

bi-x-act[®]
of FINLAND

Anti-HBc IgG ELISA 96
well plate Kit (TMB)



Productcodes: 2HBcG



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1) Intended Use

Anti-HBc IgG ELISA Test Kit is an enzyme immunoassay for in vitro qualitative detection of total antibody to hepatitis B virus core antigen (Anti-HBc Total) 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, antibody to HBcAg (Anti-HBc) is detectable in serum or plasma shortly before clinical symptoms and slightly after the appearance of HBsAg. In cases in which HBV infection resolves, anti-HBc appears in blood during the window period following loss of HBsAg and prior to the development of antibody to HBsAg (anti-HBs). Anti-HBc is found in acute and chronic hepatitis B patients and also indicates past resolved infection. Therefore, detection of anti-HBc is indicative of exposure to HBV and thus of infection by this virus. Further testing of HBV serological markers is required to define the specific disease state.^{*1-6}

Anti-HBc IgG ELISA Test is a fast test for the qualitative detection of the presence of antibodies to HBcAg in serum or plasma (heparin, citrate or EDTA) specimens. The test utilizes HBcAg on microtiter wells and human peroxidase-conjugated Anti-HBc in a competition principle to detect Anti-HBc levels in serum or plasma.

Specimens with absorbance values greater than 1.1 x Cutoff Value are considered NEGATIVE for Anti-HBc.

Specimens with absorbance values less than 0.9 x Cutoff Value are considered POSITIVE for Anti-HBc.

The test has to be repeated in duplicate for specimens with absorbance value within the retest range (Cutoff Value \pm 10 %) and interpreted as above.

If the absorbance of any of the specimens retested in duplicate is still within the retest range, it is suggested to test follow-up samples of the patient.

3) Test Description

Anti-HBc IgG ELISA Test is a solid-phase enzyme immunoassay (ELISA= enzyme-linked immune assay) - based on a competitive principle. The solid phase of the microtiter plate is made of polystyrene wells coated with HBcAg and the liquid phase of human peroxidase conjugated Anti-HBc.

When a serum or plasma specimen containing Anti-HBc is added to the HBcAg-coated wells together with the human peroxidase conjugated Anti-HBc and incubated, a competition will take place for the binding to the HBcAg on the wells. (HBcAg)-(Anti-HBc • peroxidase) complex and/or (HBcAg)-(Anti-HBc) complex will form on the wells. After washing the microtiter plate to remove unbound material, a solution of TMB substrate is added to the wells and incubated. Due to the competitive principle a color develops inversely proportional to the amount of Anti-HBc bound to HBcAg deriving from the 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 test principle is shown also in the following figure.

A Specimen containing Anti-HBc:

1. Plate well (HBcAg) + specimen (Anti-HBc) + Anti-HBc • peroxidase → Plate-HBcAg-Anti-HBc complex and Plate-HBcAg-Anti-HBc • peroxidase complex
2. + TMB substrate solution → blue to light to pale blue color/even colorless

3. Add sulfuric acid to stop the color development → Read OD at 450nm with a selected reference wavelength within 620 to 690nm^{*8}.

B Specimen without Anti-HBc:

1. Plate well (HBcAg) + specimen (without Anti-HBc) + Anti-HBc · peroxidase

→ Plate-HBcAg-Anti-HBc-peroxidase complex

2. + TMB substrate solution → blue to light blue color

3. Add sulfuric acid to stop the color development, read OD at 450nm with a selected reference

wavelength within 620 to 690nm^{*8}.

4) Description of Materials Provided & Product Code System

- Item 1 - 6 on the following reagent table should be refrigerated at +2 to +8°C . Washing Solution D (20x) and 2N H₂SO₄ can be stored at +2 to +30°C.

