

## VIDAS<sup>®</sup> AMH (AMH)

VIDAS<sup>®</sup> AMH (AMH) is an automated test for use on the VIDAS<sup>®</sup> family of instruments, for the quantitative measurement of circulating anti-Müllerian Hormone (AMH) in human serum or plasma (lithium heparin) using the ELFA (Enzyme Linked Fluorescent Assay) technique.

The VIDAS<sup>®</sup> AMH assay is intended to help assess the ovarian follicle reserve in women and young girls over 12 years of age in the context of ovarian dysfunction or controlled or assisted procreation.

### SUMMARY AND EXPLANATION

Women's capacity to procreate depends largely on good mobilization of oocytes during their cycles, from a limited reserve of follicles constituted during fetal life, until exhaustion at menopause. This complex process is regulated by the gonadal axis hormones. In women, AMH is produced by the granulosa cells of small growing follicles. Its measurement in the circulation helps to estimate the number of antral and pre-antral follicles present in the ovaries and is cycle-independent (1). Good correlation is observed between AMH measurement in peripheral blood, follicle count by transvaginal ultrasonography and age (2).

AMH is a dimeric glycoprotein, a member of the transforming growth factor  $\beta$  (TGF- $\beta$ ) superfamily. It is produced as a precursor protein consisting of two monomers linked by a disulfide bond. The cleaved complex then remains bound and can be measured in the blood with the ELISA technique by monoclonal antibodies giving sensitivity performance suited to monitoring changes in ovarian reserves from birth to menopause (3).

AMH measurement has proven to be useful in different domains for women (1). As an indicator of the natural decline of the ovarian reserve and therefore the risk of hypofertility, it is recommended as an aid for women who are considering parenthood. In the context of medically assisted procreation, AMH measurement helps to select the best strategy for the patient, by optimizing the controlled ovarian stimulation step whilst avoiding the risk of hyperstimulation (4, 5). AMH measurement can also be used to monitor the ovarian reserve in young girls and women who, for example, have undergone gonadotoxic treatment for cancer (6). For women with ovulation problems, the measurement of serum AMH levels enables better characterization of the type of ovarian dysfunction, particularly hypergonadotropic anovulation associated with ovarian insufficiency such as polycystic ovary syndrome (7).

### PRINCIPLE

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

The Solid Phase Receptacle (SPR<sup>®</sup>) serves as the solid phase as well as the pipetting device. 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<sup>®</sup> several times.

The sample is transferred into the wells containing anti-Müllerian antibody labeled with alkaline phosphatase (conjugate). The sample/conjugate mixture is cycled in and out of the SPR<sup>®</sup> several times. This operation enables the anti-Müllerian hormone to bind with the antibodies coated on the interior of the SPR<sup>®</sup> and with the conjugate to form a sandwich. Unbound components are eliminated during the washing steps.

During the final detection step, the substrate (4-Methylumbelliferyl phosphate) is cycled in and out of the SPR<sup>®</sup>. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methylumbelliferone), the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the concentration 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 - RECONSTITUTION OF REAGENTS (30 TESTS):**

