepatitis, however, spikes of anti-HBc IgM synthesis are present, confirming reactivation of HBV in hepatocytes and giving origin to permanent IgM low titers. Presence of IgM and total anti-HBc indicates an ongoing or recent HBV infection. When used in conjunction with tests for other HBV serological markers, a laboratory diagnosis or a rule out of HBV infection can be achieved.

TEST PRINCIPLE

This anti-HBc IgM ELISA kit is a two-step incubation, solid phase antibody capture assay in which polystyrene microwell strips are pre-coated with antibodies directed to human IgM (anti-μ chain). The patient's serum/plasma sample is added and during the first incubation step, any IgM-class antibodies will be captured inside the wells. After washing out all the other components of the sample and in particular IgG-class antibodies, the specific anti-HBc IgM captured on the solid phase is detected by the addition of purified HBcAg, labeled with a anti-HBc monoclonal antibody conjugated to horseradish peroxidase (HRP). During the second incubation, the HRP-conjugated antigens will specifically react only with anti-HBc IgM antibodies and after washing to remove the unbound HRP-conjugate, Chromogen solutions are added to the wells. In presence of the (anti**-**μ chain**)**-(anti-HBc IgM)-(HBcAg-Ab (HRP)) immunocomplex, the colorless Chromogens are hydrolyzed by the bound HRP-conjugate to a blue colored product. The blue color turns yellow after stopping the reaction with sulfuric acid. The amount of color can be measured and is proportional to the amount of antibody in the sample. Wells containing samples negative for anti-HBc IgM remain colorless.

Assay principle scheme: Antibody Capture ELISA

Ab(p)+IgM(s)	**→[Ab(p)–IgM(s)]+ENZ**	**→[Ab(p)–IgM(s)–ENZ]**	**→blue→yellow**	**(+)**
Ab(p)	**→[Ab(p)]+ENZ**	**→[Ab(p)]**	**→ no color**	**(-)**
Incubation1	**Incubation2**	**Immobilized Complex**	**Coloring**	**Results**
30min.	**30 min.**		**15 min.**	

Ab(p)–pre-coated anti-IgM antibodies (anti-μ chain)
IgM(s)–anti-HBc IgM antibodies in sample
ENZ– HRP conjugated HBcAg labeled with antibody

SPECIMEN COLLECTION, TRANSPORTATION AND STORAGE

1. **Sample Collection:** Either fresh serum or plasma samples can be used for this assay. Blood collected by venipuncture should be allowed to clot naturally and completely. Care should be taken to ensure that the serum samples are clear and not contaminated by microorganisms. Any visible particulate matters in the sample should be removed by centrifugation at 3000 RPM (round per minutes) for 20 minutes at room temperature or by filtration on 0.22 μm filters. Plasma samples collected into EDTA, sodium citrate or heparin may be tested, but highly lipaemic, icteric, or hemolized samples should not be used as they can give false results in the assay. Do not heat inactivate samples. This can cause sample deterioration.
2. **Transportation and Storage:** Store samples at 2-8°C. Samples not required for assay within 3 days should be stored frozen (-20°C or lower). Avoid multiple freeze-thaw cycles.

SPECIAL INSTRUCTIONS FOR WASHING

1. A good washing procedure is essential to obtain correct and precise analytical data.
2. It is therefore recommended to use a good quality ELISA microplate washer, maintained at the best level of washing performances. In general, no less than 5 automatic washing cycles of 350-400 μL/well are sufficient to avoid false positive reactions and high background.
3. To avoid cross-contaminations of the plate with sample or Enzyme Conjugate, after incubation do not discard the content of the wells but allow the plate washer to aspirate it

automatically.

4. Anyway, we recommend calibrating the washing system on the kit itself in order to match the declared analytical performances. Assure that the microplate washer liquid dispensing channels are not blocked or contaminated and sufficient volume of Wash buffer is dispensed each time into the wells.
5. In case of manual washing, we suggest to carry out at least 5 cycles, dispensing 350-400 µL/well and aspirating the liquid for 5times. If poor results (high background) are observed, increase the washing cycles or soaking time per well.
6. In any case, the liquid aspirated out the strips should be treated with a sodium hypochlorite solution at a final concentration of 2.5% for 24 hours, before liquids are wasted in an appropriate way.
7. The concentrated Washing solution should be diluted 1:20 before use. For one plate, mix 50 mL of the concentrate with 950 mL of water for a final volume of 1000 mL diluted Wash Buffer. If less than a whole plate is used, prepare the proportional volume of solution.

