

# Calibration plate • Instructions for use •

REF: RLA216, RLA216.10

## Intended purpose

The device is a calibrator, which is used for calibrating the Histareader™ instrument.

## Summary and explanation

The Calibration plate is used in combination with Pipes buffer (RLR006 / RLA706) and the RLA700 *Reagent kit* or the corresponding separate reagents (Art. no. RLA702, RLA703, RLA708)

The Calibration plate facilitates adjustment of the fluorometric detection range to obtain optimal sensitivity.

## Intended user

The Calibration plate is for professional (health care) use only.

## Composition

A1											
150	150	150	0	0	10	20	30	50	100		
150	150	150	0	0	10	20	30	50	100		
150	150	150	0	0	10	20	30	50	100		
150	150	150	0	0	10	20	30	50	100		
150	150	150	0	0	10	20	30	50	100		
150	150	150	0	0	10	20	30	50	100		
150	150	150	0	0	10	20	30	50	100		
150	150	150	0	0	10	20	30	50	100		
COL1	COL2	COL3	COL4	COL5	COL6	COL7	COL8	COL9	COL10	COL11	COL12

The concentrations (ng/mL) are expressed as histamine dihydrochloride ( $C_5H_9N_3, 2 HCl$ ), which is equivalent to the physiological histamine salt. A multiplication factor of 0.6 must be employed when converting from salt ( $C_5H_9N_3, 2 HCl$ ) to base ( $C_5H_9N_3$ ).

## Variants

Product name	Article no	UDI code	Pack size
Calibraton plate	RLA216	05744003280070	1
Calibraton plate	RLA216.10	05744003280287	10

## Material & Equipment required but not provided

Standard laboratory pipettes.  
 Distilled H<sub>2</sub>O or Pipes buffer (RLR006, RLA706)  
 Plate washer or multi-channel pipette  
 Reagents for assay completion (RLA700 Reagent kit)  
 Histareader™501 or Histareader™501-1

# Calibration plate • Instructions for use •

REF: RLA216, RLA216.10

## Test procedure

1. Pipet 50 µL distilled H<sub>2</sub>O or Pipes buffer into each well (col 1-10).
2. Incubate for 15-30 min at 20-37 °C.
3. Tap the H<sub>2</sub>O or Pipes buffer out (into waste / sink)
4. Wash the plate with distilled water 3 times. If washing manually (multi-channel pipette) gently tap the plate upside down after each wash.
5. Gently tap the plate free of any residual water on highly absorbent paper towel after finishing the washing procedure.
6. Prepare 'Coupling reagent' in accordance with IFU for 'OPA disc' or 'RLA700 Reagent kit' procedure. (Please note a 1-hour preparation time for the reagent)
7. Coupling procedure:
  - I. Pipet 75 µL Coupling reagent into each well.
  - II. Reaction time: 10 min. NOTE: it is important to time the reaction precisely.
  - III. Pipet 75 µL Stop reagent into each well
  - IV. Follow separate IFU for Histareader™ 501/501-1 for detection and adjustment of the fluorometric detection range.
  - V. Check that data comply with the given requirements and log the data in accordance with good laboratory practice

## Test principle

Precoated histamine dilutions, as displayed in the 'Composition' section above, are released from the solid phase, and thus presented in a liquid phase, at high pH by adding the coupling reagent. The fluorochrome 'OPA' (o-phthaldialdehyde) reacts with histamine and forms highly fluorescent derivatives.

## Storage and handling conditions

Store at +2 - +8 °C until labelled expiry.

## Warnings and precautions

The RLA216 Calibration plate itself is a non-hazardous product.

For in vitro diagnostic use only  
For laboratory professional use

Contact the manufacturer if discoloration or other signs of contamination appear.  
According to the EU regulation 2017/746, users shall report any serious incident related to device to the manufacturer and the competent authority of the EU Member State in which the user is established.

Please refer to Instructions for use for OPA disc or RLA700 reagent kit for reagent warnings and precautions.

## Waste disposal

The RLA216 plate itself is a non-hazardous waste.  
Please refer to Instructions for use for OPA disc or RLA700 reagent kit for reagent disposal.

# Calibration plate • Instructions for use •












REF: RLA216, RLA216.10

## Manufacturer

RefLab ApS  
Kanalholmen 1, 2 th.  
DK 2650 Hvidovre  
Denmark

Phone: +45 7070 2345  
[info@reflab.dk](mailto:info@reflab.dk)  
[www.reflab.dk](http://www.reflab.dk)

## Symbols

	CE mark
	For in vitro diagnostic use
	Catalog number
	Batch code
	Unique device identifier
	Date of manufacture
	Expiry date
	Storage temperature
	Tests
	Consult instructions for use
	Manufacturer