

PRODUCT INFORMATION

IA3109 / IA3112

2024EC

The reconstituted stability for Immunoassay Premium Plus Level 1 - lot 2024EC for **Free PSA and Total PSA** is **2 days, when stored at +2°C to +8°C**.

Free PSA and Total PSA are stable for 28 days when frozen once and stored at –20°C.

CCS6934

IMMUNOASSAY PREMIUM PLUS - LEVEL I (IA PREMIUM PLUS I)

CAT. NO. IA3109

GTIN: 05055273207255

SIZE: 12 x 5 ml

CAT. NO. IA3112

GTIN: 05055273207286

SIZE: 4 x 5 ml

LOT NO. 2024EC

EXPIRY: 2023-11-28

INTENDED USE

This product is intended for *in vitro* diagnostic use, as assayed quality control material to monitor the accuracy and reproducibility of analytes listed in the package insert.

This device is for prescription use only.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 7 days at +2°C to +8°C, if kept capped in original container and free from contamination, or 4 weeks frozen once at -20°C. Free PSA and Total PSA are stable for 2 days when stored at +2°C to +8°C. Thyroglobulin should be tested within 4 hours of reconstitution when stored at +2°C to +8°C, or within 2 weeks when stored at -20°C.

Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components. If bacterial contamination is suspected, the vial should be discarded and a fresh vial reconstituted.

PREPARATION

Immunoassay Premium Plus is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised serum with exactly 5 ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Immunoassay Premium Plus - Level I: 12 x 5 ml Tri-Level: 4 x 5 ml

MATERIAL REQUIRED BUT NOT PROVIDED

Volumetric pipette

VALUE ASSIGNMENT

Each batch of Immunoassay Premium Plus is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories, using a unique statistical analysis. Average values should normally fall within the listed ranges for analytes in the instruments specified in this product insert. However, variations may be caused by instrument reagents and laboratory technique. Therefore, the range produced herein should only be considered as a reference and it is recommended that each laboratory establish its own mean and acceptable ranges.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

超级免疫复合质控品- 水平 I (IA PREMIUM PLUS I)

货号: IA3I09	GTIN: 05055273207255	规格: 12 x 5 ml
货号: IA3I12	GTIN: 05055273207286	规格: 4 x 5 ml
批号: 2024EC	效期: 2023-11-28	

预期使用

本产品适用于体外诊断，作为定值质控监测靶值表中所列项目的准确性和重复性。

本产品说明书仅作参考

安全预防措施和警告

本产品仅用于体外诊断。禁止用口吸取。参照实验室对试剂的常规预防措施进行处理。

本产品采用人源基质，对所有人源均进行了 HIV (HIV1、HIV2) 抗体、肝炎 B 表面抗原 (HbsAg) 和肝炎 C 病毒 (HCV) 抗体的测试，发现均呈阴性。检测这些项目所采用的方法均经 FDA 认证。

但是没有方法能够完全保证避免传染物质，因此该产品和所有的病人样品均应当按照能够传播疾病的样品小心处理。

本产品可提供 Health and Safety Data Sheets。

保存和稳定性

开瓶后: 冷藏 2~8°C 保存。复溶后的血清如果保存在原始瓶中，并且无污染，可在 2~8°C 保存 7 天，或在 -20°C。

游离 PSA 和总 PSA 冷藏保存于 +2°C 到 +8°C，稳定两天，保存 4 周，只可冻融一次。甲状腺球蛋白 (TG) 复溶后如果在 2~8°C 保存，要在 4 小时内检测；若 -20°C 保存，则须在 2 周内检测。

每次使用吸取所需用量，测试剩余的样品不可倒回原瓶。

未开瓶: 冷藏 2~8 °C 可保存至效期末。

复溶后的血清在受到细菌污染后，会导致多组分稳定性的下降。如果怀疑细菌污染，需将该瓶样品抛弃，重新复溶一瓶新的血清。

预处理

超级免疫复合质控品为冻干粉。

1. 小心往瓶中准确加入 5 ml 蒸馏水，在 15~25 °C 的条件下复溶，盖上瓶盖，使用前放置 30 分钟。轻轻翻转瓶子，确保内容物完全溶解；不要振荡，避免气泡的产生。

