# Anti-HAV IgM Elisa

## *KAPG4AME3*

DIAsource ImmunoAssays S.A. - Rue de l'Industrie, 8 - B-1400 Nivelles - Belgium

**LOT** : 090515/1

# Anti-HAV IgM Elisa

CE

en

For qualitative in-vitro detection of IgM antibodies to hepatitis A virus (Anti-HAV IgM) in human serum or plasma

KAPG4AME3

*IN VITRO DIAGNOSTIC USE*

DIAsource ImmunoAssays SA - Rue de l'Industrie 8, B-1400 Nivelles, Belgium
Tel: +32 67 88 99 99 - Fax : +32 67 88 99 96

## 1. INTENDED USE

**Anti-HAV IgM ELISA** is an enzyme immunoassay kit for in vitro qualitative detection of IgM antibody to hepatitis A virus (Anti-HAV IgM) in human serum or plasma (heparin, EDTA or citrate).

## 2. SUMMARY AND TEST EXPLANATION

The hepatitis A virus (HAV) is a single-stranded RNA-containing virus without an envelope and with a diameter of 27 nm that belongs to the family of Picornaviridae (1-2). Hepatitis A - the most common form of acute viral hepatitis - is an infection of fecal-oral transmission produced in humans after an average incubation period of 28 days (range, 15-50 days). The illness caused by HAV infection typically has an abrupt onset of symptoms that can include fever, malaise, anorexia, nausea, abdominal discomfort, dark urine, and jaundice (2). Hepatitis A antigen can be detected in the feces only briefly before or at the onset of infection becoming generally undetectable during the late acute stage (3). The antibody specific to HAV during the acute phase of hepatitis A is the IgM type (Anti-HAV IgM), which decreases then being replaced by IgG type (Anti-HAV IgG) during early and late convalescence (4). Anti-HAV IgM usually disappears 3 to 4 months after the acute phase. An acute hepatitis A virus infection can be assumed if anti-HAV IgM antibody is detected (5). Anti-HAV IgM antibody develops only very rarely after vaccination (6). Assays to detect anti-HAV IgM antibodies are useful in distinguishing hepatitis A infection from other types of infections

**Anti-HAV IgM ELISA** is a fast test for the qualitative detection of IgM antibody to Hepatitis A virus in serum or plasma (heparin, citrate or EDTA) specimens. This is an enzyme linked immunosorbent assay (ELISA) which utilizes Anti-human IgM on microtiter wells as solid phase and HAV Ag and peroxidase-conjugated Anti-HAV in liquid phase in an "IgM capture" principle to detect Anti-HAV IgM levels in serum or plasma.

Specimens with absorbance values **greater** than the Cutoff Value are considered **REACTIVE for Anti-HAV IgM.**

Specimens with absorbance values **less or equal** than the Cutoff Value are considered **NONREACTIVE for Anti-HAV IgM.**

The test has to be repeated in duplicate for specimens with absorbance value within the retest range (Cutoff Value ± 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-HAV IgM ELISA is a** solid-phase enzyme immunoassay (ELISA= enzyme-linked immunosorbent assay) –- based on the principle of "IgM capture". The solid phase of the microtiter plate is made of polystyrene wells coated with anti-human IgM, while peroxidase-conjugated Anti-HAV acts as liquid phase.

When a serum or plasma specimen containing Anti-HAV IgM is added to the Anti-human IgM-coated wells and incubated, IgM antibodies present in the specimen bind to the Anti-human IgM on the wells. After addition of an HAV Ag-containing solution and a solution containing peroxidase-conjugated anti-HAV a further incubation takes place, during which (Anti-h IgM) • (Anti-HAV IgM) •(HAV Ag) • (Anti-HAV• 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-HAV IgM is present in the specimen, after washing, the activity of peroxidase on the wells reflects the content of anti-HAV 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 also shown as follows:**

