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**Instructions for use**  
**HistaSure™ Wine**

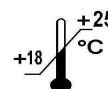
**REF**

**FC L-3400**



**RUO**

For Research use only-  
Not for use in diagnostic  
procedures



## HistaSure Wine

### 1. Intended use and principle of the test

The assay kit provides materials for the semi-quantitative determination of derivatized histamine in wine (red wine, white wine, champagne).

The derivatization of Histamine is part of the preparation of the samples. By using the acylation reagent, histamine is quantitatively derivatized into N-acylhistamine. The amount of fluorescence labelled antibody bound to the solid phase histamine is inversely proportional to the histamine concentration of the sample.

The HistaSure™ assay uses the unique *FLORIDA* Technology (Fluorescence Labelled Optical-Read Immuno Dipstick Assay) which is designed to determine Histamine with highest precision in different kinds of samples. Even under difficult light conditions or in complete darkness the test signals can be read quite easily by visual evaluation. In contrast to gold and latex beads used in traditional rapid immunoassays, HistaSure™ uses a fluorescence dye to label the antibody.

The combination of *FLORIDA* and the highly specific immunoreagents shows sensitivity as high as 1 ppm.

The cut-offs prescribed by legislations (as at February 2009) differ from country to country, e.g.:

Country	Cut-off
Germany	2 ppm
Belgium	5 ppm
France	8 ppm
Switzerland	10 ppm

For wine samples the cut-off of the assay can easily be adjusted by the operator in a range between 2 - 100 ppm with the dipsticks and reagents included in this kit just by predilution of the samples with distilled water.

### 2. Precautions

- Follow the test instructions and use the indicated incubation times. Deviations from the protocol may lead to inaccurate results.
- Do not mix reagents and solutions from different lots.
- Do not use kit components beyond the expiry dates.
- To avoid any cross-contamination clean pipette tips have to be used for each sample.
- Consider the different storage conditions of the Running Buffer Tubes (at 2-8°C) and of the other kit components (at room temperature: 20-25°C).
- Allow the Running Buffer Tubes to reach room temperature prior to use.

### 3. Storage and stability

Except of the Running Buffer Tubes the reagents should be stored dry at room temperature (20-25°C) until expiration date. The Running Buffer Tubes should be stored at 2-8°C until expiration date. Do not use components beyond the expiration date indicated on the kit labels.

### 4. Contents of the kit

The HistaSure™ Wine kit (FC L-3400) contains materials for 24 semi-quantitative determinations of histamine. This kit is manufactured by: **Labor Diagnostika Nord GmbH & Co. KG, Nordhorn, Germany.**

<b>FC L-3212</b>	<b>ACYL-REAG</b>	<b>Acylation Reagent</b>	1 x 3 mL	ready for use
<b>FC L-3231</b>	24 <b>HIS-DIPSTICK</b>	<b>Histamine Dipstick</b>	1 x 24	ready for use
<b>FC L-3232</b>	24 <b>HIS</b>	<b>Histamine Antiserum Microtiter Wells</b>	1 x 24	ready for use
<b>FC L-3233</b>	<b>RUN-BUFF-TUBES</b>	<b>Running Buffer Tubes</b>	1 x 24 x 1.5 mL	ready for use, <i>white caps!</i>
<b>FC L-3234</b>	<b>ACYL-BUFF-TUBES</b>	<b>Acylation Buffer Tubes</b>	1 x 24 x 0.6 mL	ready for use
<b>FC L-3250</b>	<b>CONTROL</b>	<b>Histamine Dipstick Control</b>	1 x 1	ready for use

## 5. Additional materials and equipment required but not provided with the kit

The following items can be ordered separately or as a complete add-on (equipment kit FC L-3500) at LDN:

Product	Cat. No.	Quantity
<b>100 µl precision pipette</b>	<b>FC L-3560</b>	1
<b>Pipetting tips</b>	<b>FC L-3561</b>	96
<b>LED Blue light source</b>	<b>FC L-3565</b>	1
<b>Tube Rack</b>	<b>FC L-3575</b>	1
<b>Orange colored lab eyewear protection glasses</b>	<b>FC L-3570</b>	1

Not available from LDN:

- Distilled water
- Pair of scissors

## 6. Test procedures

The following protocol is suitable for wine samples (red wine, white wine, champagne). The cut-off of the assay is adjusted by using different sample dilutions (the samples have to be diluted with distilled water):

Cut-off	Sample dilution	Pipetting Example
2 ppm	none	100 µl of undiluted sample
4 ppm	1:2	100 µl sample + 100 µl distilled water
8 ppm	1:4	100 µl sample + 300 µl distilled water
16 ppm	1:8	100 µl sample + 700 µl distilled water
...	...	

*Do not use any glassware for the dilution of the samples!*

After diluting the samples with distilled water just ensure a homogenous solution by shaking it manually for a short while.