2. 参照分析仪的质控说明部分。

3. 未使用的产品请冷藏或冷冻，再次使用前，确保样品充分混合均匀。

产品提供

Immunoassay Premium Plus - Level I: 12 x 5 ml Tri-Level: 4 x 5 ml

需要但未提供物质

量杯 移液管

赋值

每批质控血清都要送到一定数量的参考实验室，这些实验室通过独特的统计分析方法得到一致的结果进行赋值。平均质控值通常会在本产品靶值表中所列相应仪器范围内，但是，仪器试剂和检测系统引起的差异不可避免，所以本靶值表单仅供参考，建议每个实验室建立自己的参考靶值和可接受范围。

如果无法查询到方法学，请联系 Randox Laboratories - Technical Services, Northern Ireland, 电话: +44 (0) 28 9445 1070 或者通过邮件反馈至 Technical.Services@randox.com.

26 May 21 pl

IMMUNOASSAY PREMIUM PLUS - LEVEL 1 (IA PREMIUM PLUS 1)

Cat. No. IA3109 / IA3112		Lot No. 2024EC	Size: 12 x 5ml / 4 x 5ml		Expiry: 2023-11-28
Analyte	unit	Target	Range		methods
			low	high	
Alpha-fetoprotein	ng/ml	11.23	8.19	14.26	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	ng/ml	10.94	7.99	13.90	Mindray CL-900i
CA 15-3	U/ml	11.91	8.70	15.13	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	U/ml	11.73	8.56	14.89	Mindray CL-900i
CA 19-9	U/ml	18.53	13.53	23.54	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	U/ml	19.68	14.37	24.99	Mindray CL-900i
CA125	U/ml	11.50	8.39	14.60	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	U/ml	11.39	8.31	14.46	Mindray CL-900i
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	3.93	2.87	4.98	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	ng/ml = µg/l	3.95	2.88	5.02	Mindray CL-900i
Cortisol	µg/dL	7.12	4.98	9.26	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	µg/dL	6.96	4.87	9.05	Mindray CL-900i
DHEA-S	µg/dl	103.26	70.22	136.30	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	µg/dl	101.23	68.84	133.63	Mindray CL-900i
E2	pg/ml	43.34	31.64	55.04	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	pg/ml	39.34	28.72	49.96	Mindray CL-900i
E3	ng/ml	0.78	0.57	0.99	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	ng/ml	0.72	0.53	0.92	Mindray CL-900i
Ferritin	ng/ml = µg/l	12.03	8.42	15.64	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	ng/ml = µg/l	12.12	8.48	15.75	Mindray CL-900i
Folate	ng/ml	3.90	2.65	5.15	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	ng/ml	3.69	2.51	4.87	Mindray CL-900i
Insulin	µIU/ml	1.76	1.19	2.32	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	µIU/ml	1.76	1.20	2.33	Mindray CL-900i
LH	mIU/ml	4.18	3.05	5.30	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	mIU/ml	4.29	3.13	5.45	Mindray CL-900i
Progesterone	ng/ml	1.21	0.82	1.60	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	ng/ml	1.14	0.77	1.50	Mindray CL-900i
Prolactin	ng/ml	7.65	5.58	9.71	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	ng/ml	7.84	5.72	9.96	Mindray CL-900i
PSA Free	ng/ml = µg/l	1.18	0.86	1.50	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	ng/ml = µg/l	1.22	0.89	1.55	Mindray CL-900i
PSA Total	ng/ml = µg/l	1.60	1.09	2.11	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	ng/ml = µg/l	1.64	1.11	2.16	Mindray CL-900i
Testosterone	ng/ml	0.74	0.54	0.94	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	ng/ml	0.73	0.53	0.93	Mindray CL-900i
Tg	ng/ml	0.38	0.26	0.50	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	ng/ml	0.40	0.27	0.53	Mindray CL-900i
Total Beta hCG	mIU/ml=IU/l	25.29	18.46	32.12	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	mIU/ml=IU/l	25.85	18.87	32.83	Mindray CL-900i
VB12	pg/mL	251.83	183.83	319.82	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i
	pg/mL	278.55	167.13	389.97	Mindray CL-900i