

IMMUNOASSAY PREMIUM PLUS - LEVEL 2 (IA PREMIUM PLUS 2)

CAT. NO. IA3110	GTIN: 05055273207262	SIZE 12 x 5 ml
CAT. NO. IA3112	GTIN: 05055273207286	SIZE 4 x 5 ml
LOT NO. 2124EC	EXPIRY: 2024-10-28	

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.

The Abbott Architect CA19-9 assay utilises an antibody/antigen system based on the 1116-NA-19-9 antibody. There are reports that the formulation employed with this system may return elevated concentrations, when compared to other methods for samples expressing high levels of 1116-NA-19-9 reactive determinants.

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. C-Peptide is stable for 1 day 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.

No frozen stability claim is made for C-Peptide. 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.

- 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.
- Refer to the Control section of the individual analyser application.
- Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Immunoassay Premium Plus - Level 2: 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. Parathyroid Hormone (PTH) is present in the control, but no claim is made for the expected value or stability of this analyte.

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

EC	REP
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Rev. 26 May '22 me

免疫质控品- 水平 2 (IA PREMIUM PLUS2)

货号.	IA3110	GTIN:	05055273207262	规格:	12 x 5 ml
货号.	IA3112	GTIN:	05055273207286	规格:	4 x 5 ml
批号.	2124EC	失效日期:	2024-10-28		

预期用途

本产品适用于体外诊断，作为质控品监测靶值表中所列项目的准确性和重复性。

本产品仅供处方使用。

安全预防与警告

本产品仅用于体外诊断。不要用嘴吸移液管。采用规定的处理实验室试剂的标准预防措施。

本产品采用人源物质，对所有人源物质均进行过人类免疫缺陷病毒（HIV1、HIV2）抗体检测、乙肝表面抗原（HbsAg）检测和丙型肝炎病毒（HCV）抗体的测试，结果为非反应性。这些检测是采用 FDA 批准的方法进行的。

然而，因为没有方法能够完全保证无传染因子，该材料和所有病人样本都应将其视为能传播传染病，需进行谨慎操作并做相应处置。Abbott Architect CA19-9 检测仪采用基于 1116-NA-19-9 抗体的抗体/抗原系统。有报道称，该系统采用的制剂可能返回升高的浓度，当与其他表达高水平 1116-NA-19-9 反应决定因素样品的方法相比时。

如有需求，可提供 Health and Safety Data Sheets..

储存和稳定性

开启后：冷藏(2°C ~ 8°C)。如果密封保存在原始容器中，在不受污染的情况下，复溶血清在 2 ~ 8°C 能稳定 7 天，或在 -20°C 能稳定 7 天。C-肽在 2 ~ 8°C 能稳定 1 天。甲状腺球蛋白保存在 2°C ~ 8°C 时，应在复溶 4 小时内检测，或保存 -20°C 时应在 2 周内进行检测。

没有 C-肽的冷冻稳定性声明。只应取出需要量的试剂。使用后，剩余试剂不应放回原始试剂瓶中。

未开封：冷藏保存(2°C ~ 8°C)。在单个试剂瓶上印出的有效期内保持稳定。

复溶血清细菌污染会导致许多成分的稳定性降低。如果疑似细菌污染，应丢弃试剂瓶，复溶一瓶新的。

制备

免疫质控品以冻干品形式提供。

- 在 15°C ~ 25°C 用精确量出的 5mL 蒸馏水小心复溶每小瓶冻干血清。盖上小瓶，让其静置。30 分钟后再使用。轻轻旋转小瓶，确保冻干物质完全溶化。避免形成泡沫。不要摇晃小瓶。
- 适用于单个分析仪应用程序的质控部分。
- 任何不使用的材料都冷藏。在重新使用前，充分混合内容物。

提供的产品

免疫质控品- Level 2: 12 x 5 ml Tri-Level: 4 x 5 ml

所需未提供的产品

移液吸管

赋值

每批免疫质控品试剂盒提交到若干外部参考实验室，使用独特的统计分析由这些实验室得到的一致结果赋值。平均值通常应在本产品说明书中列出的指定仪器中分析物的范围内。然而，可能会由仪器试剂和实验室技术引起结果的变化。因此，此处显示的范围仅应视为参考，并建议每个实验室建立自己的平均值和可接受的范围。质控中出现了甲状旁腺激素（PTH），但没有该分析物的预期值或稳定性的声明。

如果某种方法不可用，请联系 Randox Laboratories – 技术支持，北爱尔兰，电话: +44 (0) 28 9445 1070 或电子邮箱

Technical.Services@randox.com.