ITEMS	Components	Description	Qt. per 96 tests
(1)	HBcAg Plate	Microtiter plate coated with HBcAg.	1 plate
(2)	Anti-HBc · Peroxidase Solution	Anti-HBc (human) · peroxidase conjugate dissolved in buffer with protein stabilizers. Preservatives: 0.003% Gentamycin and 0.01% Thimerosal.	1 bottle, 7 ml
(3)	CONTROL + Anti-HBc Positive Control	Anti-HBc positive serum in buffer with protein stabilizers. Preservatives: 0.003% Gentamycin and 0.01% Thimerosal.	1 bottle, 1 ml
(4)	CONTROL - HB Negative Control	Serum non-reactive for HBV markers. Preservatives: 0.003% Gentamycin and 0.01% Thimerosal.	1 bottle, 1.5 ml
(5)	TMB Substrate Solution A	0.6 mg/ml of 3,3',5,5'-tetramethylbenzidine (TMB) in an organic base.	1 bottle, 10 ml
(6)	TMB Substrate Solution B	Citrate acid buffer containing 0.03% H ₂ O ₂ .	1 bottle, 10 ml
(7)	Conc. Washing Solution D (20x)	Concentrated phosphate buffer with Tween-20	1 bottle 52 ml
(8)	2N H ₂ SO ₄	2N H ₂ SO ₄ (Sulfuric Acid)	1 bottle 12 ml

- ACCESSORIES: (provided as needed)

ITEMS	Components
(9)	Adhesive Slips
(10)	Absorbent Pads
(11)	Black Cover

- OTHER MATERIAL REQUIRED, BUT NOT PROVIDED

ITEMS	Components
(1)	50µl, 100µl micropipettes and tips are needed
(2)	Incubator or waterbath with temperature control at +37 °C.
(3)	Plate washing equipment.

(4)	ELISA microwell reader: Dual wavelength 450nm with 620-690nm as reference wavelength ^{*8} , bandwidth 10nm.
(5)	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 IgG ELISA Test Plate	+2~+8 °C	Original	18 months
		Once open	1 month
Anti-HBc Positive Control	+2~+8 °C	Original	18 months
		Once open	1 month
HB Negative Control	+2~+8 °C	Original	18 months
		Once open	1 month
HBcAg Plate	+2~+8 °C	Original	24 months
		Once open	2 month
Anti-HBc · Peroxidase Conjugate Solution	+2~+8 °C	Original	18 months
		Once open	1 month
Concentrated Washing Solution D (20x)	Room temp.	Original	24 months
		Once open	1 month
20x Diluted Washing Solution	Room temp.	Diluted	2 days
	+2~+8 °C	Diluted	1 week
TMB Substrate Solution A	+2~+8 °C	Original	18 months
		Once open	1 month
TMB Substrate Solution B	+2~+8 °C	Original	18 months
		Once open	1 month
2N Sulfuric Acid	Room temp.	Original	24 months
		Once open	1 month

5) Instructions 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, 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 nonacid 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) 2N sulfuric acid is an irritant to skin, eyes, respiratory tract and mucous membranes. Avoid contact of the 2N sulfuric acid 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) TMB substrate solution A contains organic solvent, which is flammable. TMB substrate solution A 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 homogeneously before test.
- 5.2.5) Avoid multiple freeze-thaw procedures
- 5.2.6) WARNINGS
 - 1. The specimen must not contain any AZIDE compounds which can inhibit the peroxidase activity of the conjugate.
 - 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 month 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 D (20x) Concentrate is stored and shipped at +2 to +8°C, which can cause crystallization. If the 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 D (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) Reserve 2 wells for blanks. Add 50µl of each control or specimen to appropriate wells of reaction plate (3 Negative Controls and 2 Positive Controls).

NOTE:

a) Use a new pipette tip for each sampling to avoid cross-contamination

b) Each plate needs its own negative controls, positive controls and blank wells.

c) Do not use cut-off value established for other plates of Anti-HBc IgG ELISA Test Kit.

5.5.3) Add 50 µl of Anti-HBc Peroxidase solution to each well except the 2 blanks.

NOTE: Do not touch the well wall for preventing contamination.

5.5.4) Gently tap the plate.

5.5.5) Remove the protective backing from the adhesive slip and press it onto the reaction plate, so that it is tightly sealed.

5.5.6) Incubate the reaction plate in a +37±1°C water bath or incubator for 1 hour.

5.5.7) At the end of the incubation period, remove and discard the adhesive slip and wash the plate in accordance with 5.4) Plate washing procedure.

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

A. Mix equal volumes of TMB Substrate Solution A and B in a clean container immediately prior to use. Add 100 µl of the mixture solution to each well including 2 blank wells.

B. Add 50 µl of TMB Substrate Solution A first, then add 50 µl of TMB Substrate Solution B into each well including the 2 blanks. Mix well gently.