A. Specimen (containing antibodies IgM Anti-HAV):

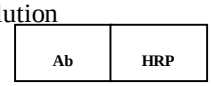
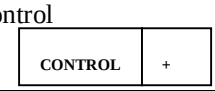
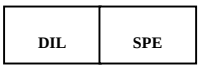
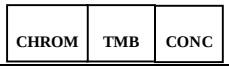
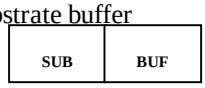
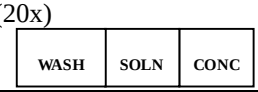
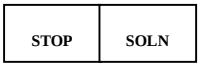
1. Plate (Anti-h IgM) + specimen (containing IgM Anti-HAV)
   → Plate (Anti-h IgM) ▪ IgM Anti-HAV
2. Plate (Anti-h IgM) ▪ IgM Anti-HAV + HAV + Anti-HAV·peroxidase
   → Plate (Anti-h IgM) ▪ IgM Anti-HAV·HAV▪ (Anti-HAV·HRPO) complex
3. Wash to remove the unbound materials.
4. plate (Anti-h IgM) ▪ IgM Anti-HAV▪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

B. Specimen (without antibodies IgM Anti-HAV):

1. Plate (Anti-h IgM) + specimen (without IgM Anti-HAV) → Plate (Anti-h IgM)
2. Plate (Anti-h IgM) + HAV + Anti-HAV▪ peroxidase → Plate (Anti-h IgM)
   ------ no complex will form
3. Wash to remove the unbound material.
4. Plate (Anti-h IgM) + TMB solution (colorless) → colorless
5. colorless + stop solution → colorless, measured at 450nm with a selected reference wavelength within 620 to 690 nm[*8].

## 4. DESCRIPTION OF MATERIALS PROVIDED

● **Storage Condition:** 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 Coated Plate  | Microtiter plate coated with purified antibody to human IgM. | 1 plate |
| (2) | Anti-HAV · Peroxidase Solution   | Anti-HAV · peroxidase (horseradish) conjugate in buffer with protein stabilizers. Preservatives: 0.003% gentamycin and 0.01% thimerosal. | 1bottle, 7 ml |
| (3) | Anti-Human-IgM Positive Control   | Serum containing diluted Anti-HAV IgM in buffer with protein stabilizers. Preservatives: 0.003% gentamycin and 0.01% thimerosal. | 1 bottle, 2 ml |
| (4) | Specimen Diluent   | Protein stabilizer in buffer. Preservatives: 0.003% gentamycin and 0.01% thimerosal. | 1 bottle 11 ml |
| (5) | Hepatitis A Virus Antigen Solution   | Hepatitis A virus antigen in buffer and protein stabilizer. Preservatives: 0.003% gentamycin and 0.01% thimerosal. | 1 bottle, 7 ml |
| (6) | Anti-HAV IgM Negative Control   | Protein stabilizer in buffer. Preservatives: 0.003% gentamycin and 0.01% thimerosal. | 1 bottle, 2 ml |
| (7) | Chromogenic TMB concentrate   | 0.6 mg/ml of 3,3',5,5'-tetramethylbenzidine (TMB) in 40% methanol. | 1 bottle, 10 ml |
| (8) | Substrate buffer   | Citric acid buffer containing 0.03% $H_2O_2$. | 1 bottle, 10 ml |
| (9) | Conc. Washing Solution (20x)   | Phosphate buffer with tween-20. | 1 bottle 52 ml |
| (10) | Stop solution   | 2N sulfuric acid | 1 bottle 12 ml |

● OTHER MATERIALS AND DEVICES REQUIRED, BUT NOT PROVIDED

| ITEMS | Components |
|---|---|
| (1) | 5 µl, 50 µl, 100µl and 1.0 ml micropipettes and tips are needed |
| (2) | 100 ml of 0.15M Normal Saline. |
| (3) | Incubator or waterbath with temperature control at +37 °C. |
| (4) | Tubes for specimen dilution. |
| (5) | Plate washing equipment. |
| (6) | ELISA Microwell Reader:<br>Dual wavelength 450 nm with 620-690 nm as reference wavelength[*8], bandwidth 10nm. |
| (7) | Purified water: distilled or deionized water. |
| (8) | 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-HAV IgM ELISA KIT | +2 to +8 °C | Original | 15 months |
| | | Once open | 1 month |
| Anti-HAV IgM Positive Control | +2 to +8 °C | Original | 15 months |
| | | Once open | 1 month |
| Anti-HAV IgM Negative Control | +2 to +8 °C | Original | 15 months |
| | | Once open | 1 month |
| HAV Antigen Solution | +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 month |
| Anti-HAV·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 |
| 2N Sulfuric Acid | 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 gently 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, HAV Antigen solution, negative control, conjugate solution and specimens should be regarded as potential hazards to health. They shall be used and discarded according to the user's laboratory safety procedures. Such safety procedures probably shall include wearing protective gloves and avoiding aerosols generation.