AMH Strips	STR	Ready-to-use.
AMH SPR®s 1 x 30	SPR®	Ready-to-use. Interior of SPR®s coated with mouse monoclonal AMH antibodies.
AMH Positive control (lyophilized) 1 x 2 mL	C1	Reconstitute with <b>2 mL of distilled water</b> . Wait for at least <b>10 minutes</b> . Mix by inverting several times and then using a vortex-type mixer until completely dissolved. After reconstitution, the control is stable for 7 days at 2-8°C or until the expiration date of the kit when stored at -25 ± 6°C. 8 freeze/thaw cycles are possible. Human serum* + preservative. MLE data indicate the acceptable range in ng/mL ("Control C1 Dose Value Range").
AMH Calibrator (lyophilized) 2 x 2 mL	S1	Reconstitute with <b>2 mL of distilled water</b> . Wait for at least <b>10 minutes</b> . Mix by inverting several times and then using a vortex-type mixer until completely dissolved. After reconstitution, the calibrator is stable for 7 days at 2-8°C or until the expiration date of the kit when stored at -25 ± 6°C. 4 freeze/thaw cycles are possible. Human serum* + protein stabilizer + preservative. MLE data indicate the calibrator concentration in ng/mL ("Calibrator (S1) Dose Value") and the acceptable range in "Relative Fluorescence Value" (Calibrator (S1) RFV Range).
AMH Sample Diluent (liquid) 1 x 4.1 mL	R1	Ready-to-use. Only for diluting samples outside the measurement range. Protein and chemical stabilizers + preservatives.
Specifications for the factory master data required to calibrate the test:		
<ul style="list-style-type: none"> <li>• MLE data (Master Lot Entry) provided in the kit or</li> <li>• MLE barcode printed on the box label</li> </ul>		
1 package insert provided in the kit or downloadable from <a href="http://www.biomerieux.com/techlib">www.biomerieux.com/techlib</a> .		

\* This product has been tested and shown to be negative for HBs antigen, and antibodies to HIV1, HIV2 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 interior of the SPR® is coated during production with mouse monoclonal AMH antibodies. Each SPR® is identified by the "AMH" code. Only remove the required number of SPR®s from the pouch and **carefully reseal the pouch after opening**.

**The Reagent Strip**

The strip consists of 10 wells covered with a labeled, foil seal. The label comprises a barcode 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 AMH strip**

Well	Reagents
1	Sample well.
2 - 3 - 4 - 5	Empty wells.
6	Conjugate: alkaline phosphatase-labeled AMH antibody + preservative (400 µL).
7 - 8 - 9	Wash buffer: preservative (600 µL).
10	Reading 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.

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.

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

**MATERIALS AND DISPOSABLES REQUIRED BUT NOT PROVIDED**

- Pipette with disposable tip to dispense 2 mL and 200 µL.
- Powderless, disposable gloves.
- For other specific materials and disposables, please refer to the Instrument User Manual.
- Instruments of the VIDAS® family.

**WARNINGS AND PRECAUTIONS**

- **For *in vitro* diagnostic use only.**
- **For professional use only by qualified laboratory personnel.**
- **The 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; do not inhale).
- Do not use the SPR®s if the pouch is pierced or if the dot sealing a SPR® has come unstuck.

- Do not use visibly deteriorated STRs (damaged foil or plastic).
- Do not use reagents after the expiration date indicated on the box 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.
- The substrate contains a preservative (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 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 Manual for cleaning spills on or in the instrument. Do not autoclave solutions containing bleach.
- The instrument should be regularly cleaned and maintained (see the User Manual for preventive maintenance operations and user maintenance operations).

**STORAGE CONDITIONS**

- Store the VIDAS® AMH kit at 2-8°C.
- **Store all unused reagents at 2-8°C.**
- **Do not freeze reagents, with the exception of the calibrator and control after reconstitution.**
- After opening the kit, check that the SPR® pouch is correctly sealed and undamaged. If not, do not use the SPR®s.
- **Carefully reseal the pouch with the desiccant inside after use to maintain stability of the SPR®s 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 box label. Refer to the kit content table for special storage conditions.

## SAMPLES

### Sample type and collection

Human serum or plasma (lithium heparin).

#### **Types of tubes validated:**

- Plastic tube with clot activator,
- Plastic tube with clot activator and separation gel,
- Plastic tube with lithium heparin,
- Plastic tube with lithium heparin and separation gel.

It is recommended to validate collection tubes before use as some may contain substances which interfere with test results.

**Note:** Blood sampling tube results may vary from one manufacturer to another depending on the materials and additives used.

It is the responsibility of each laboratory to validate the type of sample tube used and to follow the manufacturer's recommendations for use.

### Sample preparation

The current revision of the WHO/DIL/LAB/99.1 document provides recommendations for the preparation of samples.

For use of the sample tubes, follow the tube manufacturer's instructions for use.