STORAGE AND STABILITY

The components of the kit will remain stable through the expiration date indicated on the label and package when stored between 2-8°C, **do not freeze.** To assure maximum performance of this HBc IgM ELISA kit, protect the reagents from contamination with microorganisms or chemicals during storage.

PRECAUTIONS AND SAFETY

This kit is intended **FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY**

The ELISA assay is time and temperature sensitive. To avoid incorrect result, strictly follow the test procedure steps and do not modify them.

1. Do not exchange reagents from different lots or use reagents from other commercially available kits. The components of the kit are precisely matched for optimal performance of the tests.
2. Make sure that all reagents are within the validity indicated on the kit box and of the same lot. Never use reagents beyond the expiry date stated on labels or boxes.
3. Allow the reagents and samples to reach room temperature (18-30°C) before use. Shake reagent gently before use and return to 2-8°C immediately after use.
4. Do not touch the bottom exterior of the wells; fingerprints or scratches may interfere with microwell reading.
5. When reading the results, ensure that the plate bottom is dry and there are no air-bubbles inside the wells.
6. Never allow the microplate wells to dry after the washing step. Immediately proceed to the next step. Avoid the formation of air bubbles when adding the reagents.
7. Avoid assay steps long time interruptions. Assure same working conditions for all the wells.
8. Calibrate the pipette frequently to assure the accuracy. Use different disposal pipette tips for each specimen and reagents in order to avoid cross-contaminations. Never pipette solutions by mouth.
9. The use of automatic pipettes and disposable tips is recommended.

10. Assure that the incubation temperature is 37°C inside the incubator.
11. When adding samples avoid touching the well's bottom with the pipette tip.
12. When reading the absorbance with a plate reader, it is recommended to determine the absorbance at 450nm or at 450nm with reference at 630nm.
13. All specimens from human origin should be considered as potentially infectious. Strict adherence to GLP (Good Laboratory Practice) regulations can ensure the personal safety. Never eat, drink, smoke, or apply cosmetics in the assay laboratory.
14. The pipette tips, vials, strips and sample containers should be collected and autoclaved for 1 hour at 121°C or treated with 10% sodium hypochlorite for 30 minutes to decontaminate before any further steps for disposal.
15. The Stop Solution contains 0.5M H_2SO_4. Use it with appropriate care. Wipe up spills immediately or wash with water if come into contact with the skin or eyes. ProClin 300 used as a preservative can cause sensation of the skin.
16. The enzymatic activity of the HRP-Conjugate might be affected from dust, reactive chemical, and substances like sodium hypochlorite, acids, alkalins etc. Do not perform the assay in the presence of such substances.

PROCEDURE

Step1 **Reagents Preparation:** Allow the reagents to reach room temperature (18-30°C). Check the Wash buffer concentrate for the presence of salt crystals. If crystals have formed in the solution, resolubilize by warming at 37°C until crystals dissolve. Dilute the Wash Buffer **1:20** with distilled or deionized water. Use only clean vessels to dilute the Wash buffer. Mark three wells as Negative control **(e.g. B1, C1, D1),** two wells as Positive control **(e.g. E1, F1)** and one Blank. (**e.g. A1**, neither samples or Enzyme Conjugate should be added into the Blank well). Use only number of strips required for the test.

Step2 **Diluting Sample:** Dilute each sample **1:1000** with normal saline (Do not dilute the controls, they are ready to use as supplied).

Step3 **Adding Sample:** Add **100 µL** of samples and **100 µL** Positive and Negative controls and into their respective wells. **Note: Use a separate disposal pipette tip for each specimen, Negative Control and Positive Control as to avoid cross-contamination.**

Step4 **Sample Incubation:** Cover the plate with the plate cover and incubate for **30 minutes at 37°C**. It is recommended to use water tank to assure the temperature stability and humidity during the incubation. If dry incubator is used, do not open the door frequently.

