



Ministerio de Salud
Secretaría de Calidad en Salud
A.N.M.A.T.

DECLARACIÓN DE CONFORMIDAD

En nombre y representación de la firma ETC Internacional S.A., declaramos bajo juramento, en los términos previstos por la Disposición ANMAT N° 2198/22, que los Productos Médicos para Diagnóstico de Uso In-Vitro cuyos datos identificatorios y demás características se detallan a continuación, CUMPLEN los requisitos técnicos previstos en el Anexo I de la Disposición ANMAT N° 2674/99, conservándose la documentación respaldatoria a disposición de las autoridades en el domicilio de la empresa.

Número de PM:

1215-24

Nombre técnico del producto:

17027

Nombre comercial:

ImmunoCAP - Analisis para alergen

Modelos:

14-4451-01 ImmunoCAP Allergen c6, Amoxicilloyl
14-5336-01 ImmunoCAP Allergen c7, Cefaclor
14-5266-01 ImmunoCAP Allergen c202, Suxamethonium (Succinylcholine)
14-4896-01 ImmunoCAP Allergen d201, House dust mite
14-4905-01 ImmunoCAP Allergen e94, Allergen component rFel d 1 Cat
14-4913-01 ImmunoCAP Allergen e200, Canary bird droppings
14-5030-01 ImmunoCAP Rare Allergen e203, Mink epithelium
14-5009-01 ImmunoCAP Allergen e204, Allergen component nBos d 6 BSA, Cow
14-5011-01 ImmunoCAP Rare Allergen e208, Chinchilla epithelium
14-5015-01 ImmunoCAP Rare Allergen e209, Gerbil epithelium

14-5013-01 ImmunoCAP Rare Allergen e214, Finch feathers
14-5032-01 ImmunoCAP Allergen e215, Pigeon feathers
14-5157-01 ImmunoCAP Rare Allergen e217, Ferret epithelium
14-5229-01 ImmunoCAP Allergen e218, Chicken droppings
14-5230-01 ImmunoCAP Rare Allergen e219, Chicken serum proteins
14-5240-01 ImmunoCAP Allergen e220, Allergen component rFel d 2 Cat serum albumin
14-5241-01 ImmunoCAP Allergen e221, Allergen component nCan f 3 Dog serum albumin
14-4209-01 ImmunoCAP Allergen f27, Beef
14-4459-01 ImmunoCAP Allergen f55, Common millet
14-4185-01 ImmunoCAP Allergen f83, Chicken
14-4297-01 ImmunoCAP Allergen f86, Parsley
14-4329-01 ImmunoCAP Allergen f89, Mustard
14-4914-01 ImmunoCAP Allergen f124, Spelt wheat
14-5019-01 ImmunoCAP Allergen f206, Mackerel
14-5097-01 ImmunoCAP Allergen f224, Poppy seed
14-5102-01 ImmunoCAP Allergen f227, Sugar-beet seed
14-5106-01 ImmunoCAP Allergen f234, Vanilla
14-5114-01 ImmunoCAP Allergen f236, Cow's milk whey
14-5142-01 ImmnuCAP Allergen f258, Squid
14-5075-01 ImmunoCAP Allergen f263, Green pepper (unripe seed)
14-5083-01 ImmunoCAP Rare Allergen f266, Mace
14-5058-01 ImmunoCAP Rare Allergen f267, Cardamon
14-5064-01 ImmunoCAP Allergen f268, Clove
14-5048-01 ImmunoCAP Allergen f269, Basil
14-5072-01 ImmunoCAP Allergen f270, Ginger
14-5044-01 ImmunoCAP Allergen f271, Anise
14-5103-01 ImmunoCAP Allergen f272, Tarragon
14-5105-01 ImmunoCAP Allergen f273, Thyme
14-5084-01 ImmunoCAP Allergen f274, Marjoram
14-5082-01 ImmunoCAP Rare Allergen f275, Lovage
14-5069-01 ImmunoCAP Rare Allergen f277, Dill
14-5049-01 ImmunoCAP Allergen f278, Bay leaf
14-5062-01 ImmunoCAP Allergen f279, Chilipepper
14-4817-01 ImmunoCAP Allergen f280, Black pepper
14-5067-01 ImmunoCAP Allergen f281, Curry (Santa Maria)
14-5088-01 ImmunoCAP Allergen f283, Oregano
14-4818-01 ImmunoCAP Allergen f284, Turkey meat
14-5109-01 ImmunoCAP Rare Allergen f286, Mare's milk
14-5139-01 ImmunoCAP Rare Allergen f298, Tragacanth
14-5144-01 ImmunoCAP Allergen f300, Goat milk
14-5158-01 ImmunoCAP Allergen f303, Halibut
14-5159-01 ImmunoCAP Allergen f304, Langust (spiny lobster)
14-5194-01 ImmunoCAP Allergen f307, Hake
14-5195-01 ImmunoCAP Allergen f308, Sardine (Pilchard)
14-5196-01 ImmunoCAP Allergen f309, Chick pea
14-5205-01 ImmunoCAP Allergen f312, Swordfish
14-5209-01 ImmunoCAP Allergen f313, Anchovy
14-5210-01 ImmunoCAP Allergen f314, Snail
14-5211-01 ImmunoCAP Allergen f315, Green bean
14-5214-01 ImmunoCAP Allergen f317, Coriander
14-5219-01 ImmunoCAP Allergen f320, Crayfish