The pre-analytical step, including the preparation of blood samples, is an essential part of medical analyses. In accordance with Good Laboratory Practice, this step is performed under the responsibility of the laboratory manager.

Insufficient clot time can result in the formation of fibrin with micro-clots that are invisible to the naked eye. The presence of fibrin, red blood cells, or suspended particles can lead to erroneous results.

Samples containing suspended fibrin particles or erythrocyte stroma should be centrifuged before testing.

**Preparation of frozen-stored samples:** after thawing, these samples must be thoroughly mixed before testing. Mix using a vortex-type mixer. If necessary, clarify samples by centrifuging before testing (20 minutes at 2 000 g or 10 minutes at 3 900 g).

### Sample stability

Samples (serum and plasma) can be stored at +18/+25°C in open primary tubes for up to 4 hours, in closed primary tubes for up to 8 hours or at +2/+8°C for up to 5 days when aliquoted; if longer storage is required, freeze the serum or plasma at -25 ± 6°C for up to 6 months, without exceeding 3 freeze/thaw cycles.

### Sample-related interferences

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

Refer to the section "**PERFORMANCE - Study of drugs and other potentially interfering substances**" for the compounds tested.

## INSTRUCTIONS FOR USE

**For complete instructions, see the Instrument User Manual.**

### Reading VIDAS® Protocol Test Change (PTC) data and MLE data

#### **When using the assay for the first time:**

With the external instrument barcode reader, **scan the barcodes (PTC and MLE) in the following order:**

1. Depending on the instrument, scan the PTC barcode(s) at the end of the package insert or downloadable from [www.biomerieux.com/techlib](http://www.biomerieux.com/techlib). This allows VIDAS® PTC protocol data to be transferred to the instrument software for its update.
2. Scan the MLE data provided in the kit or indicated on the box label.

#### **When opening a new lot of reagents:**

With the external instrument barcode reader, it is imperative to scan the MLE data on the box label before running the assay.

**Note: These 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 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, and then every 28 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 the User Manual). The calibration value must be within the set RFV (Relative Fluorescence Value). If this is not the case, **recalibrate using S1**.

### Control

A positive control is included in each VIDAS® AMH 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.

### Procedure

1. **Remove the kit from storage at 2-8°C and take out the required number of reagents. Carefully reseal the SPR® pouch. Return the kit immediately to 2-8°C. The reagents can be used as soon as they are removed from the refrigerator.**
  2. Use one "AMH" strip and one "AMH" SPR® for each sample, control or calibrator to be tested.
  3. The test is identified by the "AMH" code on the instrument. The calibrator must be identified by "S1" and tested in duplicate. The control must be identified by "C1" and tested singly.
  4. If necessary, clarify samples by centrifugation.
  5. Mix the calibrator, control and samples (for serum or plasma separated from the pellet) using a vortex-type mixer.
  6. To obtain optimum results, refer to all the paragraphs in the **SAMPLES** section.
  7. Before pipetting, ensure that the samples, calibrator, control and diluent do not contain any bubbles.
8. **For this test, the calibrator, control, and sample test portion is 200 µL.**
9. Insert the "AMH" SPR®s and "AMH" strips into the instrument. Check to make sure the color labels with the assay code on the SPR®s and the reagent strips match.
  10. Initiate the assay as directed in the User Manual. All the assay steps are performed automatically by the instrument.
  11. Reclose the vials and return them to the required temperature after pipetting.
  12. The assay will be completed **within approximately 35 minutes**. After the assay is completed, remove the SPR®s and strips from the instrument.
  13. Dispose of the used SPR®s and strips into an appropriate recipient.

### QUALITY CONTROL

Quality control can be performed in accordance with local regulations or requirements related to accreditation, as well as requirements defined in the laboratory's quality control procedure.

### RESULTS AND INTERPRETATION

Once the assay is completed, the 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 stored calibration curves, according to a predefined mathematical model, and are expressed in ng/mL.

