# VIDAS® AFP (AFP)

IVD

VIDAS AFP is an automated quantitative test for use on the VIDAS family instruments for the quantitative measurement of human alpha feto-protein in serum, plasma (lithium heparin or EDTA) or amniotic fluid, using the ELFA technique (Enzyme Linked Fluorescent Assay).

## SUMMARY AND EXPLANATION

Alpha feto-protein (AFP) was first identified in 1956 in fetal serum and described in 1964 as oncofetal antigen. It is a glycoprotein with a molecular weight of 70,000 daltons, which is synthesized by the fetal liver, the yolk sac, and to a lesser degree, in the fetal gastrointestinal tract. It disappears in the weeks following birth. (1, 2).

During pregnancy, the AFP concentration in amniotic fluid peaks at around the 13$^{th}$ week, decreases rapidly until the 22$^{nd}$ week, and then decreases more slowly. Transplacental transfer of AFP also leads to an elevated level in maternal serum. The AFP assay using maternal serum or amniotic fluid is a useful screening test for the early pre-natal detection of open neural tube defects causing anencephaly and spina bifida. It is also used to monitor high-risk pregnancies, in association with other diagnostic techniques (2, 3, 4, 5, 6).

In cancerology, high AFP levels are found in 70% of cases of primary hepatocellular carcinomas and non-seminomatous germinal tumors of the testes. Elevated AFP levels may also be found in other pathologies: acute and chronic hepatitis, cirrhosis, cancers of the gastrointestinal tract with or without hepatic metastases, congenital tyrosinosis and ataxia telangiectasia (7, 8, 9).

In combination with ultra-sound scans and puncture-biopsy, the AFP assay is a major aid for diagnosis of liver cancers, as well as for patient follow-up, in particular after tumor exeresis, enabling early detection of recurring disease.

AFP is also a marker of choice for the prognostic monitoring of non-seminomatous germinal tumors, in order to determine response to therapy and rapidly detect recurring infection.

## PRINCIPLE

The assay principle combines a one-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA).

The Solid Phase Receptacle (SPR®), serves as the solid phase as well as the pipetting device for the assay. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips. All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times.

The sample is collected and transferred to the well containing anti-AFP antibody conjugated with alkaline phosphatase (conjugate). The sample/conjugate mixture is cycled in and out of the SPR several times to increase speed of reaction. The antigen will bind to antibodies coated on the SPR and to the conjugate forming a "sandwich". The remaining free AFP sites are then saturated by cycling the conjugate contained in another well in and out the SPR.

Unbound components are eliminated during the washing steps. During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone), the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the concentration of antigen present in the sample.

At the end of the assay, the results are automatically calculated by the instrument in relation to the calibration curve stored in memory, and then printed out.

**CONTENT OF THE KIT (60 TESTS) – RECONSTITUTION OF REAGENTS:**

| | | |
|---|---|---|
| 60 AFP strips | STR | Ready-to-use. |
| 60 AFP SPRs<br>2 x 30 | SPR | Ready-to-use.<br>Interior of SPRs coated with monoclonal anti-AFP immunoglobulins (mouse). |
| AFP control<br>1 x 2 ml (lyophilized) | C1 | Reconstitute with 2 ml of distilled water. Wait for 5 to 10 minutes. Mix. Stable after reconstitution for 14 days at 2-8°C or until the expiration date on the kit at -25 ± 6°C. Five freeze/thaw cycles are possible.<br>Human serum* + AFP (human origin) + preservatives.<br>MLE data indicate the confidence interval in IU/mL ("Control C1 Dose Value Range"). |
| AFP calibrator<br>1 x 2 ml (liquid) | S1 | Ready-to-use.<br>Tris buffer (0.05 mol/l) pH 7.5 + protein stabilizers + bovine albumin + 1 g/l sodium azide + AFP (human origin).<br>MLE data indicate the concentration in IU/mL ("Calibrator (S1) Dose Value") and the confidence interval in "Relative Fluorescence Value ("Calibrator (S1) RFV Range). |
| AFP diluent<br>2 x 25 ml (liquid) | R1 | Ready-to-use.<br>Tris buffer (0.05 mol/l) pH 7.5 + protein stabilizers + bovine albumin + 1 g/l sodium azide. |
| Specifications for the factory master data required to calibrate the test:<br>• MLE data (Master Lot Entry) provided in the kit,<br>or<br>• MLE bar code printed on the box label. | | |
| 1 Package insert provided in the kit or downloadable from www.biomerieux.com/techlib. | | |