14-5222-01 ImmunoCAP Allergen f323, Allergen component nGal d 3 Conalbumin, Egg
 12-5237-01 ImmunoCAP Allergen f325, Sheep milk
 14-5238-01 ImmunoCAP Rare Allergen f326, Sheep whey
 14-5249-01 ImmunoCAP Rare Allergen f332, Mint
 14-5250-01 ImmunoCAP Rare Allergen f333, Linseed
 14-5254-01 ImmunoCAP Allergen f335, Lupine seed
 14-5256-01 ImmunoCAP Allergen f337, Sole
 14-5279-01 ImmunoCAP Allergen f342, Olive
 14-5280-01 ImmunoCAP Allergen f343, Raspberry
 14-5282-01 ImmunoCAP Allergen f345, Macadamia nut
 14-5283-01 ImmunoCAP Allergen f346, Abalone
 14-5284-01 ImmunoCAP Rare Allergen f347, Quinoa
 14-5341-01 ImmunoCAP Allergen f352, Allergen component rAra h 8 pr-10, Peanut
 14-5340-01 ImmunoCAP Allergen f353, Allergen component rGly m 4 PR-10, Soy
 14-5343-01 ImmunoCAP Allergen f354, Allergen component rBer e 1, Brazil nut
 14-5344-01 ImmunoCAP Allergen f355, Allergen component rCyp c 1 Carp
 14-4954-01 ImmunoCAP Allergen f416, Allergen component rTri a 19 Omega-5 Gliadin, Wheat
 14-5179-01 ImmunoCAP Allergen fx17, Fruits
 14-5206-01 ImmunoCAP Allergen fx21, Fruits
 14-5212-01 ImmunoCAP Allergen fx22, Nuts
 14-4856-01 ImmunoCAP Allergen fx24, Food
 14-4857-01 ImmunoCAP Allergen fx25, Food
 14-4894-01 ImmunoCAP Allergen fx26, Food
 14-4893-01 ImmunoCAP Allergen fx27, Food
 14-4892-01 ImmunoCAP Allergen fx28, Food
 14-4915-01 ImmunoCAP Allergen fx29, Fruits
 14-4916-01 ImmunoCAP Allergen fx30, Fruits
 14-4917-01 ImmunoCAP Allergen fx31, Fruits
 14-5234-01 ImmunoCAP Allergen g205, Allergen component rPhl p 1 Timothy
 14-5235-01 ImmunoCAP Allergen g206, Allergen component rPhl p 2 Timothy
 14-5288-01 ImmunoCAP Allergen g208, Allergen component nPhl p 4 Timothy
 14-5289-01 ImmunoCAP Allergen g209, Allergen component rPhl p 6 Timothy
 14-5290-01 ImmunoCAP Allergen g210, Allergen component rPhl p 7 Timothy
 14-5291-01 ImmunoCAP Allergen g211, Allergen component rPhl p 11 Timothy
 14-5292-01 ImmunoCAP Allergen g212, Allergen component rPhl p 12 Profilin, Timothy
 14-5312-01 ImmunoCAP Allergen g213, Allergen component rPhl p 1, rPhl p 5b Timothy
 14-5313-01 ImmunoCAP Allergen g214, Allergen component rPhl P 7, rPhl p 12 Timothy
 14-5200-01 ImmunoCAP Allergen gx6, Grass pollen
 14-4527-01 ImmunoCAP Allergen i77, European paper wasp venom
 14-5151-01 ImmunoCAP Rare Allergen i203, Mediterranean flour moth
 14-5207-01 ImmunoCAP Allergen i204, Horse fly
 14-5270-01 ImmunoCAP Allergen i205, Bumble bee
 14-5274-01 ImmunoCAP Allergen i206, Cockroach, American
 14-4511-01 ImmunoCAP Allergen k82, Latex
 14-5127-01 ImmunoCAP Allergen k202, Allergen component nAna c 2 Bromelin, Pineapple
 14-5128-01 ImmunoCAP Allergen k208, Allergen component nGal d 4 Lysozyme, Egg
 14-5258-01 ImmunoCAP Rare Allergen k213, Allergen component nSus s Pepsin, Swine
 14-5286-01 ImmunoCAP Rare Allergen k214, Bougainvillea
 14-5324-01 ImmunoCAP Rare Allergen k215, Allergen component rHev b 1 Latex
 14-5326-01 ImmunoCAP Rare Allergen k217, Allergen component rHev b 3 Latex
 14-5327-01 ImmunoCAP Allergen k218, Allergen component rHev b 5 Latex