#### Conversion factors:

$$\text{ng/mL} \times 100 = \text{ng/dL}$$

$$\text{ng/mL} \times 7.14 = \text{pmol/L}$$

The VIDAS® AMH assay is calibrated against a competitor's automated method.

The instrument displays the VIDAS® AMH assay results from 0.01 to 9.00 ng/mL.

Samples with concentrations greater than 9 ng/mL must be retested preferably after 1/4 dilution in the R1 Sample Diluent provided in the kit. 1/10 and 1/20 dilutions are also possible. The patient's clinical history should be taken into account to determine the dilution factor.

If the dilution factor was entered when the Work List was created, the result is calculated automatically. If the dilution factor was not entered, 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 clinical history, and the results of any other tests performed.

### LIMITATIONS OF THE METHOD

1. 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 clinical history, and the results of any other tests performed.
2. Refer to the section "**PERFORMANCE - Study of drugs and other potentially interfering substances**" for the compounds tested.
3. Any results that do not correspond to the patient's clinical history may be due to inadequate instrument maintenance (see the Instrument User Manual).

## REFERENCE VALUES

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

The following values were obtained with the VIDAS® AMH assay using 435 serum samples from apparently healthy European females between 12 and 44 years of age. The selected females were not taking hormonal contraception and those over 18 years of age had regular menstrual cycles.

Age group	N	5 <sup>th</sup> perc. ng/mL [90% CI]*	10 <sup>th</sup> perc. ng/mL [90% CI]	50 <sup>th</sup> perc. ng/mL [90% CI]	90 <sup>th</sup> perc. ng/mL [90% CI]	95 <sup>th</sup> perc. ng/mL [90% CI]
12 - 17 years	45 **	-	1.57 [ 0.81 ; 2.01 ]	3.63 [ 3.16 ; 4.82 ]	7.60 [ 6.75 ; > 9.00 ]	-
18 - 24 years	68	1.62 [ 1.28 ; 2.37 ]	2.15 [ 1.35 ; 2.92 ]	4.37 [ 4.10 ; 5.12 ]	8.40 [ 6.93 ; > 9.00 ]	> 9.00 [ 7.93 ; > 9.00 ]
25 - 29 years	88	1.20 [ 0.56 ; 1.56 ]	1.56 [ 1.08 ; 1.83 ]	3.23 [ 2.82 ; 3.76 ]	8.76 [ 7.56 ; > 9.00 ]	> 9.00 [ 8.75 ; > 9.00 ]
30 - 34 years	103	0.80 [ 0.57 ; 1.19 ]	1.19 [ 0.86 ; 1.48 ]	3.55 [ 3.19 ; 3.95 ]	7.00 [ 6.27 ; 7.76 ]	8.18 [ 7.02 ; > 9.00 ]
35 - 39 years	65	0.11 [ 0.06 ; 0.38 ]	0.36 [ 0.10 ; 0.70 ]	1.84 [ 1.41 ; 2.35 ]	5.15 [ 3.54 ; 6.81 ]	6.72 [ 5.07 ; > 9.00 ]
40 - 44 years	66	0.10 [ < 0.01 ; 0.18 ]	0.17 [ 0.09 ; 0.20 ]	0.98 [ 0.76 ; 1.40 ]	3.84 [ 2.41 ; 5.96 ]	5.78 [ 3.64 ; 8.73 ]

\* CI = Confidence Interval

\*\* Due to the small number of patients, the extreme percentiles for this age group were not estimated.

## PERFORMANCE

Studies performed using the VIDAS® AMH assay gave the following results:

### Measurement range

The measurement range is the range of values corresponding to the acceptable performance limits (precision and linearity).

The measurement range of the VIDAS® AMH assay is: 0.02 to 9.00 ng/mL.

### Linearity

Linearity was evaluated according to CLSI® EP06-A recommendations. The VIDAS® AMH assay is linear between 0.02 and 9.00 ng/mL.