NOTE: TMB Substrate Solution A should be colorless to light blue, otherwise, it should be discarded. The mixture of TMB Substrate Solution A and B should be used within 30 minutes after mix. The mixture should be protected from exposition to intense light.

5.5.9) Cover the plate with black cover and incubate at room temperature for 15 minutes.

5.5.10) Stop the reaction by adding 100µl of 2N H₂SO₄ to each well including the two blanks.

5.5.11) Determine the absorbance of controls and test specimens within 30 minutes with a precision photometer at 450 / 620-690 nm (450 nm reading wavelength with 620-690 nm reference wavelength)*¹. Use the first blank well to blank the photometer.

NOTE:

The blanks should be colorless to light yellowish in color; otherwise, the test results are invalid.

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	0.939
2	0.944
3	0.925

$$NCx = (0.939 + 0.944 + 0.925) / 3 = 0.936$$

 NCx must be ≥ 0.4 , otherwise, the test run is invalid.

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

Example:

Sample No.	Absorbance
1	0.068
2	0.052

$$PCx = (0.068 + 0.052) / 2 = 0.060$$


 PC x must be ≤ 0.1 , otherwise, the test run is invalid.

5.6.3) Calculation of the N - P Value

$$N - P = NCx - PCx$$

Example:

$$N - P = 0.936 - 0.060 = 0.876$$

 N - P Value must be ≥ 0.3 , otherwise, the test run is invalid.

5.6.4) Calculation of the Cutoff Value

$$\text{Cutoff Value} = 0.4 NCx + 0.6 PCx$$

Example:

$$\text{Cutoff Value} = (0.4 \times 0.936) + (0.6 \times 0.060) = 0.410$$

5.6.5) Calculation of the Retest Range

$$\text{Retest Range} = \text{Cutoff Value} \pm 10\%$$

Example: Cutoff Value = 0.410

$$\text{Retest Range} = (0.410 - 0.041) \text{ to } (0.410 + 0.041) = 0.369 \text{ to } 0.451$$

5.7)  Validity of Test Runs

5.7.1) NC x must be ≥ 0.4 , otherwise, the test run is invalid.

5.7.2) PC x must be ≤ 0.1 , otherwise, the test run is invalid.

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

5.8) Interpretation of Results

If the signal/cut-off ratio is within Retest Range (0.9-1.1 x cutoff), 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.

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.
- 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 kit, largely due to technical error either on the part of the operator or malfunction of apparatus used.
- 5.10.4) Potential interfering substances:
Potential interfering samples, i.e. samples with hyperlipemia, hemolysis, hyper-bilirubinemia, and samples with monoclonal immunoglobulin components, samples containing elevated levels of autoimmune antibodies (rheumatoid factor-RF, anti 7 lear antibodies-ANA, or anti-mitochondrial antibodies-ANA) did not affect the test result with Anti-HBc IgG ELISA Test.
- 5.10.5) The anticoagulants heparin, EDTA and sodium citrate have no influence on the specificity of Anti-HBc IgG ELISA and can be used to obtain plasma samples for analysis with the Anti-HBc Total kit.

5.11) Performance Characteristics

5.11.1) Diagnostic Specificity

Negative specimens/Specimens used to evaluate the specificity

True Negative Samples	Number of samples	Anti-HBc IgG ELISA No. negative samples
Blood donor samples	5020	5010
Samples from hospitalized persons	200	200
Samples contain potential interfering factors	97	97
Samples with added	12	11

possible interfering facto				
Samples with different anticoagulants	48	48		
Total	5377	5366		5.11.1.1) Potential interfering substances
Diagnostic Specificity	-----	5366/5377	=	Potential interferences with Anti-HBc IgG
		99.8%		

ELISA Test 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 Total levels but no interfering factors. The neat samples as well as the mixtures were analyzed.

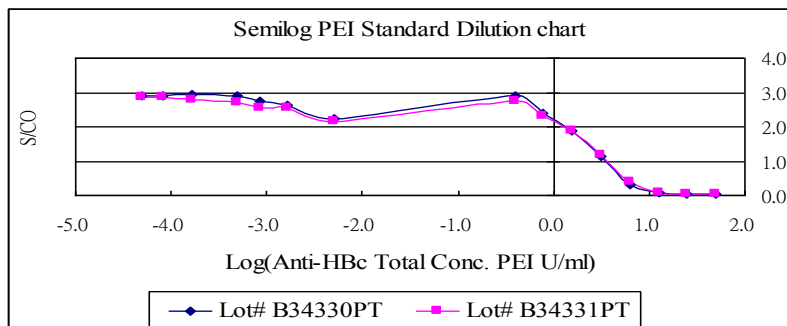
In particular the specificity study included:

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

No interferences were detected with both used lots. Neither the type of anticoagulant had an influence on both tested lots of Anti-HBc IgG ELISA Test.