14-5329-01 ImmunoCAP Rare Allergen k220, Allergen component rHev b 6.02 Latex
 14-5330-01 ImmunoCAP Rare Allergen k221, Allergen component rHev b 8 Profilin, Latex
 14-5333-01 ImmunoCAP Rare Allergen k224, Allergen component rHev b 11 Latex
 14-4259-01 ImmunoCAP Allergen m8, *Setomelanomma rostrata* (*Helminthosporium halodes*)
 14-4920-01 ImmunoCAP Allergen m36, *Aspergillus terreus*
 14-4889-01 ImmunoCAP Allergen m80, Staphylococcal enterotoxin A
 14-4890-01 ImmunoCAP Allergen m81, Staphylococcal enterotoxin B
 14-5029-01 ImmunoCAP Rare Allergen m201, *Tilletia tritici* (*Ustilago tritici*)
 14-5028-01 ImmunoCAP Rare Allergen m204, *Ulocladium chartarum*
 14-4831-01 ImmunoCAP Allergen m207, *Aspergillus niger*
 14-5202-01 ImmunoCAP Allergen m208, *Chaetomium globosum*
 14-5203-01 ImmunoCAP Allergen m209, *Penicillium glabrum*
 14-5224-01 ImmunoCAP Allergen m211, *Trichophyton ment.* var *interdigitale*
 14-5293-01 ImmunoCAP Allergen m218, Allergen component rAsp f 1 *Aspergillus fumigatus*
 14-5294-01 ImmunoCAP Allergen m219, Allergen component rAsp f 2 *Aspergillus fumigatus*
 14-5295-01 ImmunoCAP Allergen m220, Allergen component rAsp f 3 *Aspergillus fumigatus*
 14-5296-01 ImmunoCAP Allergen m221, Allergen component rAsp f 4 *Aspergillus fumigatus*
 14-5297-01 ImmunoCAP Allergen m222, Allergen component r Asp f 6 *Aspergillus fumigatus*
 14-5298-01 ImmunoCAP Allergen m223, Staphylococcal enterotoxin C
 14-5301-01 ImmunoCAP Rare Allergen m226, Staphylococcal enterotoxin TSST
 14-5321-01 ImmunoCAP Allergen m227, *Malassezia* spp
 14-5342-01 ImmunoCAP Allergen m228, *Aspergillus flavus*
 14-5346-01 ImmunoCAP Allergen m229, Allergen component rAlt a 1, *Alternaria alternata*
 14-4921-01 ImmunoCAP Allergen mx4, Moulds
 14-4476-01 ImmunoCAP Allergen o1, Cotton, crude fibers
 14-4371-01 ImmunoCAP Allergen o70, Seminal Fluid
 14-5251-01 ImmunoCAP Rare Allergen o211, Mealworm
 14-5320-01 ImmunoCAP o212, Streptavidin
 14-5339-01 ImmunoCAP Allergen o214, Allergen component MUXF3 CCD, Bromelian
 14-5193-01 ImmunoCAP Allergen rx1, Regional
 14-5184-01 ImmunoCAP Allergen rx2, Regional
 14-5198-01 ImmunoCAP Allergen rx3, Regional
 14-5246-01 ImmunoCAP Allergen rx5, Regional
 14-5322-01 ImmunoCAP Allergen rx6, Regional
 14-5323-01 ImmunoCAP Allergen rx7, Regional
 14-4147-01 ImmunoCAP Allergen t4, Hazel
 14-4924-01 ImmunoCAP Allergen t25, European ash
 14-5005-01 ImmunoCAP Allergen t201, Spruce
 14-5003-01 ImmunoCAP Allergen t203, Horse chestnut
 14-5002-01 ImmunoCAP Allergen t205, Elder
 14-5140-01 ImmunoCAP Allergen t206, Chestnut
 14-5146-01 ImmunoCAP Rare Allergen t207, Douglas fir
 14-5148-01 ImmunoCAP Allergen t209, Horn beam
 14-5155-01 ImmunoCAP Rare Allergen t211, Sweet gum
 14-5185-01 ImmunoCAP Allergen t212, Cedar
 14-5208-01 ImmunoCAP Allergen t213, Pine
 14-5218-01 ImmunoCAP Rare Allergen t214, Date
 14-5225-01 ImmunoCAP Allergen t215, Allergen component rBet v 1 PR-10, Birch
 14-5226-01 ImmunoCAP Allergen t216, Allergen component rBet v 2 Profilin, Birch
 14-5167-01 ImmunoCAP Rare Allergen t217, Peppertree
 14-5252-01 ImmunoCAP Allergen t218, Virginia live oak