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 your treatment practice of 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. 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.

### 5.2. 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 specimens 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, they should be frozen below -20 °C. Storage in self-defrosting freezer 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 open 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 should be stored at room temperature to avoid crystallization. If the crystal has been precipitated before use, warm up the solution in a +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:

Plate washing:

1. 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.

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

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**

Assay process can be performed by an automatic EIA micro-plate immuno-analyzer. Please set up the program according to the following 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. Prepare the needed number of wells, including two wells for blanks, three wells for Negative Control, two wells for Positive Control, and one well for each specimen.
Reserve 2 wells for Blanks. Add **100 µl** of Negative Control to each of three wells, **100 µl** of Positive Control to each of the two wells, and **100 µl** of Specimen Diluent to each of the other reaction wells for the test specimens.

5.5.3 Make 1 200 dilution of each specimen:
Prepare the tubes for dilution as number of specimens. Add 1.0 ml of Saline Solution and 5 µl of each specimen to each tube, respectively and shake to mix.

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 Seal the plate with an adhesive slip.

5.5.7. Incubate the plate in incubator or water bath at +37 ± 1°C for **one hour**.

5.5.8. At the end of the incubation period, remove and discard the Adhesive Slip and wash plate in accordance with "5.4. **Plate washing procedure**".

5.5.9. Add **50 µl** of Hepatitis A Virus Antigen Solution and **50 µl** of Anti-HAV·Peroxidase Conjugate Solution into each reaction well except the Blanks. Apply new adhesive slip.

5.5.10. Incubate the plate in incubator or water bath at +37 ± 1°C for **one hour**.

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

5.5.12. Choose one of the following two methods for color development:
**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 mixing. The mixture should be avoided from intense light.

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 two blank wells.

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

5.5.13 Cover the plate with 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 photometer at 450 nm with a selected reference wavelength within 620 to 690 nm[*8].

Use the blank well to blank the photomer.

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

**5.6. Calculation of Tested Results**

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

| Sample No. | Absorbance |
|---|---|
| 1 | 0.080 |
| 2 | 0.085 |
| 3 | 0.079 |

NCx = (0.080+0.085 + 0.079) / 3 = 0.081
NCx **must be ≤ 0.2, otherwise, the test is invalid.**

5.6.2. Calculation of PCx (Mean Absorbance of Positive Control)
Example:

| Sample No. | Absorbance |
|---|---|
| 1 | 1.223 |
| 2 | 1.205 |

PCx = (1.223 + 1.205) /2 = 1.214
PCx **must be ≥0.5 , otherwise, the test is invalid.**

5.6.3. Calculation of **P-N Value**
**P-N =** PCx **-** NCx
Example:
P - N = 1.214 – 0,081 = 1,133
**P - N Value must be ≥0.3, otherwise, the test is invalid.**

5.6.4. Calculation of the **Cutoff Value**
**Cutoff Value = NC**x **+ (PC**x**)/4**
Example:
Cutoff Value = 0.081+(1.214/4) = 0.385

5.6.5. Calculation of the **Retest Range**
**Retest Range = Cutoff Value ±10%**
Example: Cutoff Value = 0.385
Retest Range = (0.385 - 0.039) to (0.385 +0.039) = 0.346 to 0.424

**5.7. Validity of Test Runs**

5.7.1. **NCx must be ≤ 0.2 , otherwise, the test is invalid.**

5.7.2. **PCx must be ≥ 0.5 , 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 0.200 after subtracting the blank.**

**5.8. Interpretation Results**

5.8.1. Specimens with absorbance values **LOWER** than the **Cutoff Value** are considered **non-reactive** for Anti-HAV IgM

5.8.2. Specimen with absorbance value **GREATER** than or **EQUAL TO** the **Cutoff Value** is considered **reactive** for Anti-HAV IgM.

5.8.3. If the data is within the **Retest Range**, the test must be repeated in duplicate and interpreted as above. If the retested absorbance still within the retest range, it is suggested to test follow-up-samples.