Step5 **Washing:** At the end of the incubation remove and discard the plate cover. Wash each well **5** times with diluted Washing buffer. Each time allow the microwells to soak for **30-60 seconds**. After the final washing cycle, turn down the strip plate onto blotting paper or clean towel and tap the plate to remove any remainders.

Step6 **Adding Enzyme Conjugate:** Add **100 µL** of Enzyme Conjugate Reagent into each well except for the Blank.

Step7 **Incubating Enzyme Conjugate:** Cover the plate with the plate cover and incubate for **30 minutes at 37°C**.

Step8 **Washing:** Remove and discard the plate cover. Aspirate the liquid and rinse each well **5times** with Wash buffer (as step 5). After the final washing cycle, turn the strip plate and tap out any remainders.

Step9 **Coloring:** Add **50 µL of Substrate Solution A and after that 50 µL Substrate Solution B** into each well including the **Blank**. Incubate the plate at **37°C for 15 minutes avoiding light**. The enzymatic reaction between the Substrate Solutions and the Enzyme Conjugate produces blue color in Positive control and anti-HBc IgM Positive sample wells.

Step10 **Stopping Reaction:** Using a multichannel pipette or manually add **50 µL** Stop Solution into each well and mix gently. Intensive yellow color develops in Positive control and anti-HBc IgM Positive sample wells.

Step11 **Measuring the Absorbance:** Calibrate the plate reader with the Blank well and read the absorbance at **450 nm**. If a dual filter instrument is used, set the reference wavelength at **630 nm**. Calculate the Cut-off value and evaluate the results.
Note: read the absorbance within **5** minutes after stopping the reaction.

INTERPRETATION OF RESULTS AND QUALITY CONTROL

Each microplate should be considered separately when calculating and interpreting results of the assay, regardless of the number of plates concurrently processed. The results are calculated by relating each sample optical density (OD) value to the Cut-off value (C.O.) of the plate. If the Cut-off reading is based on single filter plate reader, the results should be calculated by subtracting the Blank well OD value from the print report values of samples and controls. In case the reading is based on Dual filter plate reader, do not subtract the Blank well OD from the print report values of samples and controls.

Calculation of Cut-off value (C.O.) = *Nc × 2.1

*Nc = the mean absorbance value for three negative controls.

Important: If the mean OD value of the negative control is lower than 0.05, take it as 0.05.

Example:
1. Calculation of Nc:

Well No	B1	C1	D
Negative controls OD value	0.02	0.012	0.016

Nc=0.016 (Nc is lower than 0.05 so take it as 0.05)
2. Calculation of Cut-off value (C.O.)= 0.05 x 2.1= 0.105

If one of the Negative control values does not meet the Quality Control Range specifications, it should be discarded, and the mean value is calculated again using the remaining two values. If more than one control OD value does not meet the Quality control range specifications, the test is invalid and must be repeated.

Quality control range

The test results are valid if the Quality Control criteria are verified. It is recommended that each laboratory must establish appropriate quality control system with quality control material similar to or identical with the patient sample being analyzed.

1. The absorbance of the Blank well, which contains only Chromogens and Stop solution, is less than 0.080 at 450 nm.
2. The absorbance value OD of the Positive control must be equal to or greater than 0.800 at 450/630 nm or at 450nm after blanking.

3. The absorbance value OD of the Negative control must be less than 0.100 at 450/630 nm or at 450nm after blanking.

Interpretations of the results
(S = the individual absorbance (OD) of each specimen)

Negative Results (S/C.O.<1): samples giving absorbance less than the Cut-off value are negative for this assay, which indicates that no IgM-class antibodies to hepatitis B core antigen have been detected with this anti-HBc IgM ELISA kit. Therefore, there are no evidences for resent infections with HBV and the patients is probably not infected with HBV

Positive Results (S/C.O.≥1): samples giving an absorbance greater than or equal to the Cut-off value are initially reactive ,which indicates that IgM-class antibodies to hepatitis B core antigen have probably been detected with this anti-HBc IgM ELISA kit. Any reactive samples must be retested in duplicates. Repeatedly reactive samples can be considered positive for anti-HBc IgM. Positive results with anti-HBc IgM detection indicate possible recent infection with HBV.