14-5287-01 ImmunoCAP Allergen t220, Allergen component rBet v 4 Birch
 14-5310-01 ImmunoCAP Allergen t221, Allergen component rBet v 2, rBet v 4 Birch
 14-5309-01 ImmunoCAP Allergen t222, Arizona cypress
 14-5308-01 ImmunoCAP Rare Allergen t223, Oil palm
 14-5705-01 ImmunoCAP Allergen t224, Allergen Component rOle e 1, Olive
 14-4993-01 ImmunoCAP Allergen t227, Allergen Component nOle e 7 LTP, Olive
 14-4999-01 ImmunoCAP Allergen t240, Allergen Component rOle e 9, Olive
 14-5183-01 ImmunoCAP Allergen tx10, Tree pollen
 14-4103-01 ImmunoCAP Allergen w6, Mugwort
 14-4452-01 ImmunoCAP Allergen w22, Japanese Hop
 14-5024-01 ImmunoCAP Allergen w203, Rape
 14-5025-01 ImmunoCAP Allergen w204, Sunflower
 14-5020-01 ImmunoCAP Allergen w206, Camomile
 14-5022-01 ImmunoCAP Rare Allergen w207, Lupin
 14-5311-01 ImmunoCAP Allergen w211, Allergen component rPar j 2 LTP, Wall pellitory

Presentaciones:

10 determinaciones para los códigos:

