



INTERNATIONAL

Empowered with Tecan ●

IBL International GmbH, Flughafenstraße 52a, 22335 Hamburg

Hamburg, 2018-08-08

Field Corrective Action 30115845 / IgG4 Food Screen 280 ELISA

Dear Customer,

This notice is to inform you about an error in the instruction for use provided with the product IgG4 Food Screen 280 ELISA :

Catalogue-No.	Lot-No.	Expiry date
30115845	SG417033	2017-07-31
30115845	S-G4.17135	2017-10-31
30115845	S-G4.17475	2018-11-30
30115845	S-G4.17481	2018-11-30
30115845	S-G4.18153	2018-11-30
30115845	S-G4.18221	2019-07-31

Description of the Problem and Hazards Associated with Failure:

IBL detected an issue in the instructions for use stating incorrectly allergen positions on micro-titer plate C. Although all listed allergens are identical, the position of the majority of the allergens are not correctly indicated in the instructions for use; and therefore, do not match the actual location on the plate.

Our records show that your laboratory received one or more of the affected lots.

As indicated in the instructions for use the allergen classification scheme has no established clinical significance and is only to provide the physician a relative ranking of the IgG4 response. The results themselves should not be the only reason for any therapeutic consequences. They have to be correlated to other clinical observations and diagnostic tests.

Investigation Results and Root Cause

A corrective and preventive action (CAPA) Investigation has been opened. The CAPA ensures corrective and preventive actions are implemented to prevent recurrence. The root cause is due to an error during creation of instructions for use. IBL takes this issue very seriously and as a result is informing customers of the issue with the affected lots.

Risk to Health

Since IgG4 is not used in isolation but is correlated with clinical history and presentation, as well as additional diagnostic laboratory testing, the health risk is minor. The IgG4 determination is used in case where classical diagnostics show no evidence. Please follow your laboratory

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Deutsche Bank
Account: 577 073 000
BLZ: 200 700 00
IBAN: DE91 2007 0000 0577 0730 00
BIC (Swift): DEUTDE33XXX

Steuernummer: 49/733/00453
Umsatzsteuer ID: DE261098089



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standard operational procedures to review all existing patient data and correct results with the new provided allergen location sheet for plate C.

Required Action to be taken by end-users:

Please immediately examine your stock for the affected lot(s). If you have any kits with the above lot numbers, promptly add the correct allergen location sheet plate C that is attached to this letter. Reevaluate all prior data obtained with the concerned lot with the corrected plate C. Additional measurements are not required.

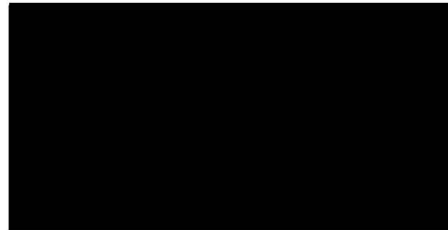
Please confirm the quantity of stock corrected with the new allergen location sheet plate C and the re-evaluation of already obtained patient data.

Please contact IBL International by returning the enclosed response form by either fax or email as soon as possible for our records.

We apologize for this issue and if you have any questions, please contact your local Tecan Helpdesk or IBL.

With kind regards

IBL International GmbH



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30115845 / IgG4 Food Screen 280 ELISA / Plate C / Corrected Allergen Position

