

Calibration plate • Instructions for use •

REF: RLA216, RLA216.10

Intended purpose

The plate is a calibrator, which is used for calibrating the Histareader instruments, which are used for performing the basophil histamine release assay (BHRA).

The RLA216 calibration plate is a BHRA-fiberplate precoated with histamine standards (0-150 ng/mL). It is used for range setting and fine adjusting of the Histareader™501 & 501-1, prior to detection of BHRA plates and panels.

For in vitro diagnostic use.

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

Storage and handling conditions

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

Material & Equipment required but not provided

Standard laboratory material & equipment
Distilled H₂O or Pipes buffer
Plate washer or multi-channel pipette

Calibration plate • Instructions for use •

REF: RLA216, RLA216.10

Reagent for assay completion.
Histareader™501 or Histareader™501-1

Test procedure

1. Pipet 50 µL distilled H₂O or Pipes buffer into each well (col 1-10).
2. Incubate for 15-30 min at 20-37 °C.
3. Tap the H₂O 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. Perform coupling procedure. See Instructions for use for OPA disc or RLA700 reagent kit
7. Refer to Histareader Instructions for use for detailed calibration procedure and calibration parameters.

Test principle

Refer to separately provided BHRA / HR-Test method-specific work instructions.

Warnings

The RLA216 plate itself is a non-hazardous product.

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

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.












Manufacturer

RefLab ApS
Copenhagen Bioscience Park 'COBIS'
Ole Maaloes Vej 3
DK 2200 Copenhagen N
Denmark

Calibration plate • Instructions for use •

REF: RLA216, RLA216.10

Symbols

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