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免疫质控品- 水平2 (IA PREMIUM PLUS 2)

货号: IA3110 / IA3112 批号: 2124EC 规格: 12 x 5ml / 4 x 5ml 失效日期: 2024-10-28

分析物	单位	靶值	范围		方法
			低值	高值	
Alpha-fetoprotein	ng/ml	52.42	38.27	66.58	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
甲胎蛋白	ng/ml	53.28	38.89	67.66	Mindray CL-900i
CA 19-9	U/ml	55.90	38.01	73.79	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
糖类抗原19-9	U/ml	60.32	41.02	79.63	Mindray CL-900i
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	20.65	15.07	26.22	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
癌胚抗原	ng/ml = µg/l	21.19	15.47	26.91	Mindray CL-900i
C-Peptide	ng/mL	6.57	4.79	8.34	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
C-肽	ng/mL	6.70	4.89	8.51	Mindray CL-900i
DHEA-S	µg/dl	596.9	405.9	787.94	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
脱氢表雄酮	µg/dl	567.3 6	385.8 1	748.92	Mindray CL-900i
E2	pg/ml	255.0	173.4	336.71	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
雌二醇	pg/ml	262.7 5	178.6 7	346.83	Mindray CL-900i
E3	ng/ml	2.57	1.87	3.26	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
雌三醇	ng/ml	2.47	1.81	3.14	Mindray CL-900i
Ferritin	ng/ml = µg/l	82.78	60.43	105.13	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
铁蛋白	ng/ml = µg/l	85.68	62.55	108.82	Mindray CL-900i
Folate	ng/ml	14.67	9.98	19.37	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
叶酸	ng/ml	15.63	10.63	20.64	Mindray CL-900i
FSH	mIU/mL	43.89	32.04	55.74	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
卵泡刺激素	mIU/mL	44.12	32.21	56.04	Mindray CL-900i
Insulin	µIU/ml	11.51	7.83	15.20	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
胰岛素	µIU/ml	12.84	8.73	16.95	Mindray CL-900i
LH	mIU/ml	39.80	29.05	50.54	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
促黄体生成素	mIU/ml	40.81	29.79	51.83	Mindray CL-900i
Progesterone	ng/ml	13.79	10.06	17.51	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
孕酮	ng/ml	13.08	9.55	16.61	Mindray CL-900i
Prolactin	ng/ml	30.45	22.23	38.67	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
催乳激素	ng/ml	30.95	22.60	39.31	Mindray CL-900i
PSA Free	ng/ml = µg/l	11.43	7.77	15.09	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
游离PSA	ng/ml = µg/l	11.65	7.92	15.38	Mindray CL-900i
PSA Total	ng/ml = µg/l	13.01	9.49	16.52	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
总PSA	ng/ml = µg/l	13.53	9.88	17.18	Mindray CL-900i
Testosterone (version 1.0)	ng/ml	5.86	3.99	7.74	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
睾酮 (1.0版本)	ng/ml	6.10	4.15	8.05	Mindray CL-900i
Testosterone (version 1.5)	ng/ml	4.84	3.53	6.15	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
睾酮 (1.5版本)	ng/ml	4.71	3.44	5.99	Mindray CL-900i
Tg	ng/ml	12.68	8.62	16.74	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
甲状腺球蛋白	ng/ml	12.82	8.72	16.93	Mindray CL-900i
VB12	pg/mL	614.1	417.6	810.72	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-
维生素B12	pg/mL	663.1 8	450.9 6	875.39	Mindray CL-900i

免疫质控品- 水平2 (IA PREMIUM PLUS 2)

货号: IA3110 / IA3112 批号: 2124EC 规格: 12 x 5ml / 4 x 5ml 失效日期: 2024-10-28

分析物	单位	靶值	范围		方法
			低值	高值	
TSH	μIU/mL	3.32	2.42	4.21	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-8000i
促甲状腺激素	μIU/mL	3.40	2.48	4.31	Mindray CL-900i
FT3	pg/mL	8.29	6.05	10.53	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-8000i
游离T3	pg/mL	8.11	5.92	10.29	Mindray CL-900i
FT4 (version 1.0)	ng/dL	2.25	1.64	2.86	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-8000i
游离T4 (1.0版本)	ng/dL	2.13	1.55	2.71	Mindray CL-900i
FT4 (version 1.5)	ng/dL	2.97	2.17	3.78	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-8000i
游离T4 (1.5版本)	ng/dL	2.92	2.13	3.71	Mindray CL-900i
T3	ng/mL	2.14	1.46	2.83	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-8000i
三碘甲状腺原氨酸	ng/mL	2.10	1.43	2.78	Mindray CL-900i
T4 (version 1.0)	μg/dL	9.70	6.60	12.80	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-8000i
四碘甲状腺原氨酸 (1.0版本)	μg/dL	9.60	6.53	12.67	Mindray CL-900i
T4 (version 1.5)	μg/dL	8.87	6.03	11.71	Mindray CL-1000i,CL-1200i,CL-2000i,CL-6000i,CL-8000i
四碘甲状腺原氨酸 (1.5版本)	μg/dL	8.58	5.83	11.33	Mindray CL-900i