CE
0344

Anti-HBc IgM Elisa

KAPG4CME3

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LOT : 090515/1

Anti-HBc IgM Elisa

CE 0344

en

For in vitro qualitative detection of IgM antibody to hepatitis B virus core antigen (Anti-HBc IgM) in human serum or plasma

KAPG4CME3

IN VITRO DIAGNOSTIC USE

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1) INTENDED USE

ANTI-HBc IgM ELISA is an enzyme immunoassay for in vitro qualitative detection of IgM antibody to hepatitis B virus core antigen (Anti-HBc IgM) in human serum or plasma (heparin, EDTA or citrate).

2) SUMMARY AND TEST EXPLANATION

The hepatitis B virus (HBV) consists of an external envelope (HBsAg) and an inner core (HBcAg). In acute HBV infection, IgM antibodies to HBcAg (Anti-HBc IgM) are detectable in serum or plasma shortly after the onset of viral replication and remain in the circulation for about 7 to 17 weeks. The detection of anti-HBc IgM antibodies is used, in conjunction with HBsAg determination, as indicative marker of the phase of the infection and for the monitoring of patients under treatment with interferon. High anti-HBc IgM titers can be found in acute HBV infection and in attacks during chronic hepatitis B. The level of anti-HBc IgM decreases throughout the course of infection. However, low levels of anti-HBc IgM may persist for over a year after infection in some patients and are found occasionally in chronic carriers.[*1-6]

ANTI-HBc IgM ELISA is a fast test for the qualitative detection of the presence of IgM antibodies to HBcAg in serum or plasma (heparin, EDTA or citrate) specimens. The test utilizes Anti-human IgM on microtiter wells as solid phase and HBcAg and peroxidase-conjugated Anti-HBc in liquid phase in an "IgM capture" principle to detect Anti-HBc IgM levels in serum or plasma.
Specimens with absorbance values ≤ 0.9 x signal/cutoff ratio are considered **NON-REACTIVE** for Anti-HBc IgM.
Specimens with absorbance values ≥ 1.1 x signal/cutoff ratio are considered **REACTIVE** for Anti-HBc IgM.
If the signal/cut-off ratio is within Retest Range (0.9 - 1.1), the test must be repeated in duplicate and interpreted as above.

3) TEST DESCRIPTION

ANTI-HBc IgM ELISA is a solid-phase enzyme immunoassay (ELISA= enzyme-linked immunosorbent assay) –- based on the principle of **"Anti-HBc IgM"**. The solid phase of the microtiter plate is made of polystyrene wells coated with anti-human IgM.
When a serum or plasma specimen containing Anti-HBc IgM is added to the Anti-human IgM-coated wells and incubated, IgM antibodies present in the specimen bind to the Anti-h IgM on the wells. After addition of an HBcAg-containing reagent and a solution containing peroxidase-conjugated anti-HBc a further incubation takes place, during which (Anti-h IgM) • (Anti-HBc IgM) •(HBcAg) • (Anti-HBc• peroxidase) complex is formed on the wells. After washing the microtiter plate to remove unbound material, a solution of TMB substrate is added to the wells and incubated. If Anti-HBc IgM is present in the specimen, after washing, the activity of peroxidase on the wells reflects the content of anti-HBc IgM in a specimen. The peroxidase-TMB reaction is stopped by addition of sulfuric acid. The optical density of developed color is read with a suitable photometer at 450 nm with a selected reference wavelength within 620 to 690 nm[*8]

The above described test principle is shown also in the following figure.

A. Specimen (containing human IgM Anti-HBc):

1. Plate (Anti-h IgM) + specimen (containing Anti-HBc IgM) -→ plate (Anti-h IgM) • Anti-HBc IgM
2. Plate (Anti-h IgM)• Anti-HBc IgM + HBcAg + Anti-HBc • peroxidase → plate (Anti-h IgM) • Anti- HBc IgM • HBcAg • (Anti-HBc• peroxidase) complex
3. Wash to remove the unbound materials.
4. Plate (Anti-h IgM) • IgM Anti-HBc IgM • HBcAg • (Anti-HBc • HRPO) complex + TMB substrate solution → light blue to blue color
5. Light blue to blue color + sulfuric acid →light yellow to yellow color, measured at 450nm with a selected reference wavelength within 620 to 690nm[*8]

B. Specimen (without IgM Anti-HBc):

1. Plate (Anti-h IgM) + specimen (without Anti-HBc IgM) → plate (Anti-h IgM)
2. Plate (Anti-h IgM) + HBcAg + Anti-HBc • peroxidase → plate (Anti-h IgM)------ no complex will form
3. Wash to remove the unbound materials.
4. Plate (Anti-human IgM) + TMB substrate solution (colorless) → colorless
5. Colorless + sulfuric acid →colorless, measured at 450nm with a selected reference wavelength within 620 to 690nm[*8]

4) DESCRIPTION OF MATERIALS PROVIDED

- Item 1 - 8 on the following reagent table should be refrigerated at + 2 to +8°C . Washing Solution (20X) and stop solution can be stored at +2 to +30°C.

ITEMS	Components	Description	Qt. per 96 tests
(1)	Anti-IgM Microtiter Plate	One microtiter plate (removable strips) with 96 wells coated with Anti-human IgM.	1 plate
(2)	Ab | HRP Anti-HBc • Peroxidase Solution	Anti-HBc (human) • peroxidase (horseradish) conjugate in buffer with protein stabilizer. Preservatives: 0.003% Gentamycin and 0.01% Thimerosal.	1bottle, 7 ml
(3)	CONTROL | + Anti-HBc IgM Positive Control	Human Anti-HBc IgM in buffer with protein stabilizers. Preservatives: 0.003% Gentamycin and 0.01% Thimerosal.	1 bottle, 2 ml
(4)	DIL | SPE Specimen Diluent	Buffer containing protein stabilizers. Preservatives: 0.003%Gentamycin and 0.01% Thimerosal.	2 bottles 35 ml
(5)	Ag HBcAg Reagent	HBcAg in buffer containing protein stabilizers. Preservatives: 0.003% Gentamycin and 0.01% Thimerosal.	1 bottle, 7 ml
(6)	CONTROL | - Anti-HBc IgM Negative Control	Normal (Anti-HBc IgM negative) human serum containing protein stabilizers. Preservatives: 0.003% Gentamycin and 0.01% Thimerosal.	1 bottle, 2 ml
(7)	CHROM | TMB | CONC Chromogenic TMB concentrate	0.6 mg/ml of 3,3',5,5'-tetramethylbenzidine (TMB) in 40% methanol.	1 bottle, 10 ml
(8)	SUB | BUF Substrate buffer	Citric acid buffer containing 0.03% H_2O_2.	1 bottle, 10 ml
(9)	WASH | SOLN | CONC Conc. Washing Solution (20x)	Phosphate buffer with Tween-20.	1 bottle 52 ml
(10)	STOP | SOLN Stop Solution	2N H_2SO_4 (Sulfuric acid)	1 bottle 12 ml

- OTHER MATERIALS REQUIRED, BUT NOT PROVIDED

ITEMS	Components
(1)	5µl, 50µl and 100 µl micropipettes and tips are needed
(2)	Incubator or waterbath with temperature control at +37 ±1°C
(3)	Tubes for specimen dilution.
(4)	Plate washing equipment.
(5)	Purified water: distilled or deionized water.
(6)	ELISA microwell reader: Dual wavelength 450nm with 620-690nm as reference wavelength[*8], bandwidth 10nm.
(7)	Fully automatic EIA micro-plate analyzer is optional. User should validate the automatic EIA micro-plate analyzer in combination with the kit.