* This product has been tested and shown to be negative for HBs surface antigen, and antibodies to HIV and HCV. However, since no existing test method can totally guarantee their absence, this product must be treated as potentially infectious. Therefore, usual safety procedures should be observed when handling.

**The SPR**

The SPR is coated during production with monoclonal anti-AFP immunoglobulins (mouse). Each SPR is identified by the AFP code. Only remove the required number of SPRs from the pouch and **carefully reseal the pouch after opening.**

**The strip**

The strip consists of 10 wells covered with a labeled, foil seal. The label comprises a bar code which mainly indicates the assay code, kit lot number and expiration date. The foil of the first well is perforated to facilitate the introduction of the sample. The last well of each strip is a cuvette in which the fluorometric reading is performed. The wells in the center section of the strip contain the various reagents required for the assay.

**Description of the AFP strip**

| Wells | Reagents |
|---|---|
| 1 | Sample well. |
| 2 - 3 - 4 | Empty wells. |
| 5 | Conjugate: Alkaline phosphatase-labeled monoclonal anti-AFP immunoglobulins (mouse) + 1 g/l sodium azide (600 µl). |
| 6 - 7 | Wash buffer: Sodium phosphate (0.01 mol/l) pH 7.4 + 1 g/l sodium azide (600 µl). |
| 8 | Washing buffer: diethanolamine* (1.1 mol/l or 11.5%) pH 9.8 + 1 g/l sodium azide (600 µl). |
| 9 | Empty well. |
| 10 | Cuvette with substrate: 4-Methyl-umbelliferyl-phosphate (0.6 mmol/l) + diethanolamine** (DEA) (0.62 mol/l or 6.6 %) pH 9.2 + 1 g/l sodium azide (300 µl). |

* Signal Word: **DANGER**

Hazard statement

H318 : Causes serious eye damage.
H373 : May cause damage to organs through prolonged or repeated exposure.
H315 : Causes skin irritation.
H302 : Harmful if swallowed.

Precautionary statement

P280 :Wear protective gloves/protective clothing/eye protection/face protection.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P309 + P311 : IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

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For further information, refer to the Material Safety Data Sheet.

## MATERIALS AND DISPOSABLES REQUIRED BUT NOT PROVIDED

- Pipette with disposable tip to dispense 2 ml and 100 µl.
- Powderless, disposable gloves.
- For other specific materials and disposables, please refer to the Instrument User's Manual.
- Instrument of the VIDAS family.

## WARNINGS AND PRECAUTIONS

- **For *in vitro* diagnostic use only.**
- **For professional use only.**
- **This kit contains products of human origin. No known analysis method can totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (see Laboratory Biosafety Manual - WHO - Geneva - latest Edition).**
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (do not ingest or inhale).
- Do not use the SPRs if the pouch is pierced.
- Do not use visibly deteriorated STRs (damaged foil or plastic).
- Do not use reagents after the expiration date indicated on the label.
- Do not mix reagents (or disposables) from different lots.
- Use **powderless** gloves, as powder has been reported to cause false results for certain enzyme immunoassay tests.
- Kit reagents contain sodium azide which can react with lead or copper plumbing to form explosive metal azides. If any liquid containing sodium azide is disposed of in the plumbing system, drains should be flushed with water to avoid build-up.
- The wash buffer in well 8 contains a harmful agent (11.5% diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- The substrate in well 10 contains an irritant agent (6.6% diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- Spills should be wiped up thoroughly after treatment with liquid detergent or a solution of household bleach containing at least 0.5% sodium hypochlorite. See the User's Manual for cleaning spills on or in the instrument. Do not autoclave solutions containing bleach.
- The instrument should be regularly cleaned and decontaminated (see the User's Manual).