Borderline (S/C.O.=0.9-1.1): samples with absorbance to Cut-off ratio between 0.9 and 1.1 are considered borderline samples and retesting of these samples in duplicates is recommended. Repeatedly positive samples can be considered positive for anti-HBc IgM.
The result from this assay should not be used alone to establish the infection state.

TEST PERFORMANCE AND EXPECTED RESULTS

Analytical Endpoint Sensitivity: 26PEI U/ml

The **clinical specificity** of this assay has been determined by a panel of samples obtained from 2500 healthy blood donors and 230 undiagnosed hospitalized patients. The repeatedly reactive samples and samples confirmed positive with the reference test were not included in the calculation of specificity.

The **clinical sensitivity** of this anti-HBc IgM ELISA kit has been calculated by a panel of samples obtained from 548 hepatitis B patients with well-characterized clinical history based upon reference assays for detection of HBsAg, HBeAg, anti-HBs, anti-HBe, and anti-HBc. This panel included samples from acute, chronic and recovered hepatitis B patients. Licensed anti-HBc IgM ELISA test was used as a confirmatory assay. The evaluation results are given below. Results obtained in individual laboratories may differ.

Specificity	Samples	-	+	Confirmed positive	Specificity	False positive
Blood donors	2500	2492	8	5	99.87%	3
Hospitalized patients	230	210	20	20	100%	0
TOTAL	**2730**	**2702**	**28**	**25**	**99.93%**	**3**
Sensitivity	Samples	-	+	Confirmed positive	**Sensitivity**	False negative
Acute	318	3	314	315	99.68%	1
Chronic	128	110	18	18	100%	0
TOTAL	**446**	**113**	**332**	**333**	**99.84%**	**1**
Recovery	102	101	1	1	100%	0

Marker prevalence in follow up of patients infected with HBV:

Days since infection	Number of samples	+	-	Detected prevalence of anti-HBc IgM
0	10	2	8	20%
1-10	12	3	8	25%
11-20	13	4	7	30%
21-30	9	8	1	88%
31-50	9	9	0	100%
51-70	14	14	14	100%
71-100	11	11	11	100%
101-120	8	8	8	100%
121-150	3	3	3	100%
151-170	2	1	1	50%
171-200	1	0	1	0%
Total:	92	63	29	73.66%

Analytical Specificity:

No cross reactivity observed with samples from patients infected with HAV, HCV, HIV, CMV, TP, and HTLV.

No interferences from rheumatoid factors up to 2000 U/mL were observed during clinical testing. The assay performance characteristics are unaffected from elevated concentrations of bilirubin, hemoglobin, and triolein.

Reproducibility		Within run		Between run	
Specimen Type	N0.	Mean OD	CV%	Mean OD	CV%
Weak positive	10	0.352	8.1%	0.302	8.5%
Moderate positive	10	0.884	7.3%	0.805	7.6%
Strong positive	10	1.821	4.6%	1.783	5.1%
Positive control	10	2.0	4.3%	1.958	4.4%

LIMITATIONS

1. Non-repeatable reactive results may be obtained with any ELISA test due to the general characteristics of this type of assays. A negative result with an antibody detection test does not preclude the possibility of infection. Antibodies may be undetectable during the early stages of the disease and in some immunosuppresed individuals.
2. Any positive results must be interpreted in conjunction with the patient clinical information and other laboratory results.
3. Common sources for mistakes: kits beyond the expiry date, bad washing procedures and wrong washing buffer concentration, contaminated reagents, incorrect assay procedure steps, insufficient aspiration during washing, failure to add samples or reagents, equipment, timing, volumes, sample nature and quality.
4. The prevalence of the marker will affect the assay's predictive values.
5. False negative results can occur from inhibition of specific IgM in the presence of high titers of specific IgG. The removal of IgG can be helpful to prevent false negative results and methods for this are given elsewhere.

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DIALAB Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, A-2351 Wiener Neudorf, Austria
Phone: ++43 (0) 2236 660910-0, Fax: ++43 (0) 2236 660910-30, e-mail: office@dialab.at