4.1) Storage Conditions and Stability of Kit and Components

Kit/components	Storage condition	State	Stability
ANTI-HBc IgM ELISA KIT	+2 to +8 °C	Original	15 months
		Once open	1 month
Anti-HBc IgM Positive Control	+2 to +8 °C	Original	15 months
		Once open	1 month
Anti-HBc IgM Negative Control	+2 to +8 °C	Original	15 months
		Once open	1 month

HBcAg Reagent	+2 to +8 °C	Original	15 months
		Once open	1 month
Specimen Diluent	+2 to +8 °C	Original	16 months
		Once open	1 month
Anti-human IgM Plate	+2 to +8 °C	Original	15 months
		Once open	2 months
Anti-HBc • Peroxidase Conjugate Solution	+2 to +8 °C	Original	15 months
		Once open	1 month
Concentrated Washing Solution (20x)	Room temp.	Original	24 months
		Once open	1 month
20x Diluted Washing Solution	Room temp.	Diluted	2 days
	+2 to +8 °C	Diluted	1 week
Chromogenic TMB concentrate	+2 to +8 °C	Original	18 months
		Once open	1 month
Substrate buffer	+2 to +8 °C	Original	18 months
		Once open	1 month
Stop Solution	Room temp.	Original	24 months
		Once open	1 month

5) INSTRUCTION FOR USE

5.1) Warnings:

5.1.1) This reagent kit is for professional use only.
5.1.2) This reagent kit is for *in vitro* diagnostic use only.
5.1.3) Bring all kit reagents and samples to room temperature (+20 to +30 °C) and mix carefully before use.
5.1.4) Do not use reagent beyond its expiration date.
5.1.5) Do not interchange reagents between different lots.
5.1.6) Do not pipette in the mouth.
5.1.7) Do not smoke or eat in areas where specimens or reagents are handled.
5.1.8) The positive control, negative control, HBcAg Reagent, conjugate solution and specimens should be regarded as potential hazards to health. They should be used and discarded according to the user's laboratory safety procedures. Such safety procedures probably will include the wearing of protective gloves and avoiding the generation of aerosols.
5.1.9) Potential infectious specimens and non-acid containing spills or leakages should be wiped up thoroughly with 5% sodium hypochlorite or treated in accordance with the laboratory's practice for potential bio-hazard control.
5.1.10) Prior to dispose the waste of used specimens and kit reagents as general waste, it should be treated in accordance with the local procedures for potential bio-hazardous waste or treated as follows:
Both liquid and solid waste should be autoclaved maintaining +121 °C for at least 30 minutes.
Solid waste can also be incinerated.
Non-acidic liquid waste can be treated with sodium hypochlorite diluted to a final concentration of 1%.
Acidic liquid wastes must be neutralized before treatment with sodium hypochlorite as mentioned above and should stand for 30 minutes to obtain effective disinfection.
5.1.11) Stop solution is an irritant to skin, eyes, respiratory tract and mucous membranes. Avoid contact of the stop solution with skin and mucous membranes. In case of contact, clean with large lots of water immediately. In case of inhalation, supply fresh air and seek medical advice in case of complaints.
5.1.12) Chromogenic TMB concentrate contains 40% methanol which is toxic: danger of serious irreversible effects through inhalation, in contact with skin and if swallowed. Chromogenic TMB concentrate contains dimethyl sulfoxide, an irritant to skin and mucous membranes.
5.1.13) Although all human sourced material are tested non-reactive for Anti-HCV and Anti-HIV, and inactivated at +56 °C for one hour, the reagent shall be handled as potential infectious material.[*7]

5.2) Specimen Collection and Preparation for Analysis

5.2.1) No special preparation of the patient is required prior to blood collection. Blood should be collected by approved medical techniques.
5.2.2) Either serum or plasma can be used with this diagnostic kit. Whole blood specimen should be separated as soon as possible in order to avoid hemolysis. Any particulates (e.g. fibrin clots, erythrocytes) contained in the specimen should be removed prior to use.
5.2.3) Specimens must be stored at +2 to +8 °C and avoided heat-inactivation to minimize deterioration. For long-term storage, specimens should be frozen below -20 °C. Storage in self-defrosting freezers is not recommended.
5.2.4) Frozen specimens must be thoroughly thawed and mixed homogenously before test.
5.2.5) Avoid multiple freeze-thaw procedures

5.2.6) **WARNING**

1. The specimen must not contain any compounds of AZIDE, which inhibits the peroxidase activity.
2. Incompletely coagulated serum samples and microbial-contaminated specimens should not be used.

5.3) Reagents Storage

5.3.1) The kit must be stored at + 2 to +8 °C. Do not freeze.

5.3.2) Strips of the plate should be used within 2 months after opening the original aluminum foil bag. The unused strips should be kept in the aluminum foil bag and taped the opening tightly.

5.3.3) Return reagents to +2 to +8 °C immediately after use.

5.3.4) Washing Solution (20x) Concentrate is stored and shipped at +2 to +8 °C, which can cause crystallization. If crystal has been precipitated before use, warm up the solution in +37 °C water bath till the crystal is dissolved.

5.4) Plate washing procedure

5.4.1) Preparation of washing solution:
Dilute Washing Solution (20x) Concentrate with distilled or de-ionized water to 1:20 dilution. Do not use tap water.

5.4.2) Plate washing:

(a) For plate washer with overflow aspirating function: 6 cycles with at least 0.5ml washing buffer per well per cycle

or

(b) For plate washer without overflow aspirating function: 8 cycles with at least 0.35ml washing buffer per well per cycle.

5.4.3) Blot dry by inverting the plate and tapping firmly onto absorbent paper. Too much residual wash buffer will cause false results.

⚠**WARNING**
Improper washing will cause false results.

5.5) Test Procedure

5.5.1) Bring all reagents and specimens to room temperature (+20 to +30 °C) before assay. Adjust water bath or incubator to +37±1 °C.

5.5.2) Make 1+100 dilution of each specimen:
Prepare for each specimen a tube for dilution, with exception of the controls. Add 500 µl of Specimen Diluent and 5 µl of each specimen to each tube respectively and shake to mix.

⚠**NOTE:**
a) Do not dilute the controls.
b) Use a new pipette tip after each sampling to avoid cross-contamination.

5.5.3) Reserve one well for Blank. Add 100 µl of Negative Control to each three wells, 100 µl of Positive Control to each two wells, 100 µl of Specimen Diluent to each of the other reaction wells for test specimen.

5.5.4) Add 5 µl of each diluted specimen to each well containing Specimen Diluent, respectively.

5.5.5) Gently tap the plate.

5.5.6) Remove the protective backing of the adhesive slip and press it on the reaction plate, so that it is tightly sealed.

5.5.7) Incubate the plate at +37 °C for 1 hour.

5.5.8) At the end of the incubation period, remove and discard the Adhesive Slip and wash plate by following "5.4. PLATE WASHING PROCEDURE".