14-5336-01, 14-5266-01, 14-4896-01, 14-4905-01, 14-4913-01, 14-5030-01, 14-5011-01, 14-5015-01, 14-5013-01, 14-5032-01, 14-5157-01; 14-5229-01, 14-5230-01, 14-5240-01, 14-5241-01, 14-4297-01, 14-4329-01, 14-4914-01, 14-5019-01, 14-5097-01, 14-5102-01, 14-5106-01, 14-5114-01, 14-5142-01, 14-5075-01, 14-5083-01, 14-5058-01, 14-5064-01, 14-5048-01, 14-5072-01, 14-5044-01, 14-5103-01, 14-5105-01, 14-5084-01, 14-5082-01, 14-5069-01, 14-5049-01, 14-5062-01, 14-4817-01, 14-5067-01, 14-5088-01, 14-4818-01, 14-5109-01, 14-5139-01, 14-5144-01, 14-5158-01, 14-5159-01, 14-5194-01, 14-5195-01, 14-5196-01, 14-5205-01, 14-5209-01, 14-5210-01, 14-5211-01, 14-5214-01, 14-5219-01, 14-5222-01, 14-5237-01, 14-5238-01, 14-5249-01, 14-5250-01, 14-5254-01, 14-5256-01, 14-5279-01, 14-5280-01, 14-5282-01, 14-5283-01, 14-5284-01, 14-5341-01, 14-5340-01, 14-5343-01, 14-5344-01, 14-4954-01, 14-5179-01, 14-5206-01, 14-5212-01, 14-4856-01, 14-4857-01, 14-4894-01, 14-4893-01, 14-4892-01, 14-4915-01, 14-4916-01, 14-4917-01, 14-5234-01, 14-5235-01, 14-5288-01, 14-5289-01, 14-5290-01, 14-5291-01, 14-5292-01, 14-5312-01, 14-5313-01, 14-5200-01, 14-4527-01, 14-5151-01, 14-5207-01, 14-5270-01, 14-5274-01, 14-4511-01, 14-5127-01, 14-5128-01, 14-5258-01, 14-5286-01, 14-5324-01, 14-5326-01, 14-5327-01, 14-5329-01, 14-5330-01, 14-5333-01, 14-4920-01, 14-4889-01, 14-4890-01, 14-5029-01, 14-5028-01, 14-4831-01, 14-5202-01, 14-5203-01, 14-5224-01, 14-5293-01, 14-5294-01, 14-5295-01, 14-5296-01, 14-5297-01, 14-5298-01, 14-5301-01, 14-5301-01, 14-5321-01, 14-5342-01, 14-5346-01, 14-4921-01, 14-4371-01, 14-5251-01, 14-5320-01, 14-5339-01, 14-5193-01, 14-5184-01, 14-5198-01, 14-5246-01, 14-5322-01, 14-5323-01, 14-4924-01, 14-5005-01, 14-5003-01, 14-5002-01, 14-5140-01, 14-5146-01, 14-5148-01, 14-5155-01, 14-5185-01, 14-5208-01, 14-5218-01, 14-5225-01, 14-5226-01, 14-5167-01, 14-5252-01, 14-5287-01, 14-5310-01, 14-5309-01, 14-5308-01, 14-5705-01, 14-4993-01, 14-4999-01, 14-5183-01, 14-5024-01, 14-5025-01, 14-5020-01, 14-5022-01, 14-5311-01

16 determinaciones para los códigos:

14-4451-01, 14-4209-01, 14-4185-01, 14-4459-01, 14-4259-01, 14-4476-01, 14-4147-01, 14-4103-01, 14-4452-01

Uso previsto:

ImmunoCAP Specific IgE es un sistema de ensayo in vitro para la medición cuantitativa de la IgE específica de los alérgenos en el suero o plasma humanos. Está destinado al uso diagnóstico in vitro como ayuda en el diagnóstico clínico de trastornos alérgicos mediados por IgE, junto con

otros hallazgos clínicos, y debe utilizarse en laboratorios clínicos. ImmunoCAP Specific IgE debe utilizarse con los instrumentos Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 o Phadia 5000.

Período de vida útil:

12 meses para los códigos:

14-5266-01, 14-4451-01, 14-5336-01, 14-5058-01, 14-5067-01, 14-5139-01, 14-5258-01, 14-5286-01, 14-5320-01, 14-5193-01, 14-5184-01, 14-5198-01, 14-5246-01, 14-5322-01, 14-5323-01, 14-5146-01