	1	2	3	4	5	6	7	8	9	10	11	12
A	Hen egg white <i>Gallus gallus domesticus</i> f1	Sole <i>Solea solea</i> f174	Black salsify <i>Scorzonera hispanica</i> f195	Black currant <i>Ribes nigrum</i> f217	Turnip f304	Chocolate white f348	Goose meat <i>Anser anser domesticus</i> f57	Curd cheese <i>Bos primigenius f. taurus</i> f810	Paraguay tea <i>Ilex paraguariensis</i> f849	Mozzarella, cow <i>Bos primigenius f. taurus</i> f875	Litchi <i>Litchi chinensis</i> f943	Pectin le024
B	Honey mel f124	Haddock <i>Melanogrammus aeglefinus</i> f175	Savoy cabbage <i>Brassica oleracea conivar. capitata var. sabauda</i> f196	molasses <i>Beta vulgaris</i> f223	Lime <i>Citrus limon</i> f306	Chocolate dark <i>Theobroma cacao</i> f349	Ovalbumine <i>Gallus gallus domesticus</i> f67	Pistachio nut <i>Pistacia vera</i> f818	Sea buckthorn juice <i>Hippophae rhamnoides</i> f850	Halibut <i>Hippoglossus hippoglossus</i> f902	Carambole <i>Averrhoa carambola</i> f945	Carrageenan le026
C	Peppermint tea <i>Mentha piperita</i> f126	Squid <i>Loligo spp.</i> f176	Parmesan <i>Bos primigenius f. taurus</i> f201	Cow whey <i>Bos primigenius f. taurus</i> f236	White radish <i>Raphanus sativus</i> f310	Aloe vera <i>Aloe vera</i> f406	Ovomucoid <i>Gallus gallus domesticus</i> f68	Kamut wheat <i>Triticum polanicum</i> f831	Mirabelle <i>Prunus domestica subsp. Syriaca</i> f851	Unripe spelt grain <i>Triticum spelta</i> f912	Passion fruit <i>Passiflora edulis</i> f948	Anis seed <i>Pimpinella anisum</i> s1
D	Grapevine snail <i>Helix spec.</i> f128	Oyster <i>Ostrea edulis</i> f177	Sheep milk cheese <i>Ovis aries</i> f202	northern prawn <i>Pandalus borealis</i> f241	Water melon <i>Citrullus lanatus</i> f329	Caviar black <i>Adspensidae</i> f415	Red wine <i>Vino</i> f681	Mallow <i>Malva sivestris</i> f833	Parsnip <i>Pastinaca sativa</i> f854	tragacanth <i>Astragalus</i> f920	Bamboo shoots <i>Bambusoideae</i> f951	Summer savory <i>Satureja hortensis</i> s12
E	Olive, black <i>Olea europaea</i> f130	Crayfish <i>Procambarus clarkii</i> f178	Goat milk cheese <i>Capra hircus</i> f203	Tarragon <i>Artemisia dracunculoides</i> f272	Saffron <i>Crocus sativus</i> f331	Bear`s garlic <i>Allium ursinum</i> f471	White wine <i>Vino</i> f682	Stinging nettle <i>Urtica dioica</i> f838	Lemon balm <i>Melissa officinalis</i> f858	Hare <i>Lepus europaeus</i> f931	Sweet potato <i>Ipomoea batatas</i> f953	Chervil <i>Anthriscus cerefolium</i> s16
F	Poppy seed <i>Papaver somniferum</i> f165	Oyster mushroom <i>Pleurotus ostreatus</i> f180	Yoghurt <i>Bos primigenius f. taurus</i> f205	Mare`s milk <i>Equus caballus</i> f286	Chocolate <i>Theobroma cacao</i> f342	Shallote <i>Allium ascalonicum</i> f481	Spiny lobster <i>Palinurus elephas</i> f71	Verbena <i>Aloysia citriodora</i> f845	Cream <i>Bos primigenius f. taurus</i> f863	Kelp <i>Saccharina japonica</i> f936	Liquorice <i>Glycyrrhiza glabra</i> f964	Chili pepper <i>Capiscum frutescens</i> s17
G	Horse meat <i>Equus caballus</i> f169	Red cabbage <i>Brassica oleracea capitata</i> f189	Rhubarb <i>Rheum rhabarbarum</i> f212	Red kidney bean <i>Phaseolus vulgaris</i> f287	Macadamia nut <i>Macademia ternifolia</i> f345	Pomegranate s <i>Punica granatum</i> f491	Hen egg yolk <i>Gallus gallus domesticus</i> f75	Boletus <i>Boletus edulis</i> f846	Honeydew melon <i>Cucumis melo var. inodorus</i> f87	Guava <i>Psidium guajava</i> f940	Jalapeno pepper fx163	Lovage <i>Levisticum officinale</i> s18
H	Anchovy <i>Engraulis encrasicolus</i> f172	Edam cheese <i>Bos primigenius f. taurus</i> f190	Raisin <i>Vitis vinifera</i> f213	Romanescu broccoli f303	Quince <i>Cydonia oblonga</i> f347	Eel <i>Anguilla anguilla</i> f55	Pikeperch <i>Sander lucioperca</i> f803	Rooibos tea <i>Aspalathus linearis</i> f847	Cheese, Emmentaler type <i>Bos primigenius f. taurus</i> f873	Persimon (kaki fruit, sharon) <i>Diospyros kaki</i> f942	Gelatine <i>Sus scrofa f. domestica</i> le020	Capers <i>Capparis spinosa</i> s800

Yellow marked / new position of the allergen / Re-evaluation of the data required.

Green marked / no change of allergen position / no action required



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RESPONSE FORM – IgG4 Food Screen 280 ELISA

To:	IBL International GmbH
Fax:	+49 (0) 40 53 28 91- 938
Email:	Nastya.yeska@tecan.com
Re:	Field Corrective Action IgG4 Food Screen 280 ELISA

Customer name:	
Contact person:	
Phone number:	

Please check ALL appropriate box(es)

- I have read and understood the instructions in August 2018 letter.
- I have checked my stock and added the correct plate C layout.
- I have informed my end-users of this Field Corrective Action

Please check ALL boxes to describe your business

- | | |
|--|---|
| <input type="checkbox"/> Wholesale / Distributor | <input type="checkbox"/> Re-packer |
| <input type="checkbox"/> Hospital / Medical Facility | <input type="checkbox"/> Medical Laboratory |
| <input type="checkbox"/> University Laboratory | <input type="checkbox"/> Research Institute |

Please confirm:

Product Description, Reference	Lot Number	Quantity of product on stock	Quantity of re-evaluated patient data (plate C)
IgG4 Food Screen 280 ELISA, 30115845	SG417033	Expired already.	
IgG4 Food Screen 280 ELISA, 30115845	S-G4.17135	Expired already.	
IgG4 Food Screen 280 ELISA, 30115845	S-G4.17475		
IgG4 Food Screen 280 ELISA, 30115845	S-G4.17481		
IgG4 Food Screen 280 ELISA, 30115845	S-G4.18153		
IgG4 Food Screen 280 ELISA, 30115845	S-G4.18221		

PLEASE RESPOND BY AUGUST 31st, 2018.

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