5.5.9) Add 50 µl of HBcAg reagent to each reaction well except the Blank followed by 50 µl of Anti-HBc-Peroxidase solution. Apply a new adhesive slip.

5.5.10) Incubate the plate at +37 $\pm$ 1°C °C for 1 hour.

5.5.11) At the end of the incubation period, remove and discard the adhesive slip, wash the plate by following "5.4. PLATE WASHING PROCEDURE".

5.5.12) Select one of the following two methods for color development:

A. Mix equal volumes of **Chromogenic TMB concentrate and Substrate buffer** in a clean container immediately prior to use. Add **100 µl** of the mixture solution to each well including the blank well.

B. Add **50 µl** of **Chromogenic TMB concentrate** first, and then add **50 µl** of **Substrate buffer** into each well including the blank. Mix well gently .

⚠**NOTE:** Chromogenic TMB concentrate should be colorless to light blue; otherwise, it should be discarded. The mixture of Chromogenic TMB concentrate and substrate buffer should be used within 30 minutes after mix. The mixture should be protected from exposition to intense light.

5.5.13) Cover the plate with the black cover and incubate at room temperature for 30 minutes.

5.5.14) Stop the reaction by adding 100 µl of stop solution to each well including the blank.

5.5.15) Determine the absorbance of controls and test specimens within 15 minutes with a precision photometer at 450 nm with a selected reference wavelength within 620 to 690nm[*8].
Use the blank well to blank the photometer.

⚠**NOTE:** The color of the blank should be colorless to light yellowish; otherwise, the test result is invalid. In this case the tests must be repeated.
Substrate blank : absorbance value must be less than 0.100.

5.6) Calculation of Test Results

5.6.1) Calculation of the NCx (Mean Absorbance of Negative Control).

Example:

Sample No.	Absorbance
1	0.068
2	0.072
3	0.070

NCx = (0.068+0.072 + 0.070) / 3 = 0.070

⚠ **NOTE:** NCx **must be ≤ 0.1, otherwise, the test is invalid.**

5.6.2) Calculation of PCx (Mean Absorbance of Positive Control)

Example:

Sample No.	Absorbance
1	1.612
2	1.613

PCx = (1.612 + 1.613) /2 = 1.613

⚠ **NOTE:** PCx **must be ≥ 0.4 , otherwise, the test is invalid.**

5.6.3) Calculation of **P-N Value**

P-N = PCx - NCx

Example:

P - N = 1.613 – 0.070 = 1.543

⚠ **NOTE: P - N Value must be ≥ 0.3, otherwise, the test is invalid.**

5.6.4) Calculation of the **Cutoff Value**

Cutoff Value = NCx + (PCx)/4

Example:

Cutoff Value = 0.070 + (1.613)/4 = 0.473

5.6.5) Calculation of the **Retest Range**

Retest Range = Cutoff Value ±10%

Example: Cutoff Value = 0.473

Retest Range = (0.473 - 0.047) to (0.473 +0.047) = 0.426 to 0.520

5.7) Validity of Test Runs

5.7.1) **NCx must be ≤ 0.1, otherwise, the test is invalid.**

5.7.2) **PCx must be ≥ 0.4 , otherwise, the test is invalid.**

5.7.3) **P-N Value must be ≥ 0.3 , otherwise, the test is invalid.**

⚠ **NOTE:** Negative Control: absorbance value must be less than or equal to 0.100 after subtracting the blank.

5.8) Interpretation of Results

Specimens with signal/cut-off ratio≤ 0.9 are considered non-reactive for Anti-HBc IgM. Specimens with signal/cut-off ratio ≥ 1.1 are considered reactive for Anti-HBc IgM.

If the signal/cut-off ratio is within Retest Range (0.9 - 1.1), the test must be repeated in duplicate and interpreted as above. If both results are non-reactive the final result is non-reactive, if both results are reactive the final result is reactive. Any other combination is an indeterminate result. Testing of follow up samples and other hepatitis B serological markers should be taken into account in case of an indeterminate result.

⚠ **NOTE:**

Interpretation of Results: The result of an Anti-HBc IgM test should always be interpreted taking into account other hepatitis B serological and NAT markers as well as clinical symptoms.

5.9) Troubleshooting

If the result cannot be reproduced, a preliminary troubleshooting should be performed by checking the possibilities listed below:

5.9.1) Improper washing procedure.
5.9.2) Contaminated with positive specimen.
5.9.3) Wrong volume of sample, conjugate or substrate.
5.9.4) Contamination of well rim with conjugate.
5.9.5) Improper specimen such as hemolyzed serum or plasma, specimen containing precipitate and specimen not thoroughly mixed before use.
5.9.6) Wrong incubation time or temperature.
5.9.7) Obstructed or partial obstructed washer aspirate/dispense head and needles.
5.9.8) Insufficient aspiration.

5.10) Limitations and Interferences

5.10.1) This reagent kit is to be used for un-pooled human serum or plasma samples only. It cannot be used for testing of non-human serum or plasma samples.
5.10.2) The reagent kit has not been validated for use with cadaveric samples.
5.10.3) Non-repeatable false positive results may be obtained with any enzyme immunoassay kits, largely due to technical error either on the part of the operator or malfunction of apparatus used.
5.10.4) When Anti-HBc IgM test results are used to differentiate acute from non-acute HBV infections, the clinical history of the patient and the results of other markers (if available) shall be taken into account.
5.10.5) A negative Anti-HBc IgM result does not preclude the possibility of previous infection with HBV.
5.10.6) Potential interfering substances:

Potential interfering samples, i.e. samples with hyperlipemia, hemolysis, hyper-bilirubinemia, samples with monoclonal immunoglobulin components, samples containing elevated levels of autoimmune antibodies (rheumatoid factor-RF, antinuclear antibodies-ANA, or anti-mitochondrial antibodies-ANA) did not affect the test result with the present Anti-HBc IgM kit ANTI-HBc IgM ELISA.

5.10.7) The anticoagulants heparin, EDTA and sodium citrate have no influence on the specificity of ANTI-HBc IgM ELISA and can be used to obtain plasma samples for analysis with the present Anti-HBc IgM kit.

5.11) Performance Characteristics

5.11.1) Diagnostic Specificity

		Negative Result	
Characteristics of the samples	**No. of sample**	**Reference Assay**	**ANTI-HBc IgM Assay**
Clinical/hospitalized patients (HBV negative 'clinicals')	200	200	200
Blood donors (HBV/Anti-HBc negative 'donors')	200	198	200
Sample containing potentially interfering substances	50	50	50
Total	450	448	450
Diagnostic Specificity	-------	99.5%	**100%**

5.11.1.1) Potential interfering substances

Potential interferences with the ANTI-HBc IgM assay were investigated.

For each potential interfering substance, at least two serum samples containing different amounts of the potentially interfering substance were mixed in fixed ratios of 10 + 0; 7 + 3; 5 + 5; 3 + 7; 0 + 10 with other serum samples containing increased Anti-HBc IgM levels but no interfering factors. The neat samples as well as the mixtures were analyzed.

In particular the specificity study included:

- lipemic (turbid) samples before and after high speed centrifugation
- hemolytic samples or hemolysate
- icteric samples (=hyperbilirubinemia)
- samples with monoclonal immunoglobulin components
- samples containing elevated levels of autoimmune antibodies (rheumatoid factor - RF, antinuclear antibodies – ANA, or antimitochondrial antibodies-AMA)

No interference was detected with both used lots, neither the type of anticoagulant had an influence on both tested lots of ANTI-HBc IgM ELISA.