## STORAGE CONDITIONS

- Store the VIDAS AFP kit at 2-8°C.
- **Do not freeze the SPRs, strips or calibrator.**
- **Store all unused reagents at 2-8°C.**
- After opening the kit, check that the SPR pouch is correctly sealed and undamaged. If not, do not use the SPRs.
- **Carefully reseal the pouch with the desiccant inside after use to maintain the stability of the SPRs and return the complete kit to 2-8°C.**
- If stored according to the recommended conditions, all components are stable until the expiration date indicated on the label. Refer to the kit composition table for special storage conditions.

## SPECIMENS

**Specimen type and collection**:

Serum (plain tube), plasma (lithium heparin or EDTA) or amniotic fluid.
It is recommended that each laboratory checks the compatibility of collection tubes used.
Samples containing impurities must be centrifuged before analysis.
None of the following factors have been found to significantly influence this assay for serum samples.

- hemolysis (after spiking samples with hemoglobin, 0 to 300 µmol/l (monomer)),
- lipemia (after spiking samples with lipids, 0 to 2 g/l equivalent in triglycerides),
- bilirubinemia (after spiking samples with bilirubin, 0 to 196 µmol/l).

However, it is recommended not to use samples that are clearly hemolyzed, lipemic or icteric and, if possible, to collect a new sample.

**Specimen stability:**

Serum samples can be stored at 2-8°C in stoppered tubes for up to 7 days; if longer storage is required, freeze the sera or plasma at - 25 ± 6°C. Avoid successive freezing and thawing.
Use fresh amniotic fluid for the assay. It is stable for 7 days if stored at 2-8°C and 2 months at - 25 ± 6°C. Avoid successive freezing and thawing.

## INSTRUCTIONS FOR USE

**For complete instructions, see the User's Manual.**

**Reading Master lot data**

Before each new lot of reagents is used, enter the specifications (or factory master data) into the instrument using the master lot entry (MLE) data.

If this operation is not performed **before initiating the tests**, the instrument will not be able to print results.

**Note: the master lot data need only be entered once for each lot.**
It is possible to enter MLE data **manually or automatically** depending on the instrument (refer to the User's Manual).

**Calibration**

Calibration, using the calibrator provided in the kit, must be performed each time a new lot of reagents is opened, after the master lot data have been entered. Calibration should then be performed every 14 days. This operation provides instrument-specific calibration curves and compensates for possible minor variations in assay signal throughout the shelf-life of the kit.
The calibrator, identified by S1, must be tested in **duplicate** (see User's Manual). The calibrator value must be within the set RFV "Relative Fluorescence Value" range. If this is not the case, recalibrate.

**Procedure**

1. **Only remove the required reagents from the refrigerator and allow them to come to room temperature for at least 30 minutes.**
2. Use one "AFP" strip and one "AFP" SPR for each sample, control or calibrator to be tested. **Make sure the storage pouch has been carefully resealed after the required SPRs have been removed.**
3. The test is identified by the "AFP" code on the instrument. The calibrator must be identified by "S1", and tested in duplicate. If the control needs to be tested, it should be identified by C1.
4. Mix the calibrator, control and samples using a vortex-type mixer (for serum, plasma or amniotic fluid separated from the pellet).
5. **For this test, the calibrator, control, and sample test portion is 100 µl.**
6. Insert the "AFP" SPRs and "AFP" strips into the instrument. Check to make sure the color labels with the assay code on the SPRs and the Reagent Strips match.
7. Initiate the assay as directed in the User's Manual. All the assay steps are performed automatically by the instrument.
8. Reclose the vials and return them to the required temperature after pipetting.
9. The assay will be completed within approximately 30 minutes. After the assay is completed, remove the SPRs and strips from the instrument.
10. Dispose of the used SPRs and strips into an appropriate recipient.