5.11.2) Analytical Sensitivity and Linearity:

To evaluate the sensitivity of Anti-HBc IgG ELISA serial dilutions of the Standard Material for Anti-HBc Total of Paul Ehrlich Institute (PEI) (Langen, Germany) (100 PEI U/ml) were used.



For Lot 1 Linearity, R=		-0.994
For Lot 2 Linearity, R =		-0.991
Worst Case: Linearity, R =		-0.991
Lot#	A	B
1	2.1397	-2.0009
2	2.0757	-1.8801
Lot#	X=(Y-A)B	
1	Detection Limit =	1.858 PEI U/ml
2	Detection Limit =	1.869 PEI U/ml
Worst Case	Detection Limit =	1.869 PEI U/ml

The analytical sensitivity (detection limit) was defined as the lowest concentration which can be detected, i.e. at $CO/S \geq 1.1$ (i.e. $S/CO \leq 0.9$) calculated by using the linear regression function.

5.11.3) Diagnostic Sensitivity

5.11.3.1) HBV infected individuals

435 HBV-positive samples were measured with both Anti-HBc IgG ELISA Test and the reference assay. The diagnostic sensitivity for the assay was 100% as it was for the reference assay.

5.11.4) Precision

5.11.4.1) Intra-run repeatability

For determination of intra-assay (within-run) precision, the Positive Control provided with the test kit and two patient serum samples with different Anti-HBc Total titer (slightly above the cutoff level and at medium level) were analyzed in replicates of 20 in a single “run” over 3 days. The CVs were in an acceptable range for both tested lots.’

Item tested	Sample size	Precision
Positive Control	N = 20	CV ≤ 12.68%
Patient Serum #1	N = 20	CV ≤ 10.62%
Patient Serum #2	N = 20	CV ≤ 16.72%

5.11.4.2) Inter-run reproducibility

Item tested	Sample size	Precision
Positive Control	N = 60	CV ≤ 7.44%
Patient Serum #1	N = 60	CV ≤ 8.81%

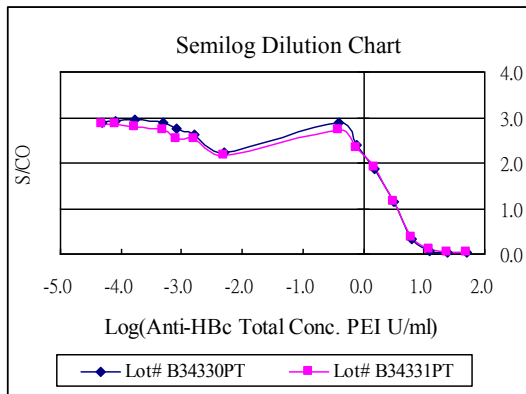
Patient Serum #2	N = 60	CV ≤14.67%
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5.11.5) Traceability

Concentration of Positive Control of Anti-HBc IgG ELISA Test referred to the PEI Anti-HBc Total Reference Material = 70 PEI U/ml ± 30%