5.11.2) Analytical Sensitivity and Linearity:

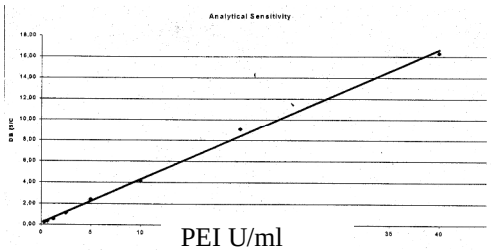
5.11.2.1) Detection limit using dilution of Anti-HBc IgM Reference Materials:

A serial dilutions of the Paul Ehrlich Institute (PEI) (Langen, Germany) Standard Material for Anti-HBc IgM (100 PEI U/ml) was used to evaluate the analytical sensitivity (detection limit) of ANTI-HBc IgM ELISA.

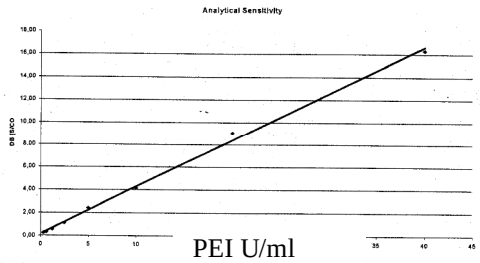
The analytical sensitivity (detection limit) was defined as the lowest concentration that can be detected.

Both lots of ANTI-HBc gGM ELISA had an analytical sensitivity at 2.5 PEI U/ml, better than the reference assay by one twofold dilution.

Analytical Sensitivity of Lot #B44333PT
S/C vs Concentration

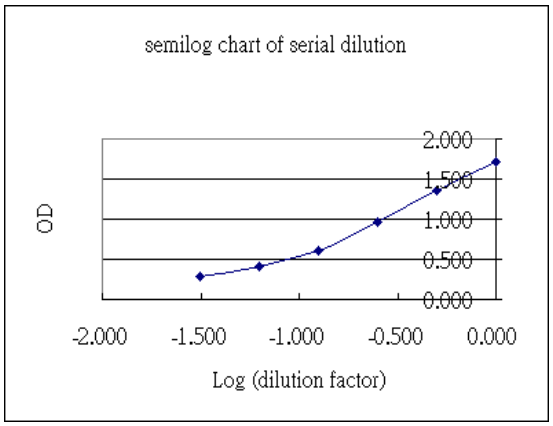


Analytical Sensitivity of Lot #B44334PT
S/C vs Concentration

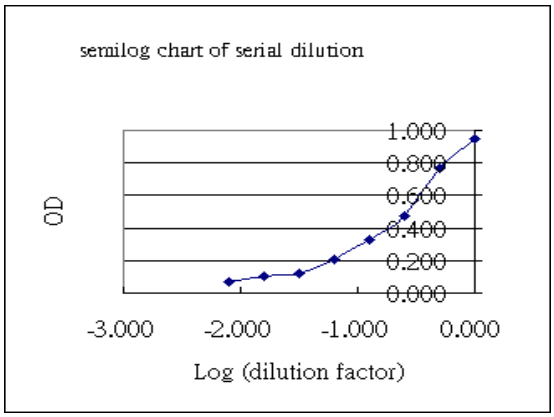


5.11.2.2) Linearity using blood samples

Linearity was evaluated with 2 lots of ANTI-HBc IgM ELISA using high Anti-HBc-IgM positive serum samples after diluting them throughout the measuring range and then around the cutoff level in narrow dilution steps.



Linear Range: OD from 1.714 to 0.290
Linearity (semilog chart): R = 0.983



Linear Range: OD from 0.95 to 0.118
Linearity (semilog chart): R = 0.980

5.11.3) Diagnostic Sensitivity

Positive specimens/Specimens used to evaluate the diagnostic sensitivity/ Patients with HBV infection.

5.11.3.1) HBV infected individuals

207 known Anti-HBc-IgM positive samples were tested in the ANTI-HBc IgM ELISA, in which 199 of these 207 samples were detected as positive, 1 as negative and 7 as indeterminate.

The resolved diagnostic sensitivity for the ANTI-HBc IgM ELISA was 96.1 % (199/207) and better than the sensitivity of the CE marked reference assay, which showed a resolved diagnostic sensitivity of 90.8 % (188/207), detecting 188 of these 207 samples as positive, 13 as negative and 6 as indeterminate.

Samples	ANTI-HBc IgM	Reference Assay
positive	199	188
negative	1	13
indeterminate	7	6
total	207	207
Resolved diagnostic sensitivity	96.1%	90.8%

5.11.3.2) Commercial seroconversion panels

Eight commercially available seroconversion panels (from Boston Biomedica Inc., BBI; West Bridgewater, MA USA; Pyramid-Profile Diagnostics, Sherman Oaks, CA, USA and NABI, Boca Roton, FL, USA), consisting of follow-up samples which were collected at weekly or monthly intervals from patients suffering from acute hepatitis B, were used. All the panels had been characterized for HBV-specific serological markers (anti-HBs, anti-HBc, anti-HBc-IgM, and HBsAg).

When testing the seroconversion panels DIAsource ANTI-HBc IgM ELISA detected Anti-HBc IgM about 1 bleed earlier in the NABI panel RP-009 and the reference device detected the Anti-HBc IgM two bleeds earlier in the BBI Panel 935A and one bleed earlier in the Nabi panel RP-017. In summary there was no significant difference between the DIAsource ANTI-HBc IgM ELISA assay and the reference device.

5.11.4) Precision

5.11.4.1) Intra-run repeatability

For determination of intra-assay (within-run) precision, the positive control and two patient serum samples with different Anti-HBc IgM titer (slightly above the cutoff level and at medium level) were analyzed in replicates of 20 in a single “run” over 3 days and the measured absorbance were registered.

The mean and the within-run coefficient of variation (CV) for the positive control and patient sample were calculated.

Item tested	Sample size	precision
Positive Control	N = 20	CV ≤ 17.31%
Patient Serum #1	N = 20	CV ≤ 20.11%
Patient Serum #2	N = 20	CV≤ 13.53%

5.11.4.2) Inter-run reproducibility

Item tested	Sample size	precision
Positive Control	N = 60	CV ≤ 12.83%
Patient Serum #1	N = 60	CV ≤ 12.00%
Patient Serum #2	N = 60	CV ≤8.24%

