2013 年 T_4 檢驗準確度 (Accuracy) 測試結果報告

送檢批號：AQ2013-06　　調查期間：2013 年 06 月 03～10 日　　參加單位數：21

檢驗單位代碼	確診醫院代碼	檢體方法編碼	檢體試劑編碼	Sample S1				Sample S2			
				(μg/dL)	D [1]	Z [2]	Da% [3]	(μg/dL)	D [1]	Z [2]	Da% [3]
RH01b	RH01	2	5	9.1	-0.4	-0.5	-18%	4.6	-0.4	-1.0	-33%
RH07b	RH07	2	3	9.8	0.3	0.4	13%	5.5	0.5	1.3	42%
RH15	RH15	2	8	8.7	-0.8	-1.1	-35%	5.0	0.0	0.0	0%
CL009	CL009	2	4	9.3	-0.2	-0.3	-9%	5.1	0.1	0.2	8%
CL010	CL010	2	6	11.5	2.0	2.6	88%	4.9	-0.1	-0.2	-8%
CL012	CL012	2	3	10.0	0.5	0.7	22%	3.5	-1.5	-3.8	-125%
CL014a	CL014	2	8	8.7	-0.8	-1.1	-35%	5.1	0.1	0.2	8%
CL015	CL015	2	5	9.2	-0.3	-0.4	-13%	4.6	-0.4	-1.0	-33%
Median of RIA Group				9.3				5.0			
Range of RIA Group				8.7 - 11.5				3.5 – 5.5			
Robust average[4] of RIA Group				9.4 (n = 8)				4.9 (n = 8)			
Robust SD[4] of RIA Group				0.72				0.46			
CV of RIA Group				7.7%				9.4%			
RH01a	RH01	4	9	9.4	-0.1	-0.1	-4%	5.5	0.5	1.3	42%
RH02c	RH02	4	1	7.3	-2.2	-2.9	-96%	4.1	-0.9	-2.3	-75%
RH06	RH06	4	9	9.3	-0.2	-0.3	-9%	5.0	0.0	0.0	0%
RH07a	RH07	4	2	8.4	-1.1	-1.4	-48%	6.8[5]	1.8	4.5	150%
RH12	RH12	4	2	8.9	-0.6	-0.8	-26%	6.3[5]	1.3	3.3	108%
RH14	RH14	4	14	8.2	-1.3	-1.7	-57%	4.8	-0.2	-0.5	-17%
RH19	RH19	4	2	8.9	-0.6	-0.8	-26%	6.8[5]	1.8	4.5	150%
RH20	RH20	4	7	9.7	0.2	0.3	9%	5.1	0.1	0.2	8%
CL005	CL005	4	9	9.1	-0.4	-0.5	-18%	5.0	0.0	0.0	0%
CL006a	CL006	4	7	10.4	0.9	1.2	39%	6.2	1.2	3.0	100%
CL008	CL008	4	1	7.3	-2.2	-2.9	-96%	4.2	-0.8	-2.0	-67%
CL011	CL011	4	13	9.1	-0.4	-0.5	-18%	5.4	0.4	1.0	33%
CL013	CL013	4	1	7.1	-2.4	-3.2	-105%	3.8	-1.2	-3.0	-100%
Median of CLIA Group				8.9				5.0			
Range of CLIA Group				7.1 – 10.4				3.8 – 6.2			
Robust average[4] of CLIA Group				8.7 (n = 13)				4.9 (n = 10, 不含 Kit 2)[5]			
Robust SD[4] of CLIA Group				1.13				0.80			
CV of CLIA Group				13.0%				16.3%			
Median of Kit 2 Labs[5]				—				6.8			
Range of Kit 2 Labs[5]				—				6.3-6.8			
Average of Kit 2 Labs[5]				—				6.6 (n = 3)			
SD of Kit 2 Labs[5]				—				0.29			
CV of Kit 2 Labs[5]				—				4.4			
Median of All Labs				9.1				5.0			
Range of All Labs				7.1 – 11.5				3.5 – 6.2			
Robust average[4] of All Labs				9.0 (n = 21)				4.9 (n = 18, 不含 Kit 2)[5]			
Robust SD[4] of All Labs				0.92				0.62			
CV of All Labs				10.2%				12.7%			
Certified target value (Xa)*(μg/dL)				**9.5**				**5.0**			
Uncertainty (Ua) *				**0.09**				**0.05**			
Target SD (σ_{Targ})[6]				**0.76**				**0.40**			

1. D = X - Xa
2. $Z_{score} = D / \sigma_{Targ}$
3. Da% (Your result from target as percentages of allowed deviation) = D/(Xa x MAD) x 100%
4. Robust results were calculated by Algorithm A according to ISO 13528:2005 and IUPAC/CITAC Guide: Selection and use of proficiency testing scheme for a limited number of participants. Pure Appl Chem 2010;82:1099 – 135.
5. This control material (human serum, off-the clot) did show different behavior than similar samples used in European surveys. The reason for this is not clear up to now. For the evaluation this was taken into consideration from the target by a separate evaluation of the collective.
6. Maximum allowable deviation (MAD) 24%, σ_{Targ} = 8% x Xa

*The Certified **Target Value** of Thyroxine in Serum was determined using Isotope dilution mass spectrometry (IDMS) reference method by an international certified reference laboratory.