### Detection limits

Limit of Blank (LoB)	0.00 ng/mL
Limit of Detection (LoD)	0.01 ng/mL
Limit of Quantitation (LoQ)	0.02 ng/mL

LoB, LoD and LoQ values were determined according to CLSI® EP17-A2 recommendations.

The Limit of Blank (LoB) is the concentration below which 95% of analyte-free samples are found.

The Limit of Detection (LoD) is the lowest concentration of analyte in a sample that can be distinguished from the analyte-free sample with a probability of 95% (observed result greater than the LoB with a 95% probability).

The Limit of Quantitation (LoQ) is the lowest concentration of analyte that can be detected and measured with an acceptable level of precision. For the VIDAS® AMH assay, the acceptable level of precision corresponds to within-lot precision fixed at 20% CV.

### Hook effect

No hook effect was found up to anti-Müllerian hormone concentrations of 1 600 ng/mL.

### Precision

A precision study was performed according to CLSI® EP05-A3 recommendations. A panel of human samples representing 5 concentration levels in the measurement range was analyzed on the instruments of the VIDAS® family so as to include the following main sources of variability: repeatability, run, day, calibration and lot.

Repeatability (within-run precision), within-lot precision and within-laboratory precision (between-lot within-instrument) were estimated for each level of concentration studied. The values obtained in this study are reported in the following table:

Sample	N (observations)	Concentration level (ng/mL)	Repeatability CV%	Within-lot precision CV%	Within-laboratory precision (between-lot within-instrument) CV%
1	519*	0.22	4.1	6.6	8.3
2	520	1.08	4.4	8.0	9.9
3	520	2.99	4.4	7.4	9.8
4	520	5.45	4.8	7.6	8.9
5	520	7.37	4.4	8.2	10.6

\* 1 statistical outlier removed

### Specificity

#### Cross-reactivity

The analytical specificity of the VIDAS® AMH assay was established by testing cross-reactive compounds according to CLSI® document EP07-A2 recommendations. Cross-reactivity was evaluated by spiking serum samples, containing 1 ng/mL and 4 ng/mL of AMH, with cross-reactive compounds.

The results of this study are reported in the following table:

Tested compound	Tested concentration	Cross-reactivity %
Activin A	100 ng/mL	≤ 0.10%
Inhibin A	100 ng/mL	≤ 0.12%
LH	500 IU/L	≤ 0.21%
FSH	500 IU/L	≤ 0.23%

#### Study of drugs and other potentially interfering substances

Potential interference by commonly used drugs and other substances was studied according to CLSI® EP07-A2 recommendations. No significant interference was detected up to the maximum concentrations tested.

Tested drug	Maximum concentration
Acetaminophen	1 324 µmol/L
Acetylsalicylic Acid	3.62 mmol/L
Ampicillin	152 µmol/L
Ascorbic Acid	342 µmol/L
Codeine	5.34 µmol/L
Ibuprofen	2 425 µmol/L

Tested substance	Maximum concentration
Hemoglobin	4.85 g/L
Lipids	30 g/L
Bilirubin	300 mg/L
Albumin	60 g/L
HAMA	2 µg/mL
Rheumatoid factor	800 IU/mL