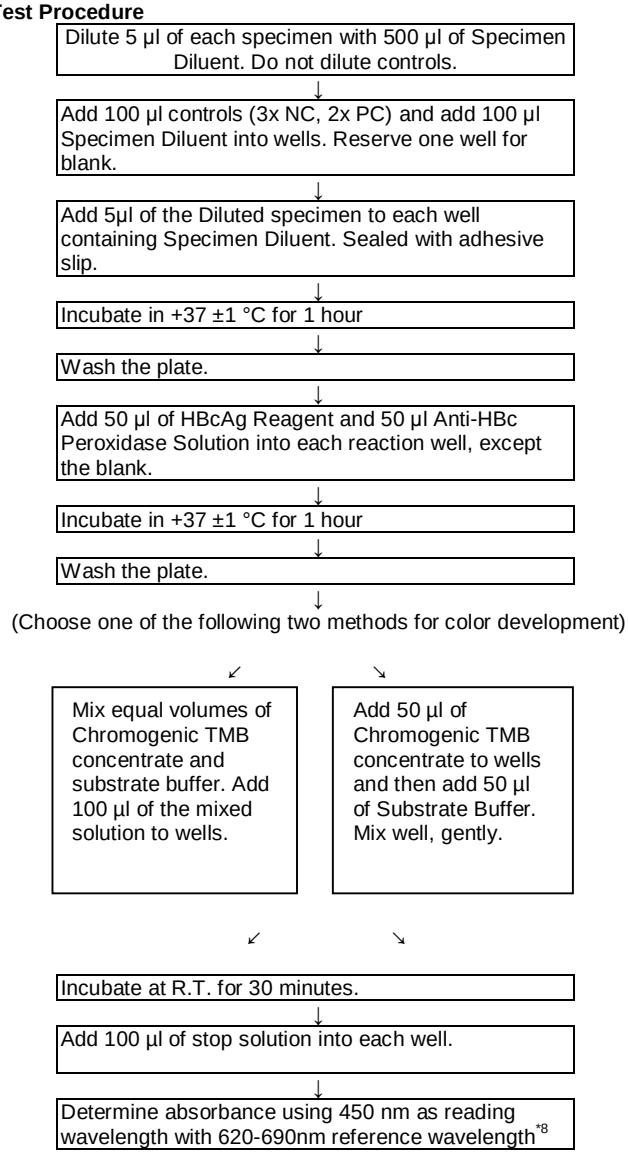
5.11.5) Traceability

Concentration of Positive Control of ANTI-HBc IgM ELISA = 640 PEI U/ml ±30%

5.11.6) Antibody Excess/High-dose Hook Effect

To check the antigen excess/high-dose hook effect of ANTI-HBc IgM ELISA two serum samples with a very high Anti-HBc IgM titer (OD□1.5) were tested in serial dilution. No antibody excess/high-dose hook effect was observed in the two samples.

5.12) Flow Chart of the Test Procedure



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NOTES:

*8 The reference wavelength of spectrometer can be 620nm to 690nm. However, user should validate the photometer in combination with this kit before use.

Revision Date : 2009-05-15

	Used symbols	**Symboles utilisés**
	Consult instructions for use	Consulter les instructions d'utilisation
	Storage temperature	Température de conservation
	Use by	Utiliser jusque
LOT	Batch code	Numéro de lot
REF	Catalogue number	Référence de catalogue
CONTROL	Control	Contrôle
IVD	In vitro diagnostic medical device	Dispositif médical de diagnostic in vitro
	Manufacturer	Fabricant
	Contains sufficient for <n> tests	Contenu suffisant pour <n> tests
WASH SOLN CONC	Wash solution concentrated	Solution de lavage concentrée
CAL 0	Zero calibrator	Calibrateur zéro
CAL N	Calibrator #	Calibrateur #
CONTROL N	Control #	Contrôle #
Ag 125I	Tracer	Traceur
Ab 125I	Tracer	Traceur
Ag 125I CONC	Tracer concentrated	Traceur concentré
Ab 125I CONC	Tracer concentrated	Traceur concentré
	Tubes	Tubes
INC BUF	Incubation buffer	Tampon d'incubation
ACETONITRILE	Acetonitrile	Acétonitrile
SERUM	Serum	Sérum
DIL SPE	Specimen diluent	Diluant du spécimen
DIL BUF	Dilution buffer	Tampon de dilution
ANTISERUM	Antiserum	Antisérum
IMMUNOADSORBENT	Immunoadsorbent	Immunoadsorbant
DIL CAL	Calibrator diluent	Diluant de calibrateur
REC SOLN	Reconstitution solution	Solution de reconstitution
PEG	Polyethylene glycol	Glycol Polyéthylène
EXTR SOLN	Extraction solution	Solution d'extraction
ELU SOLN	Elution solution	Solution d'elution
GEL	Bond Elut Silica cartridges	Cartouches Bond Elut Silica
PRE SOLN	Pre-treatment solution	Solution de pré-traitement
NEUTR SOLN	Neutralization solution	Solution de neutralisation
TRACEUR BUF	Tracer buffer	Tampon traceur
	Microtiterplate	Microplaque de titration
Ab HRP	HRP Conjugate	HRP Conjugué
Ag HRP	HRP Conjugate	HRP Conjugué
Ab HRP CONC	HRP Conjugate concentrate	HRP Conjugué concentré
Ag HRP CONC	HRP Conjugate concentrate	HRP Conjugué concentré
CONJ BUF	Conjugate buffer	Tampon conjugué
CHROM TMB CONC	Chromogenic TMB concentrate	Chromogène TMB concentré
CHROM TMB	Chromogenic TMB solution	Solution chromogène TMB
SUB BUF	Substrate buffer	Tampon substrat
STOP SOLN	Stop solution	Solution d'arrêt
INC SER	Incubation serum	Sérum d'incubation
BUF	Buffer	Tampon
Ab AP	AP Conjugate	AP Conjugué
SUB PNPP	Substrate PNPP	Tampon PNPP
BIOT CONJ CONC	Biotin conjugate concentrate	Biotine conjugué concentré
AVID HRP CONC	Avidine HRP concentrate	Avidine HRP concentré
ASS BUF	Assay buffer	Tampon de test
Ab BIOT	Biotin conjugate	Biotine conjugué
Ab	Specific Antibody	Anticorps spécifique
SAV HRP CONC	Streptavidin HRP concentrate	Concentré streptavidine HRP
NSB	Non-specific binding	Liant non spécifique
2nd Ab	2nd Antibody	Second anticorps
ACID BUF	Acidification Buffer	Tampon d'acidification