## RESULTS AND INTERPRETATION

Once the assay is completed, results are analyzed automatically by the computer. Fluorescence is measured twice in the Reagent Strip's reading cuvette for each sample tested. The first reading is a background reading of the substrate cuvette before the SPR is introduced into the substrate. The second reading is taken after incubating the substrate with the enzyme remaining on the interior of the SPR. The RFV (Relative Fluorescence Value) is calculated by subtracting the background reading from the final result. This calculation appears on the result sheet.
The results are automatically calculated by the instrument using calibration curves which are stored by the instrument (4-parameter logistics model).
The AFP concentrations are expressed in "IU/ml" of the international standard 72/225: 1 "IU" = 1.21 ng. See the User's Manual to change units.
Samples with AFP concentrations greater than 400 IU/ml must be reassayed after dilution to 1/20 or 1/200 in the AFP diluent (R1). If the dilution factor has not been entered when the Work List was created (see User's Manual), multiply the result by the dilution factor to obtain the sample concentration.
Interpretation of test results should be made taking into consideration the patient's history, and the results of any other tests performed (biology, imaging, histology etc.).

## QUALITY CONTROL

A control is included in each VIDAS AFP kit. This control must be performed immediately after opening a new kit to ensure that reagent performance has not been altered. Each calibration must also be checked using this control. The instrument will only be able to check the control value if it is identified by C1.
Results cannot be validated if the control value deviates from the expected values.

**Note**

It is the responsibility of the user to perform Quality Control in accordance with any local applicable regulations.

## LIMITATIONS OF THE METHOD

Interference may be encountered with certain sera containing antibodies directed against reagent components. For this reason, assay results should be interpreted taking into consideration the patient's history, and the results of any other tests performed.
The VIDAS AFP assay has not been validated within the context of screening for trisomy 21 syndrome.

## RANGE OF EXPECTED VALUES

These figures are given as a guide; it is recommended that each laboratory establish its own reference values from a rigorously selected population.

**In men and non-pregnant women:**

The distribution of values for a population of 107 individuals is as follows:

| Range of values (IU/ml) | 0-2 | 2-4 | 4-6 | 6-10 | > 10 |
|---|---|---|---|---|---|
| Frequency | 77.5% | 17.8% | 2.8% | 1.9% | 0 |

**In pregnant women (maternal serum):**

AFP was assayed in the serum of 297 pregnant women divided according to gestational age:

| Week of amenorrhea | 15th | 16th | 17th | 18th | 19th | 20th |
|---|---|---|---|---|---|---|
| Number | 51 | 67 | 49 | 51 | 43 | 36 |
| Median IU/ml | 32.0 | 39.0 | 44.0 | 50.0 | 64.0 | 68.0 |
| 2,5 x Median IU/ml | 80.0 | 97.0 | 110 | 125 | 160 | 170 |

**In pregnant women (amniotic fluid):**

AFP was assayed in amniotic fluid collected from 296 pregnant women divided according to gestational age:

| Week of amenorrhea | 15th | 16th | 17th | 18th | 19th | 20th |
|---|---|---|---|---|---|---|
| Number | 54 | 54 | 52 | 54 | 54 | 28 |
| Median IU/ml | 16350 | 13050 | 11800 | 10000 | 8950 | 7000 |
| Multiplying factor | 3 | 3 | 3 | 3 | 3 | 3 |
| IU/ml | 49050 | 39150 | 35400 | 30000 | 26850 | 21000 |

Certain authors (5, 6) report that the median multiplying factor should be modulated according to the number of weeks of amenorrhea:

| Week of amenorrhea | 15th | 16th | 17th | 18th | 19th | 20th |
|---|---|---|---|---|---|---|
| Number | 54 | 54 | 52 | 54 | 54 | 28 |
| Median IU/ml | 16350 | 13050 | 11800 | 10000 | 8950 | 7000 |
| Multiplying factor | 2.5 | 3 | 3 | 3 | 3.5 | 3.5 |
| IU/ml | 40875 | 39150 | 35400 | 30000 | 31325 | 24500 |

**PERFORMANCE**

Studies performed using VIDAS AFP gave the following results:

**Measurement range**

The measurement range of the VIDAS AFP kit is: 0.5 to 400 IU/ml.