### Method comparison

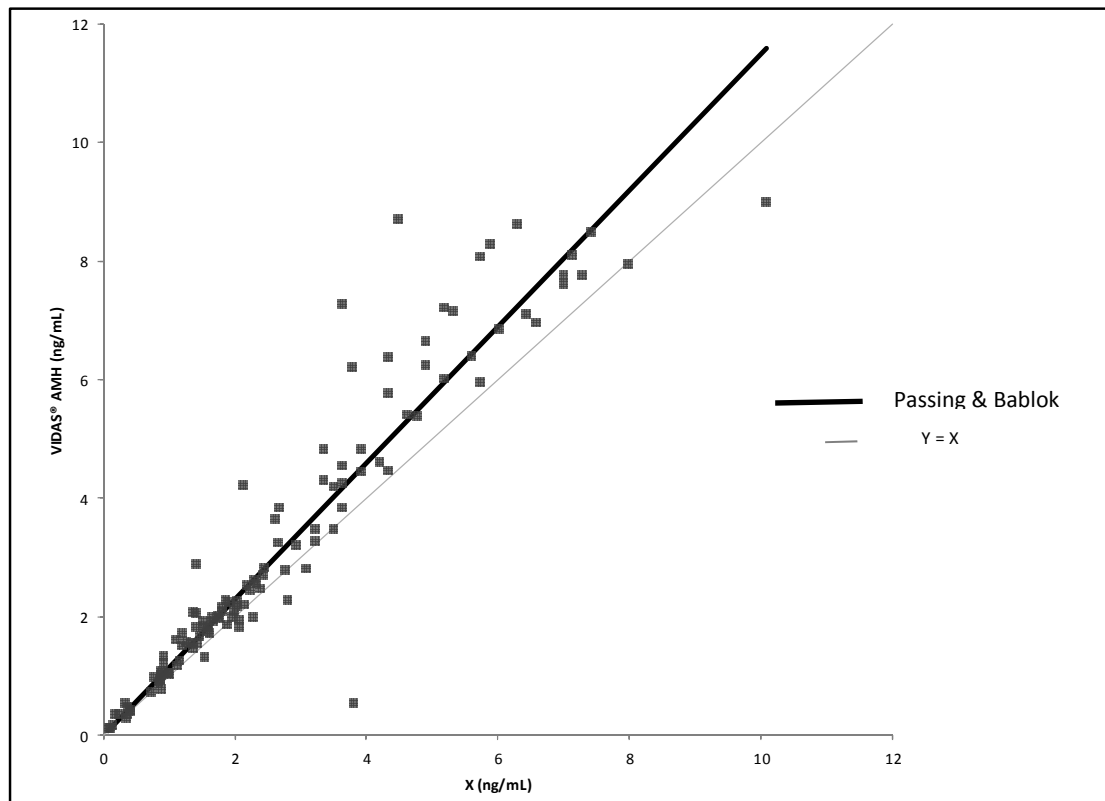
A comparative study was performed according to CLSI® EP09-A3 recommendations.

118 serum samples from patients over 12 years of age (collected in routine practice at 2 laboratories), were prospectively collected and tested simultaneously using the VIDAS® AMH assay and another commercially available immunoassay.

These patients were consulting prior to undergoing medically assisted procreation treatment or showed symptoms of one of the following ovarian dysfunctions:

- polycystic ovary syndrome
- modification of ovarian reserve following previous exposure to gonadotoxic treatment.

The comparison of the VIDAS® AMH assay (Y) with another commercially available immunoassay (X) gave the following results:



Equation for Passing-Bablok regression:  $Y = 1.15 X - 0.02$

Correlation Coefficient:  $r = 0.95$

Furthermore, 15 samples from patients with suspected early ovarian insufficiency were also tested using the 2 methods. All of the samples showed concentrations below the limits of quantitation of both techniques and were therefore not included in the analysis presented above.

These results, which are close to the limits of quantitation of both techniques, show the agreement between the VIDAS® AMH assay and the commercially available test in this clinical context.



## 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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- WORLD HEALTH ORGANIZATION, USE OF ANTICOAGULANTS IN DIAGNOSTIC, LABORATORY INVESTIGATIONS, 2002, WHO/DIL/LAB/99.1 Rev.2

## REVISION HISTORY

### Change type categories:

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
<b>Note:</b>	<i>Minor typographical, grammar, and formatting changes are not included in the revision history</i>










Release date	Part Number	Change Type	Change Summary
2016/05	9308852A	Administrative	CREATION
		Technical	CREATION

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## INDEX OF SYMBOLS

Symbol	Meaning
	Catalog number
	<i>In Vitro</i> Diagnostic Medical Device
	Manufacturer
	Temperature limit
	Use by date
	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Date of manufacture

## LIMITED WARRANTY

bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

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