	Gebruikte symbolen	**Gebrauchte Symbolen**
	Raadpleeg de gebruiksaanwijzing	Gebrauchsanweisung beachten
	Bewaartemperatuur	Lagern bei
	Houdbaar tot	Verwendbar bis
LOT	Lotnummer	Chargenbezeichnung
REF	Catalogusnummer	Bestellnummer
CONTROL	Controle	Kontrolle
IVD	Medisch hulpmiddel voor in-vitro diagnostiek	In Vitro Diagnostikum
	Fabrikant	Hersteller
	Inhoud voldoende voor <n> testen	Ausreichend für <n> Ansätze
WASH SOLN CONC	Wasoplossing, geconcentreerd	Waschlösung-Konzentrat
CAL 0	Nulkalibrator	Null kalibrator
CAL N	Kalibrator #	Kalibrator #
CONTROL N	Controle #	Kontrolle #
Ag 125I	Tracer	Tracer
Ab 125I	Tracer	Tracer
Ag 125I CONC	Tracer geconcentreerd	Tracer Konzentrat
Ab 125I CONC	Tracer geconcentreerd	Tracer Konzentrat
	Buisjes	Röhrchen
INC BUF	Incubatiebuffer	Inkubationspuffer
ACETONITRILE	Acetonitrile	Azetonitril
SERUM	Serum	Humanserum
DIL SPE	Specimen diluent	Probenverdünner
DIL BUF	Verdunningsbuffer	Verdünnungspuffer
ANTISERUM	Antiserum	Antiserum
IMMUNOADSORBENT	Immunoadsorbent	Immunadsorbens
DIL CAL	Kalibratorverdunner	Kalibratorverdünnung
REC SOLN	Reconstitutieoplossing	Rekonstitutionslösung
PEG	Polyethyleen glycol	Polyethylenglykol
EXTR SOLN	Extractieoplossing	Extraktionslösung
ELU SOLN	Elutieoplossing	Eluierungslösung
GEL	Bond Elut Silica kolom	Bond Elut Silikakartuschen
PRE SOLN	Pre-behandelingsoplossing	Vorbehandlungslösung
NEUTR SOLN	Neutralisatieoplossing	Neutralisierungslösung
TRACEUR BUF	Tracerbuffer	Tracer-Puffer
	Microtiterplaat	Mikrotiterplatte
Ab HRP	HRP Conjugaat	HRP Konjugat
Ag HRP	HRP Conjugaat	HRP Konjugat
Ab HRP CONC	HRP Conjugaat geconcentreerd	HRP Konjugat Konzentrat
Ag HRP CONC	HRP Conjugaat geconcentreerd	HRP Konjugat Konzentrat
CONJ BUF	Conjugaat buffer	Konjugatpuffer
CHROM TMB CONC	Chromogene TMB geconcentreerd	Chromogenes TMB Konzentrat
CHROM TMB	Chromogene Oplossing TMB	Farblösung TMB
SUB BUF	Substraatbuffer	Substratpuffer
STOP SOLN	Stopoplossing	Stopplösung
INC SER	Incubatieserum	Inkubationsserum
BUF	Buffer	Puffer
Ab AP	AP Conjugaat	AP Konjugat
SUB PNPP	Substraat PNPP	Substrat PNPP
BIOT CONJ CONC	Geconcentreerd Biotine conjugaat	Biotin-Konjugat-Konzentrat
AVID HRP CONC	Geconcentreerd Avidine-HRP conjugaat	Avidin-HRP-Konzentrat
ASS BUF	Assay buffer	Assaypuffer
Ab BIOT	Biotine conjugaat	Biotin-Konjugat
Ab	Specifiek antilichaam	Spezifischer Antikörper
SAV HRP CONC	Streptavidine-HRP concentraat	HRP Streptavidinkonzentrat
NSB	Aspecifieke binding	Unspezifische Bindung
2nd Ab	2de antilichaam	Sekundärer Antikörper
ACID BUF	Verzuringsbuffer	Ansäuerungspuffer

	Simboli utilizzati	**Símbolos utilisados**
	Consultare le istruzioni per l'uso	Consultar las instrucciones de uso
	Limitazioni di temperatura	Limitación de temperatura
	Utilizzare entro	Fecha de caducidad
LOT	Numero di lotto	Codigo de lote
REF	Numero di catalogo	Número de catálogo
CONTROL	Controllo	Control
IVD	Dispositivo medico-diagnostico in vitro	Producto sanitario para diagnóstico in vitro
	Fabbricante	Fabricante
	Contenuto sufficiente per <n> saggi	Contenido suficiente para <n> ensayos
WASH SOLN CONC	Tampone di lavaggio concentrato	Solución de lavado concentrada
CAL 0	Calibratore zero	Calibrador cero
CAL N	Standard #	Calibrador #
CONTROL N	Controllo #	Control #
Ag 125I	Marcato	Trazador
Ab 125I	Marcato	Trazador
Ag 125I CONC	Marcato concentrato	Trazador concentrada
Ab 125I CONC	Marcato concentrato	Trazador concentrada
	Provette	Tubos
INC BUF	Tampone incubazione	Tampón de incubación
ACETONITRILE	Acetonitrile	Acetonitrilo
SERUM	Siero	Suero
DIL SPE	Diluente campione	Diluyente de Muestra
DIL BUF	Tampone diluizione	Tampón de dilución
ANTISERUM	Antisiero	Antisuero
IMMUNOADSORBENT	Immunoassorbente	Inmunoadsorbente
DIL CAL	Diluente calibratore	Diluyente de calibrador
REC SOLN	Soluzione di ricostituzione	Solución de Reconstitución
PEG	Polietilenglicole	Glicol Polietileno
EXTR SOLN	Soluzione di estrazione	Solución de extracción
ELU SOLN	Soluzione di eluizione	Solución de elución
GEL	Cartucce di silice bond elut	Cartuchos Bond Elut Silica
PRE SOLN	Soluzione di pretrattamento	Solución de Pre-tratamiento
NEUTR SOLN	Soluzione di neutralizzazione	Solución de Neutralización
TRACEUR BUF	Tracer Buffer	Tampón de trazador
	Piastra di microtitolazione	Placa de microvaloración
Ab HRP	HRP Coniugato	HRP Conjugado
Ag HRP	HRP Coniugato	HRP Conjugado
Ab HRP CONC	HRP Coniugato concentrato	HRP Conjugado concentrada
Ag HRP CONC	HRP Coniugato concentrato	HRP Conjugado concentrada
CONJ BUF	Buffer coniugato	Tampón de Conjugado
CHROM TMB CONC	Cromogena TMB concentrato	Cromógena TMB concentrada
CHROM TMB	Soluzione cromogena TMB	Solución Cromógena TMB
SUB BUF	Tampone substrato	Tampón de sustrato
STOP SOLN	Soluzione di arresto	Solución de Parada
INC SER	Incubazione con siero	Suero de Incubación
BUF	Buffer	Tampón
Ab AP	AP Coniugato	AP Conjugado
SUB PNPP	Substrato PNPP	Sustrato PNPP
BIOT CONJ CONC	Concentrato coniugato con biotina	Concentrado de conjugado de biotina
AVID HRP CONC	Concentrato avidina HRP	Concentrado avidina-HRP
ASS BUF	Soluzione tampone per test	Tampón de ensayo
Ab BIOT	Coniugato con biotina	Conjugado de biotina
Ab	Anticorpo Specifico	Anticuerpo específico
SAV HRP CONC	Streptavidina-HRP concentrata	Estreptavidina-HRP Concentrado
NSB	Legame non-specifico	Unión no específica
2nd Ab	2° Anticorpo	Segundo anticuerpo
ACID BUF	Tampone Acidificante	Tampón de Acidificación