24 meses para los códigos

14-4896-01, 14-4905-01, 14-4913-01, 14-5030-01, 14-5009-01, 14-5011-01, 14-5015-01, 14-5013-01, 14-5032-01, 14-5157-01, 14-5229-01, 14-5230-01, 14-5240-01, 14-5241-01, 14-4209-01, 14-4459-01, 14-4185-01, 14-4297-01, 14-4329-01, 14-4914-01, 14-5019-01, 14-5097-01, 14-5102-01, 14-5106-01, 14-5114-01, 14-5142-01, 14-5075-01, 14-5083-01, 14-5064-01, 14-5048-01, 14-5072-01, 14-5044-01, 14-5103-01, 14-5105-01, 14-5084-01, 14-5082-01, 14-5069-01, 14-5049-01, 14-5062-01, 14-4817-01, 14-5088-01, 14-4818-01, 14-5109-01, 14-5144-01, 14-5158-01, 14-5159-01, 14-5194-01, 14-5195-01, 14-5196-01, 14-5205-01, 14-5209-01, 14-5210-01, 14-5211-01, 14-5214-01, 14-5219-01, 14-5222-01, 14-5237-01, 14-5238-01, 14-5249-01, 14-5250-01, 14-5254-01, 14-5256-01, 14-5279-01, 14-5280-01, 14-5282-01, 14-5283-01, 14-5284-01, 14-5341-01, 14-5340-01, 14-5343-01, 14-5344-01, 14-4954-01, 14-5179-01, 14-5206-01, 14-5212-01, 14-4856-01, 14-4857-01, 14-4894-01, 14-4893-01, 14-4892-01, 14-4915-01, 14-4916-01, 14-4917-01, 14-5234-01, 14-5235-01, 14-5288-01, 14-5289-01, 14-5290-01, 14-5291-01, 14-5292-01, 14-5312-01, 14-5313-01, 14-5200-01, 14-4527-01, 14-5151-01, 14-5207-01, 14-5270-01, 14-5274-01, 14-4511-01, 14-5127-01, 14-5128-01, 14-5324-01, 14-5326-01, 14-5327-01, 14-5329-01, 14-5330-01, 14-5333-01, 14-4259-01, 14-4920-01, 14-4889-01, 14-4890-01, 14-5029-01, 14-5028-01, 14-4831-01, 14-5202-01, 14-5203-01, 14-5224-01, 14-5293-01, 14-5294-01, 14-5295-01, 14-5296-01, 14-5297-01, 14-5298-01, 14-5301-01, 14-5321-01, 14-5342-01, 14-5346-01, 14-4921-01, 14-4476-01, 14-4371-01, 14-5251-01, 14-5339-01, 14-4147-01, 14-4924-01, 14-5005-01, 14-5003-01, 14-5002-01, 14-5140-01, 14-5148-01, 14-5155-01, 14-5185-01, 14-5208-01, 14-5218-01, 14-5225-01, 14-5226-01, 14-5167-01, 14-5252-01, 14-5287-01, 14-5310-01, 14-5309-01, 14-5308-01, 14-5705-01, 14-4993-01, 14-4999-01, 14-5183-01, 14-4103-01, 14-4452-01, 14-5024-01, 14-5025-01, 14-5020-01, 14-5022-01, 14-5311-01

Para todos los códigos: 2 a 8°C

Nombre y domicilio del fabricante:

Phadia AB, Rapskatan 7P, P.O.Box 6460, SE-751 37 Uppsala, Sweeden

Categoría:

Uso profesional exclusivo

LUGAR Y FECHA: Argentina, 17 mayo 2023



RAVEGLIA Mariela Andrea
CUIL 23264116514
Responsable Legal
Firma y Sello



GONZÁLEZ Daniela Alejandra
CUIL 27324884500
Responsable Técnico
Firma y Sello



Ministerio de Salud
Secretaria de Calidad en Salud
A.N.M.A.T.

La presente DECLARACIÓN DE CONFORMIDAD ha sido emitida de acuerdo con las previsiones de la Disposición ANMAT N° 2198/22, quedando autorizada la comercialización del/los producto/s identificados en la misma.

Inscripta en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) bajo el número PM **1215-24**

Ciudad de Buenos Aires a los días 17 mayo 2023

Dirección de Evaluación de Registro

Firma y Sello



ARANDA Mariela Ines
CUIL 23240846934



BODNAR Andrea Veronica
CUIL 27254978472

Instituto Nacional de Productos Médicos

Firma y Sello



RIZZO Marcela Claudia
CUIL 27169736184



La validez del presente documento deberá verificarse mediante el código QR.

Tramitada por Expediente N°: 1-0047-3110-002433-23-9