The reference laboratory is signatory to the multilateral agreements of the European co-operation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC) for the mutual recognition of calibration certificates.

The uncertainty stated is the expanded uncertainty obtained by multiplying the standard uncertainty by the coverage factor *k*. At a *t*-distribution with *v(eff)* effective degrees of freedom the value of the measured lies within the assigned range of values with a probability of 95%. It has been determined in accordance with EA-4/02.

Reference:

Thienpont LM, Van Uytfanghe K, Beastall G, *et.al*. Report of the IFCC Working Group for Standardization of Thyroid Function Tests; Part 3:Total Thyroxine and Total Triiodothyronine. Clin Chem 2010; 56: 921 – 9.

	Sample S1	Sample S2
Certified Target Value* (1 nmol/L = 0.0777 μg/dL)	122.3 nmol/L (9.5 μg/dL)	64.88 nmol/L (5.0 μg/dL)
Expanded uncertainty	1.2 nmol/L (0.09 μg/dL)	0.68 nmol/L (0.05 μg/dL)
Relative expanded uncertainty	1.0%	1.0%
Coverage factor *k*	2.6	2.6
Effective degrees of freedom *v(eff)*	5	5

Method Name	Method Code	Laboratory
Radioimmunoassay (Competitive - type)	2	RH01b, RH07b, RH15, CL009, CL010, CL012, CL014a, CL015,
Chemiluminescent Immunoassay (Competitive - type)	4	RH01a, RH02c, RH06, RH07a, RH12, RH14, RH19, RH20, CL005, CL006a, CL008, CL011, CL013,

Reagent Kit	Reagent Code	Laboratory
Abbott Architect	1	CL008, CL013, RH02c,
Beckman Coulter Access	2	RH07a, RH12, RH19,
Cisbio RIA-gnost	3	CL012, RH07b,
Diasorin	4	CL009,
Immunotech	5	CL015, RH01b,
MP	6	CL010,
Siemens ADVIA Centaur	7	CL006a, RH20,
Siemens COAT-A-COUNT	8	CL014a, RH15,
Siemens Immulite 2000	9	CL005, RH01a, RH06,
Roche	13	CL011,
Johnson & Johnson ortho vitros	14	RH14,

備註：

1. 品管結果報告刊載於網際網路 <http://cht.qap.tw>
2. 若有任何問題請洽 預防醫學基金會 范美羚小姐

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備註說明 :

1. D 值 = 檢驗值 (X) 與目標值 (Xa) 之差距。 (D = X – Xa)
2. Z_{score} = 檢驗值差距 (D) 與目標標準差 (σ_{Targ}) 之比值。 ($Z_{score} = D / \sigma_{Targ}$)
3. Da% 為貴單位的檢驗值與目標值之差距,以最大允許偏差 (MAD) 的百分比表示。 D / (Xa x MAD) x 100%
4. 穩健 (Robust) 運算結果乃根據 ISO 13528:2005 及 IUPAC/CITAC 指引中的演算法 (Algorithm A) 計算所得。*(參考資料 : ISO 13528:2005 and IUPAC/CITAC Guide: Selection and use of proficiency testing scheme for a limited number of participants. Pure Appl Chem 2010;82:1099-135.)*
5. 此品管檢體 (無添加抗凝劑之人體血清) 於歐洲地區的院際品管調查結果中顯示，有明顯的特定試劑組差異，造成原因仍在調查中。因此本次測試亦考量此差異，將特定試劑組另外統計。
6. 最大允許偏差 (Maximum Allowable Deviation ; MAD) 為 24% ; 目標標準差 (σ_{Targ} ; Target SD) 為 8% x Xa

＊ 此品管檢體的 T_4 目標值為國際認證的參考實驗室使用同位素稀釋質譜分析 (Isotope dilution mass spectrometry ; IDMS) 標準參考方法標定。

該參考實驗室為歐洲認證聯盟 (European co-operation for Accreditation ; EA) 及國際實驗室認證聯盟 (International Laboratory Accreditation Cooperation ; ILAC) 認證之參考實驗室。

表列之不確定度 (uncertainty)為標準不確定度 (standard uncertainty) 乘以涵蓋因子 (coverage factor : *k*) 所得之擴充不確定度 (expanded uncertainty)。被測量 (measurand) 值在有效自由度 (*v(eff)* effective degrees of freedom) 之 t 分布 (*t*-distribution) 條件下，有 95% 的機率在標定範圍內。(依據 EA-4/02 標準測定)

參考文獻: *Thienpont LM, Van Uytfanghe K, Beastall G, et.al. Report of the IFCC Working Group for Standardization of Thyroid Function Tests; Part 3:Total Thyroxine and Total Triiodothyronine. Clin Chem 2010; 56: 921 – 9.*