	Símbolos utilizados	**Använda symboler**
	Consulte instruções de utilização	Läs instruktionerna före användning
	Temperatura de conservação	Förvaringstemperatur
	Utilizar antes de	Används av
LOT	Código de lote	Lotnummer
REF	Número de catálogo	Katalognummer
CONTROL	Controlo	Kontroll
IVD	Dispositivo médico de diagnóstico in vitro	In vitro diagnostiskt kit
	Fabricante	Tillverkare
	Conteúdo suficiente para <n> testes	Innehållet räcker till <n> prover
WASH SOLN CONC	Solução de lavagem concentrada	Tvättlösning, koncentrerad
CAL 0	Calibrador zero	Nollkalibrerare
CAL N	Calibrador #	Kalibrator #
CONTROL N	Controlo #	Kontroll #
Ag 125I	Marcador	Radioisotop, antigen
Ab 125I	Marcador	Radioisotop, antikropp
Ag 125I CONC	Marcador concentrada	Radioisotop, antigen koncentrerad
Ab 125I CONC	Marcador concentrada	Radioisotop, antikropp koncentrerad
	Tubos	Rör
INC BUF	Tampão de incubação	Inkuberingsbuffert
ACETONITRILE	Acetonitrilo	Acetonitril
SERUM	Soro	Serum
DIL SPE	Diluidor de espécimes	Spädningsbuffert för prover
DIL BUF	Tampão de diluição	Spädningsbuffert
ANTISERUM	Anti-soro	Antiserum
IMMUNOADSORBENT	Imunoadsorvente	Immunoadsorberare
DIL CAL	Diluente do calibrador	Kalibratordiluent
REC SOLN	Solução de Reconstituição	Rekonstitutionslösning
PEG	Polietileno-glicol	Polyetylenglykol
EXTR SOLN	Solução de Extracção	Extraktionslösning
ELU SOLN	Solução de Eluição	Elueringslösning
GEL	Cartuchos de silica Bond Elut	Silikonpatroner för elueringsbindning
PRE SOLN	Solução de pré-tratamento	Förbehandlingslösning
NEUTR SOLN	Solução de neutralização	Neutraliseringslösning
TRACEUR BUF	Tampão Marcador	Tracerbuffert
	Placa de micro titulação	Microtiterplatta
Ab HRP	HRP Conjugação	HRP-konjugat
Ag HRP	HRP Conjugação	HRP-konjugat
Ab HRP CONC	HRP Conjugação concentrada	HRP-konjugat-koncentrat
Ag HRP CONC	HRP Conjugação concentrada	HRP-konjugat-koncentrat
CONJ BUF	Conjugue o tampão	Konjugatbuffert
CHROM TMB CONC	Cromogénica TMB concentrada	Kromogeniskt TMB-koncentrat
CHROM TMB	Solução Cromogénica TMB	Kromogenisk TMB-lösning
SUB BUF	Tampão de substrato	Substratbuffert
STOP SOLN	Solução de Paragem	Stoplösning
INC SER	Soro de incubação	Inkubationsserum
BUF	Tampão	Buffert
Ab AP	AP Conjugação	AP-konjugat
SUB PNPP	Substrato PNPP	Substrat-PNPP
BIOT CONJ CONC	Concentrado conjugado de biotina	Biotinkonjugat koncentrat
AVID HRP CONC	Concentrado HRP de avidina	Avidin HRP-koncentrat
ASS BUF	Tampão de ensaio	Provbuffert
Ab BIOT	Conjugado de biotina	Biotinkonjugat
Ab	Anticorpo específico	-
SAV HRP CONC	Estreptavidina HRP concentrado	-
NSB	Ligações não especificas	-
2nd Ab	Anticorpo secundário	-
ACID BUF	Tampão de acidificação	-

	Επεξήγηση συμβόλων	**Anvendte symboler**
	Συμβουλευτείτε τις οδηγίες χρήσης	Læs brugsvejledningen
	Θερμοκρασία αποθήκευσης	Opbevaringstemperatur
	Ημερομηνία λήξης	Anvend inden
LOT	Αριθμός παρτίδας	Batchkode
REF	Αριθμός καταλόγου	Katalognummer
CONTROL	Πρότυπο ελέγχου	Kontrol
IVD	In Vitro Διαγνωστικό Ιατροτεχνολιγικό προιόν	Medicinsk udstyr til in vitro-diagnosticering
	Κατασκευαστής	Fabrikant
	Περιεχόμενο επαρκές για «ν» εξετάσεις	Indeholder nok til <n> test
WASH SOLN CONC	Συμπυκνωμένο διάλυμα έκπλυσης	Koncentreret vaskeopløsning
CAL 0	Μηδενικός βαθμονομητής	Nul-kalibrator
CAL N	Βαθμονομητής #	Kalibrator nr.
CONTROL N	Ορός ελέγχου #	Kontrol nr.
Ag 125I	Ιχνηθέτης	Markør
Ab 125I	Ιχνηθέτης	Markør
Ag 125I CONC	Χρωμογόνος Ιχνηθέτης	Koncentreret markør
Ab 125I CONC	Χρωμογόνος Ιχνηθέτης	Koncentreret markør
	Σωληνάρια	Tuber
INC BUF	Ρυθμιστικό διάλυμα επώασης	Inkubationsbuffer
ACETONITRILE	Ακετονιτρίλιο	Acetonitril
SERUM	Ορός	Serum
DIL SPE	Διάλυμα αραίωσης δειγμάτων	Prøvediluent
DIL BUF	Ρυθμιστικό διάλυμα αραίωσης	Fortyndingsbuffer
ANTISERUM	Αντιορός	Antiserum
IMMUNOADSORBENT	Ανοσοπροσροφητικό	Immonoadsorbent
DIL CAL	Αραιωτικό βαθμονομητών	Kalibratordiluent
REC SOLN	Διάλυμα ανασύστασης	Rekonstitueringsopløsning
PEG	Πολυαιθυλενογλυκόλη	Polyetylenglykol
EXTR SOLN	Διάλυμα εκχύλισης	Ekstraktionsopløsning
ELU SOLN	Διάλυμα έκλουσης	Elueringsopløsning
GEL	Φύσιγγες πυριτίου Bond Elut	Patroner med bindingselueringssilica
PRE SOLN	Διάλυμα προεπεξεργασίας	Forbehandlingsopløsning
NEUTR SOLN	Διάλυμα εξουδετέρωσης	Neutraliseringsopløsning
TRACEUR BUF	Ρυθμιστικό διάλυμα	Markørbuffer
	Πλάκα μικροτιτλοδότησης	Mikrotiterplade
Ab HRP	HRP Σύζευγμα	HRP-konjugat
Ag HRP	HRP Σύζευγμα	HRP-konjugat
Ab HRP CONC	Χρωμογόνος HRP Σύζευγμα	HRP-konjugat-koncentreret
Ag HRP CONC	Χρωμογόνος HRP Σύζευγμα	HRP-konjugat-koncentreret
CONJ BUF	Ρυθμιστικό διάλυμα συζεύγματος	Konjugatbuffer
CHROM TMB CONC	Χρωμογόνος TMB	Kromogen TMB-koncentreret
CHROM TMB	Διάλυμα χρωμογόνου TMB	Kromogen TMB-opløsning
SUB BUF	Ρυθμιστικό διάλυμα υποστρώματος	Substratbuffer
STOP SOLN	Ανασχετικό αντιδραστήριο	Stopopløsning
INC SER	Ορός επώασης	Inkubationsserum
BUF	Ρυθμιστικό διάλυμα	Buffer
Ab AP	AP Σύζευγμα	AP-konjugat
SUB PNPP	PNPP υποστρώματος	Substrat PNPP
BIOT CONJ CONC	Συμπυκνωμένο αντιδραστήριο συζευγμένο με βιοτίνη	Biotin konjugat koncentrat
AVID HRP CONC	Συμπυκνωμένο διάλυμα αβιδίνης-HRP	Avidin HRP koncentrat
ASS BUF	Ρυθμιστικό διάλυμα προσδιορισμού	Prøvebuffer
Ab BIOT	αντιδραστήριο συζευγμένο με βιοτίνη	Biotin konjugat
Ab	Ειδικό Αντίσωμα	-
SAV HRP CONC	Συμπυκνωμένη στρεπταβιδίνη συνεξευγμένη με HRP	-
NSB	μη-ειδική δέσμευση	-
2nd Ab	2ο Αντίσωμα	-
ACID BUF	Ρυθμιστικό Διάλυμα όξινο	-