*Allow all reagents – especially the Running Buffer Tubes - to reach room temperature prior to use.*

### 6.1 Sample preparation and acylation

<b>1.</b>	Pipet <b>100 µl</b> of the wine sample into the <b>Acylation Buffer Tubes</b> .
<b>2.</b>	Add <b>100 µl</b> of <b>Acylation Reagent</b> to each <b>Acylation Buffer Tube</b> ( <i>the colour change to pink indicates that all pipetting steps so far have been performed accurately</i> ), cap the tubes and mix gently. <b>Incubate</b> the tubes for <b>5 minutes</b> at room temperature (after this acylation step, the samples can be stored in the Acylation Buffer Tubes at 2-8°C for 2 week or at -18°C for 1 year).
<b>3.</b>	Pipet <b>100 µl</b> of the <b>acylated samples</b> into the <b>Running Buffer Tubes</b> (white caps!). Cap the tubes and mix gently.
<b>4.</b>	Fix the needed amount of <b>Histamine Antiserum Microtiter Wells</b> in the strip holder (Histamine Antiserum Microtiter Wells which are not needed should be stored in the foil with desiccant).
<b>5.</b>	Transfer <b>100 µl</b> of the <b>samples</b> from the Running Buffer Tubes into the corresponding <b>Histamine Antiserum Microtiter Wells</b> . Mix the samples with the antiserum by pipetting it up and down 5 times (foaming has no negative influence on the assay performance).
<b>6.</b>	Incubate for 5 minutes (increased incubation times for up to 10 minutes have no negative influence on the assay performance).
<b>7.</b>	Place the <b>Histamine Dipsticks</b> (blue area, arrow pointing down) onto <b>the bottom</b> of the <b>Histamine Antiserum Microtiter Wells</b> and incubate for 5 minutes.
<b>8.</b>	<b>Remove</b> the dipstick from the wells and cut off the blue area with a pair of scissors.
<b>9.</b>	Before inspecting the sample dipsticks, the LED blue light lamp has to be controlled by use of the <b>Histamine Dipstick Control</b> (BA 50-3050): by illuminating the Histamine Dipstick Control with the LED blue light lamp two bands should be visible. If not, replace the batteries of the LED blue light lamp.
<b>10.</b>	Put on the orange glasses and <b>inspect</b> the sample dipsticks <b>visually</b> through illumination with the LED blue light lamp (the distance of the LED blue light lamp to the dipstick should be 1-2 cm).

## 7. Results and Interpretation

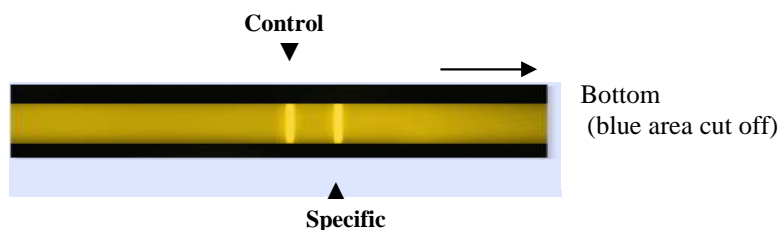
The visual inspection of the dipsticks with the LED blue light lamp can give the following results: 2 lines or 1 line\*).

The Histamine Dipstick Control can be used to allocate the lines: the lower line corresponds to the specific line, the upper to the control line (please refer to Figure 1). First one should check if the control line exists: this is the main proof that the assay worked well.

The results have to be interpreted the following way:

- 2 lines:** the histamine concentration of the sample is below the effective cut-off; the sample has **passed**.
- 1 line:** *Control line visible:* the histamine concentration of the sample is above the effective cut-off; the sample has **failed** and further investigations have to be performed (e.g. quantification of Histamine with a highly-specific ELISA such as BA 10-3100).

**Figure 1:** Typical example for a sample showing 2 lines:  
The sample has passed



\*) If no line is visible please check the functionality of the LED blue light lamp first. If the lamp is working well, the performance of the assay was incorrect and the problem has to be solved by trouble-shooting. In that case the sample has to be re-assayed.

## 8. Warranty

This test kit was produced according to the latest developments in technology and subjected to stringent internal and external quality control checks. Any alteration of the test kit or the test procedure as well as the usage of reagents from different charges may have a negative influence on the test results and are therefore not covered by warranty. The manufacturer is not liable for damages incurred in transit.

### Customer Service











For customer assistance and technical support please call: +49 5921 8197 0 or +49 5921 8197 131 or e-mail us: [support@ldn.de](mailto:support@ldn.de)

### Training

In contrast to other available methods for the screening of Histamine in wine, the performance of the HistaSure™ is quite easy to learn and can be run by each quality control personnel.

Nonetheless LDN offers training sessions in its own laboratories or on-site. Please contact us to arrange a testified demonstration.

## Used symbols:

	Contains sufficient for <n> tests		Manufacturer		Storage temperature
	Catalogue number		Batch code		Expiry date
	Caution		Content		Consult instructions for use
	For research use only!				