



Free Sales Certificate

The Danish Medicines Agency hereby certifies that the medical devices specified in the attached list are manufactured by:

RefLab ApS
Ole Maaløes Vej 3
2200 Copenhagen N
Denmark

Medical devices which are CE marked in conformity with Directive 98/79/EEC meet the essential requirements for safety and performance. They may therefore be manufactured and marketed in Denmark and exported without any approval from the Danish Medicines Agency.



Valid from: 21 November 2021
Valid Until: 21 November 2023

Freja Bauch
Freja Bauch



PANEL, Test Kit

RLA211-CM	Customer material Test Kit
RLA212	Inhalation panel Test Kit
RLA213	Food panel Test Kit
RLA214	Derma panel Test Kit
RLA222	Inhalation Asia Panel Test Kit
RLA223	Food Asia Panel Test Kit
RLA800	Customer Designed Panel Test Kit
RLA5-CIU	HR-Urticaria Test Kit

PANEL, Plate only

RLA211-CM-SPEC	Customer material. Box of 15
RLA212-SPEC	Inhalation panel. Box of 15
RLA213-SPEC	Food panel. Box of 15
RLA214-SPEC	Derma panel. Box of 15
RLA222-SPEC	Inhalation Asia Panel. Box of 15
RLA223-SPEC	Food Asia Panel. Box of 15
RLA800-SPEC	Customer Designed Panel. Box of 15

STRIP (single allergen) Test Kit

RLA5-XXX*	Single Allergen Strip Test Kit (5)
RLA5-CM	Customer Material Strip Test Kit (5)

*) According to Strip Allergen List

STRIP (single allergen), Strip only

RLA12-XXX*	Single Allergen Strips (Frame of 12)
RLA12-CM	Customer Material Strips (Frame of 12)

*) According to Strip Allergen List

REAGENTS for Histareader detection

RLA700	HR-Test Reagent Kit
RLA216	Histareader Calibration Kit

HISTAREADERS

RLA501	HISTAREADER™S01
RLA501-1	HISTAREADER™S01-1

SUPPLEMENTARY REAGENTS

RLA500	Preparation vials, 5 pcs
RLA701	Stripping buffer, 100 mL
RLA702	Diluent, 1000 mL
RLA703	Stop solution, 1000 mL
RLA704	HClO ₄ 7 %, 10 x 10 mL
RLA705	Detergent for Histareader, 100 mL

SUPPLEMENTARY REAGENTS

RLA706	Pipes buffer, 1000 mL
RLR006	Pipes buffer, 100 mL
RLA708	OPA Discs 25 mg, 20 pcs
RLA709	Acidious Clean for Histareader, 100 mL
RLR007W	Wash buffer, 200 mL
RLR007S	Wash buffer concentrate, 10 mL

STRIP ALLERGEN LIST

F069 Almond	F043 Lamb	F071Walnut	M009 Alternaria alternata
F054 Banana	F047 Mackerel	F013 Wheat flour	M035 Aspergillus fumigatus
F067 Barley	F081 Melon	P026 Alder	M077 Aspergillus versicolor
F041 Beef	F011 Milk	P028 Ash	M022 Baker's yeast
F079 Blue mussel	F063 Oat	P025 Hazel	M037 Botrytis cinerea
F070 Brazil nut	F080 Octopus	P085 Japanese hop	M024 Candida albicans
F065 Buckwheat	F052 Orange	P003 Mugwort	M010 Cladosporium herbarum
F056 Carrot	F015 Peanut	P100 Platanus acerifolia	M007 Derm pteronyssinus
F019 Celery	F060 Pepper	P083 Ragweed	M008 Derm farinae
F044 Chicken	F045 Plaice	P001 Silver birch	M038 Penicillium expansum
F072 Cocoa	F042 Pork	P002 Timothy grass	M039 Penicillium chrysogenum
F016 Cod Fish	F057 Potato	E006 Cat epithelia	M021 Pityrosporum ovale
F066 Corn	F068 Rice	E082 Cockroach	M040 Trichoderma viride
F048 Crab	F064 Rye	E005 Dog epithelia	V073 Bee venom
F012 Egg white	F078 Salmon	E033 Guinea pig epithelia	V074 Wasp venom
F059 Green bean	F017 Shrimp	E032 Hamster epithelia	O075 Latex
F061 Green pea	F018 Soybean	E004 Horse epithelia	
F014 Hazelnut	F053 Strawberry	E031 Rabbit epithelia	
F046 Herring	F058 Tomato	E030 Rat epithelia	
F020 Kiwi	F049 Tuna		