	Stosowane symbole	**Használt szimbólumok**
	Przed zastosowaniem zapoznać się z instrukcją	Olvassa el a használati útmutatót
	Temperatura przechowywania	Tárolási hőmérséklet
	Zużyć przed	Lejárati idő
LOT	Kod serii	Gyártási kód
REF	Numer katalogowy	Katalógus szám
CONTROL	Kontrola	Kontrol
IVD	Urządzenie medyczne do diagnostyki in vitro	In vitro diagnosztikai eszköz
	Producent	Gyártó
	Zawartość wystarczająca do <n> testów	Tartalma <n> teszt elvégzésére elegendő
WASH SOLN CONC	Roztwór płuczący stężony	Mosó folyadék koncentrátum
CAL 0	Kalibrator zerowy	Zero kalibrátor
CAL N	Kalibrator nr	Kalibrátor #
CONTROL N	Kontrola nr	Kontrol #
Ag 125I	Znacznik izotopowy	Nyomjelző izotóp
Ab 125I	Znacznik izotopowy	Nyomjelző izotóp
Ag 125I CONC	Znacznik izotopowy stężony	Nyomjelző izotóp koncentrátum
Ab 125I CONC	Znacznik izotopowy stężony	Nyomjelző izotóp koncentrátum
	Probówki	Csövek
INC BUF	Wymagana inkubacja buforu	Inkubáló puffer
ACETONITRILE	Acetonitryl	Acetonitril
SERUM	Surowica	Szérum
DIL SPE	Rozcieńczalnik próbki	Mintahigító
DIL BUF	Bufor do rozcieńczania	Higító puffer
ANTISERUM	Antysurowica	Antiszérum
IMMUNOADSORBENT	Immunoadsorbent	Immunadszorbens
DIL CAL	Rozcieńczalnik kalibratora	Kalibrátor higító
REC SOLN	Roztwór do rozcieńczania	Mintaelőkészítő oldat
PEG	Glikol poli(oksy)etylenowy	Polietilén glikol
EXTR SOLN	Roztwór ekstrakcyjny	Extrakciós oldat
ELU SOLN	Roztwór elucyjny	Eluáló oldat
GEL	Kolumny krzemionkowe Bond Elut	Bond Elut Silica szilikagél patronok
PRE SOLN	Roztwór do przygotowania wstępnego	Előkezelő oldat
NEUTR SOLN	Roztwór neutralizujący	Semlegesítő oldat
TRACEUR BUF	Bufor znacznika	Nyomjelző izotóp higító puffer
	mikropłytka	Mikrotiter lemez
Ab HRP	Koniugat peroksydazy chrzanowej	HRP konjugátum
Ag HRP	Koniugat peroksydazy chrzanowej	HRP konjugátum
Ab HRP CONC	Koncentrat koniugatu peroksydazy chrzanowej	HRP konjugátum koncentrátum
Ag HRP CONC	Koncentrat koniugatu peroksydazy chrzanowej	HRP konjugátum koncentrátum
CONJ BUF	Bufor do koniugacji	Konjugátum puffer
CHROM TMB CONC	Koncentrat chromogenu TMB (czterometylobenzydyny)	Kromogén TMB koncentrátum
CHROM TMB	Roztwór chromogenu TMB (czterometylobenzydyny)	Kromogén TMB oldat
SUB BUF	Bufor substratu	Szubsztrát puffer
STOP SOLN	Roztwór zatrzymujący reakcję	Stop oldat
INC SER	Wymagana inkubacja surowicy	Inkubációs szérum
BUF	Bufor	Puffer
Ab AP	Koniugat AP (fosfatazy alkalicznej)	AP konjugátum
SUB PNPP	p-nitrofenylofosforan substratowy	Szubsztrát PNPP
BIOT CONJ CONC	Koncentrat koniugatu biotyny	Biotin konjugátum koncentrátum
AVID HRP CONC	Koncentrat peroksydazy chrzanowej z awidyną	Avidin HRP koncentrátum
ASS BUF	Bufor do oznaczania	Vizsgálati puffer
Ab BIOT	Koniugatu biotyny	Biotin konjugátum
Ab	Przeciwciało swoiste	Specifikus ellenanyag
SAV HRP CONC	Koncentrat streptawidyny HRP	Sztreptavidin HRP koncentrátum
NSB	Wiązanie nieswoiste	Nem-specifikus kötődés
2nd Ab	Drugie przeciwciało	Másodlagos ellenanyag
ACID BUF	Bufor zakwaszający	Savas puffer

	Използвани символи
	Вижте инструкцията за работа
	Температура на съхранение
	Използвайте с
LOT	Партиден код
REF	Каталожен номер
CONTROL	Контрол
IVD	Ин витро диагностично медицинско изделие
	Производител
	Съдържание достатъчно за <n> теста
WASH SOLN CONC	Концентриран измиващ разтвор
CAL 0	Нулев калибратор
CAL N	Калибратор #
CONTROL N	Контрол #
Ag 125I	Трейсър
Ab 125I	Трейсър
Ag 125I CONC	Концентриран маркер
Ab 125I CONC	Концентриран маркер
	Епруветки
INC BUF	Инкубационен буфер
ACETONITRILE	Ацетонитрил
SERUM	Серум
DIL SPE	Разредител за пробите
DIL BUF	Буфер за разреждане
ANTISERUM	Антисерум
IMMUNOADSORBENT	Имуноабсорбент
DIL CAL	Разредител за калибратора
REC SOLN	Пресъздаващ разтвор
PEG	Полиетилен гликол
EXTR SOLN	Екстрактов разтвор
ELU SOLN	Разтвор за елюиране
GEL	Силикагелни пълнители
PRE SOLN	Пред-лечебен разтвор
NEUTR SOLN	Неутрализиращ ратвор
TRACEUR BUF	Маркерен буфер
	Микротитърна пластина
Ab HRP	HRP конюгат / Конюгат на хрянова пероксидаза
Ag HRP	HRP конюгат / Конюгат на хрянова пероксидаза
Ab HRP CONC	HRP конюгиран концентрат
Ag HRP CONC	HRP конюгиран концентрат
CONJ BUF	Буфер за конюгата
CHROM TMB CONC	Хромогенен TMB концентрат
CHROM TMB	Хромогенен TMB разтвор
SUB BUF	Субстратен буфер
STOP SOLN	Стоп разтвор
INC SER	Инкубационен серум
BUF	Буфер
Ab AP	AP конюгат / конюгат на алкална фосфатаза
SUB PNPP	Субстрат PNPP / пара нитрофенил фосфат
BIOT CONJ CONC	Биотин конюгиран концентрат
AVID HRP CONC	Авидин HRP концентрат
ASS BUF	Буфер за пробите
Ab BIOT	Биотин конюгат
Ab	специфично антитяло
SAV HRP CONC	стрептавидин HRP концентрат
NSB	не специфично свързване
2nd Ab	второ антитяло
ACID BUF	киселинизиращ буфер