**Detection limit**

Defined as the smallest concentration of AFP which is significantly different from the zero concentration with a probability of 95%: **≤ 0.5 IU/ml**

**Hook effect**

No hook effect was found up to AFP concentrations of 200,000 IU/ml.

**Precision**

Intra-assay reproducibility:

Four samples were tested 30 times in a same run.

| Sample | 1 | 2 | 3 | 4 |
|---|---|---|---|---|
| Mean concentration (IU/ml) | 1.04 | 11.13 | 80.74 | 335.60 |
| CV % | 9.68 | 3.95 | 2.57 | 3.40 |

Inter-assay reproducibility

Four samples were assayed singly in 29 different runs on the same VIDAS instrument over a period of 8 weeks.

| Sample | 1 | 2 | 3 | 4 |
|---|---|---|---|---|
| Mean concentration (IU/ml) | 1.15 | 12.05 | 86.37 | 342.70 |
| CV % | 7.39 | 4.01 | 4.19 | 3.87 |

**Accuracy**

Dilution test

Three samples were diluted in the AFP diluent (R1) and tested singly in 3 runs. The ratio of the mean concentration measured over the expected concentration is expressed as a mean recovery percentage.

| Samples | Dilution factor | Expected concentration (IU/ml) | Mean measured concentration (IU/ml) | Mean recovery percentage (%) |
|---|---|---|---|---|
| 1 | 1/1 | 87.5 | 87.50 | 100 |
| | 1/2 | 43.8 | 46.64 | 106.6 |
| | 1/4 | 21.9 | 23.02 | 105.2 |
| | 1/8 | 10.9 | 12.35 | 113.0 |
| | 1/16 | 5.5 | 5.94 | 108.7 |
| | 1/32 | 2.73 | 2.96 | 108.4 |
| 2 | 1/1 | 379.3 | 379.30 | 100 |
| | 1/2 | 189.6 | 184.81 | 97.5 |
| | 1/4 | 94.8 | 94.30 | 99.5 |
| | 1/8 | 47.4 | 45.67 | 96.3 |
| | 1/16 | 23.7 | 24.27 | 102.4 |
| | 1/32 | 11.9 | 12.47 | 105.2 |
| 3 | 1/1 | > 400 | > 400 | - |
| | 1/2 | 290.8 | 291.46 | 100.2 |
| | 1/4 | 145.4 | 161.04 | 110.7 |
| | 1/8 | 72.7 | 79.21 | 108.9 |
| | 1/16 | 36.4 | 38.47 | 105.8 |
| | 1/32 | 18.2 | 20.51 | 112.8 |

**Comparison with other test methods**

Correlation was established between the VIDAS AFP kit and another commercially available method (X):

Using serum samples
VIDAS AFP = 1.131 X – 2.12
r = 0.991 (n = 446)

Using amniotic fluid
VIDAS AFP = 1.124 X – 1.81
r = 0.993 (n = 275)

**WASTE DISPOSAL**

Dispose of used or unused reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

## LITERATURE REFERENCES


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## INDEX OF SYMBOLS

| Symbol | Meaning |
|---|---|
| REF | Catalog number |
| IVD | *In Vitro* Diagnostic Medical Device |
|  | Manufacturer |
|  | Temperature limit |
|  | Use by date |
| LOT | Batch code |
|  | Consult Instructions for Use |
|  | Contains sufficient for <n> tests |
|  | Date of manufacture |

## WARRANTY

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**REVISION HISTORY**

Change type categories :

| | |
|---|---|
| N/A | Not applicable (First publication) |
| Correction | Correction of documentation anomalies |
| Technical change | Addition, revision and/or removal of information related to the product |
| Administrative | Implementation of non-technical changes noticeable to the user |

***Note:*** *Minor typographical, grammar, and formatting changes are not included in the revision history.*

| Release date | Part Number | Change Type | Change Summary |
|---|---|---|---|
| 2015/01 | 06991L | Administrative | INDEX OF SYMBOLS<br>REVISION HISTORY |
| | | Technical | CONTENT OF THE KIT (60 TESTS) – RECONSTITUTION OF REAGENTS<br>WARNINGS AND PRECAUTIONS<br>INSTRUCTIONS FOR USE |



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