**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. Contamination with positive specimens.

5.9.3. Wrong volume of sample, conjugate or substrates.

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 being mixed well 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. Non-repeatable reactive results may be obtained with any enzyme immunoassay kit**,** largely due to technical error e**i**ther on the part of the operator or malfunction of apparatus used.

5.10.3. The reagent kit has not been validated for use with cadaveric samples.

5.10.4. Potential interfering substances: By addition tests the following results were obtained:

1. The anticoagulants heparin, citrate and EDTA had no effect on the test result.
2. Hemoglobin up to 8.0 mg/ml had no effect on the test result.
3. Bilirubin up to 0.3 mg/ml had no effect on the test result.
4. Triglyceride up to 5.0 mg/ml had no effect on the test result.
5. A rheumatoid factor high positive specimen exhibited a false positive result.
6. Pregnancy did not affect the test result.

## 5.11. Performance Characteristics

### 5.11.1. Diagnostic Sensitivity and Diagnostic Specificity

1. Specimens from hospitalized patients:

| | | DIAsource Anti-HAV IgM ELISA | | |
|---|---|---|---|---|
| | | NON-REACTIVE | REACTIVE | Total |
| Comparison assay | NON-REACTIVE | 1378 | 0 | 1378 |
| | REACTIVE | 4 | 188 | 192 |
| | total | 1382 | 188 | 1570 |
| Diagnostic sensitivity = 100% x 188/192 = 98%<br>Diagnostic specificity = 100% x 1378/1378=100% | | | | |

2. Patients with acute hepatitis B:

| | | DIAsource Anti-HAV IgM ELISA | | |
|---|---|---|---|---|
| | | NON-REACTIVE | REACTIVE | Total |
| Comparison assay | NON-REACTIVE | 51 | 0 | 51 |
| | REACTIVE | 0 | 0 | 0 |
| | total | 51 | 0 | 51 |
| Conformity = 100% | | | | |

3. Hepatitis B patients in convalescent period:

| | | DIAsource Anti-HAV IgM ELISA | | |
|---|---|---|---|---|
| | | NON-REACTIVE | REACTIVE | Total |
| Comparison assay | NON-REACTIVE | 28 | 0 | 28 |
| | REACTIVE | 0 | 0 | 0 |
| | total | 28 | 0 | 28 |
| Conformity = 100% | | | | |

4. Chronic hepatitis B carriers:

| | | DIAsource Anti-HAV IgM ELISA | | |
|---|---|---|---|---|
| | | NON-REACTIVE | REACTIVE | Total |
| Comparison assay | NON-REACTIVE | 107 | 0 | 107 |
| | REACTIVE | 0 | 0 | 0 |
| | total | 107 | 0 | 107 |
| Conformity = 100% | | | | |

5. Auto-immune patients:

| | | DIAsource Anti-HAV IgM ELISA | | |
|---|---|---|---|---|
| | | NON-REACTIVE | REACTIVE | Total |
| Comparison assay | NON-REACTIVE | 20 | 0 | 20 |
| | REACTIVE | 0 | 0 | 0 |
| | total | 20 | 0 | 20 |
| Conformity = 100% | | | | |

6. Patients with acute hepatitis A:

| | DIAsource Anti-HAV IgM ELISA | | | |
|---|---|---|---|---|
| Comparison assay | | NON-REACTIVE | REACTIVE | Total |
| | NON-REACTIVE | 0 | 0 | 0 |
| | REACTIVE | 0 | 24 | 0 |
| | total | 0 | 24 | 24 |

Diagnostic sensitivity = 100%

Diagnostic specificity = 100%

7. Patients with other viral infections:

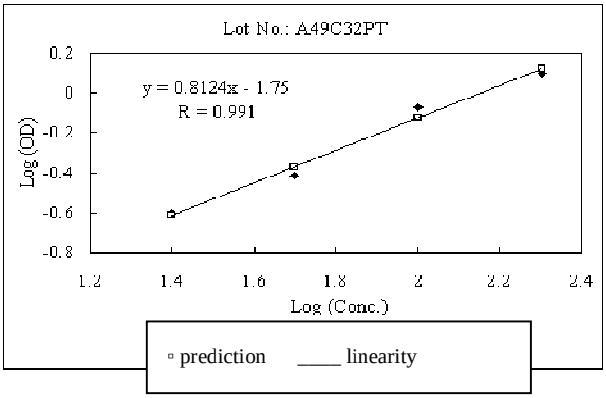
| | DIAsource Anti-HAV IgM ELISA | | | |
|---|---|---|---|---|
| Comparison assay | | NON-REACTIVE | REACTIVE | Total |
| | NON-REACTIVE | 35 | 0 | 35 |
| | REACTIVE | 0 | 0 | 0 |
| | total | 35 | 0 | 35 |