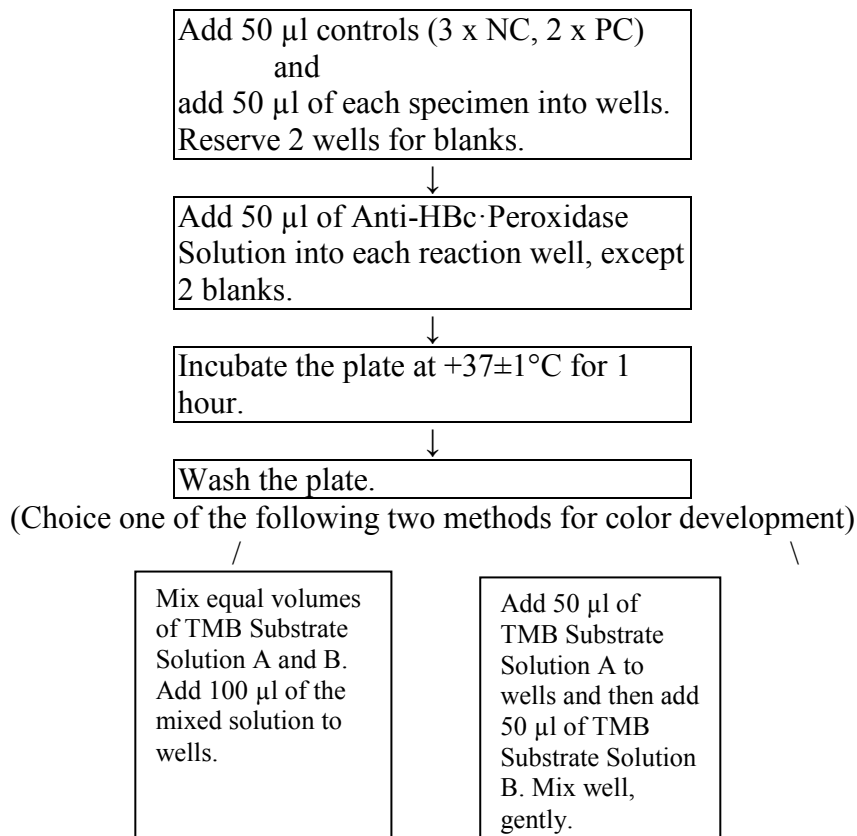
5.11.6) Antibody Excess/High-Dose Hook Effect

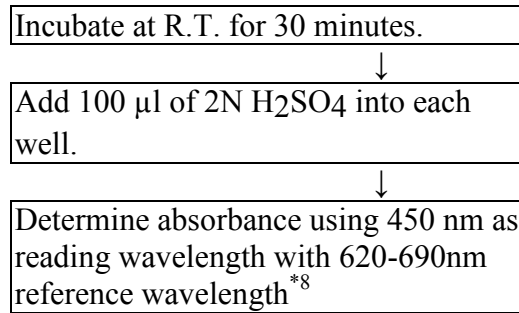
The effect of antibody excess was 10^{-1} by consecutive dilution of a standard material having very high Anti-HBc levels (PEI Anti-HBc Total Reference Material).



The Semilog PEI Standard Dilution chart illustrates that an antigen/antibody excess is not occurring also because of the reverse reaction used in this assay format. An antigen/antibody excess will not influence the reactive/non-reactive interpretation.

5.12) Flow Chart of Test Procedure













6) Bibliography

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7. Shikata T, Karasawa T, Abe K, et al. Incomplete inactivation of hepatitis B virus after heat treatment at +60°C for 10 hours, J. Infect. Dis. 1978; 138:242-244.
8. The reference wavelength of spectrometer can be 620nm to 690nm. However, user should validate the photometer in combination with this kit before use.

Symbols Key / Symbolschlüssel / Explication des Symboles / Interpretazione simboli /Clave dos Simbolos

	In Vitro Diagnostic Medical Device / In-Vitro-Diagnostikum / Producto sanitario para diagnóstico in vitro / Dispositivo medico-diagnostico in vitro / Dispositif médical de diagnostic in vitro / Dispositivo médico para diagnóstico in vitro
	Batch code / Chargenbezeichnung / Código de lote / Codice del lotto / Code du lot / Código do lote
	Use By / Verwendbar bis / Fecha de caducidad / Utilizzare entro / Utiliser jusque / Prazo de validade
	Temperature limitation / Temperaturbegrenzung / Límite de temperatura / Limiti di temperatura / Limites de température / Limites de temperatura
	CE Mark / CE-Zeichen / Marquage CE / Marchio CE / CE Marca / Marca CE
	Catalogue number / Bestellnummer / Número de catálogo / Numero di catalogo / Référence du catalogue / Referência de catálogo
	Consult Instructions for Use- / Gebrauchsanweisung beachten / Consulte las instrucciones de uso / Consultare le istruzioni per l'uso / Consulter les instructions d'utilisation / Consulte as instruções de utilização
	Caution,consult accompanying documents / Achtung, Begleitdokumente beachten / Atención,ver instrucciones de uso / Attenzione, vedere le istruzioni per l'uso / Attention voir notice d'instructions / Atenção, consulte a documentação incluída