Diagnostic specificity/Conformity = 100%

5.11.2. **Analytical sensitivity ≤ 100 AU/ml**

**Analytical Sensitivity** **e.g. (Lot. No.: A49C32PT) Analytical sensitivity = 61.7 AU/ml**

| **Conc. (AU/ml)** | **OD** | **Log (Conc.)** | **Log (OD)** |
|---|---|---|---|
| 200 | 1.256 | 2.30103 | 0.09898964 |
| 100 | 0.846 | 2 | -0.07262964 |
| 50 | 0.385 | 1.69897 | -0.41453927 |
| 25 | 0.250 | 1.39794001 | -0.60205999 |
| Cutoff | 0.506 | 1.79003187 | -0.29584948 |
| Sensitivity **(AU/ml)** | 61.7 | ---------- | ---------- |



| Linear regression | |
|---|---|
| R | 0.991195 |
| $R^2$ | 0.982468 |
| Adjusted $R^2$ | 0.973702 |
| Standard error | 0.051643 |
| Number of observed value | 4 |

5.11.3. **Precision**

Intra-assay reproducibility: Intra-assay CV% < 15

Inter-assay reproducibility: Inter-assay CV% < 20

5.11.4. **Traceability**

Concentration of Anti-HAV IgM Positive Control = 800±200 AU/ml

**5.12. Flow chart of the test procedure**

**Simplified procedure of Anti-HAV IgM ELISA**

**Dilute 5 µl of each specimen with 1 ml saline solution. DO NOT DILUTE CONTROLS.**

↓

**Add 100 µl Controls (3 x NC, 2x PC) and 100 µl specimen diluent into wells. Reserve 2 wells for Blanks.**

↓

**Add 5 µl of the diluted specimen into each of wells containing 100 µl specimen diluent, respectively. Seal with adhesive slip.**

↓

**Incubate at +37 ±1°C for one hour**

↓

**Wash the plate**

↓

**Add 50µl of HAV Antigen Solution and 50µl Anti-HAV·Peroxidase Conjugate Solution into each reaction well, except Blanks.**

↓

**Incubate at +37 ±1 °C for one hour**

↓

**Wash the plate**

(Choose one of the following two methods for color development)

/ \

**Mix equal volumes of Chromogenic TMB concentrate and Substrate buffer. Add 100 µl of the mixed solution to wells.**

**Add 50 µl of Chromogenic TMB concentrate to wells and then add 50 µl of Substrate buffer. Mix well, gently.**

\ /

**Incubate at R.T. for 30 minutes.**

↓

**Add 100 µl of stop solution into each well.**

↓

**Determine absorbance using 450nm as reading wavelength with 620-690 nm reference wavelength[*8].**

## 6. BIBLIOGRAPHY


1. Melnick JL. History and epidemiology of hepatitis A virus. J Infect Dis 1995;171(Suppl 1):2-8.
2. Koff RS. Hepatitis A. Lancet 1998;341:1643–49.
3. Lemon SM, Binn LN. Serum neutralizing antibody response to hepatitis A virus. J Infect Dis. 1983;148**:** 1033-1039.
4. Duermeyer W, Van der Veen J, Koster B. ELISA in Hepatitis A. Lancet. 1978; 1(8068):823-824.
5. Bower WA, Nainan OV, Han X, Margolis HS. Duration of viremia in hepatitis A virus infection. J Infect Dis. 2000;182:12-17.
6. Craig AS, Schaffner W. Prevention of hepatitis A with the hepatitis A vaccine N Engl J Med 2004; 350:476-481
7. The reference wavelength of spectrometer can be 620nm to 690nm. However, user should validate the photometer in combination with this kit before use.


NOTE :

*8. The reference wavelength of spectrometer could be 620nm to 690nm. However, user should validate the spectrometer 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 |