

2016 年度 CHT 確診醫院第 3 次 T₄ 檢驗院際品管結果報告

送檢批號：CHT2016-03 檢體寄出日期：2016-07-11 報告回收截止日期：2016-07-18 回收份數：21

T₄ 檢驗院際品管結果：

1. 各確診醫院 T₄ 檢驗院際品管結果一覽表
4. 至本次各機構 z score 分佈圖

2. 歷次品管檢體 T₄ 檢驗值之實驗室間 CV 分佈圖
5. 至本次各機構 D% 分佈圖

3. 確診醫院 T₄ 檢驗院際品管結果分佈圖
6. 至本次各機構 SDI 分佈圖

各確診醫院 T₄ 檢驗院際品管結果一覽表

| 檢驗單位 <代碼> | 確診醫院 <代碼> | 回報 天數 | 檢驗方 法編碼 | 檢體試 劑編碼 | 檢體 S1 | | | | | | 檢體 S2 | | | | | |
|---|--------------|----------|------------|------------|--------------|------|-------|------|------|-----|--------------|------|-------|------|------|-----|
| | | | | | (µg/dL) | D | D% | z | SDI | Da% | (µg/dL) | D | D% | z | SDI | Da% |
| RH01b | RH01 | 1 | 2 | 5 | 5.4 | -0.9 | -14.3 | -1.8 | -0.2 | -60 | 6.9 | -1.1 | -13.8 | -1.7 | 0.2 | -57 |
| RH07b | RH07 | 7 | 2 | 3 | 6.3 | 0.0 | 0.0 | 0.0 | 1.5 | 0 | 7.3 | -0.7 | -8.8 | -1.1 | 0.9 | -36 |
| RH15 | RH15 | 7 | 2 | 6 | 6.1 | -0.2 | -3.2 | -0.4 | 1.1 | -13 | 7.6 | -0.4 | -5.0 | -0.6 | 1.5 | -21 |
| CL009 | CL009 | 3 | 2 | 5 | 4.9 | -1.4 | -22.2 | -2.8 | -1.1 | -93 | 6.8 | -1.2 | -15.0 | -1.9 | 0.0 | -63 |
| CL010 | CL010 | 4 | 2 | 5 | 5.3 | -1.0 | -15.9 | -2.0 | -0.4 | -67 | 6.7 | -1.3 | -16.3 | -2.0 | -0.2 | -68 |
| CL012 | CL012 | 8 | 2 | 3 | 5.7 | -0.6 | -9.5 | -1.2 | 0.4 | -40 | 6.9 | -1.1 | -13.8 | -1.7 | 0.2 | -57 |
| CL014a | CL014 | 4 | 2 | 5 | 5.3 | -1.0 | -15.9 | -2.0 | -0.4 | -67 | 6.3 | -1.7 | -21.3 | -2.7 | -0.9 | -89 |
| CL015 | CL015 | 4 | 2 | 5 | 5.2 | -1.1 | -17.5 | -2.2 | -0.6 | -73 | 6.1 | -1.9 | -23.8 | -3.0 | -1.3 | -99 |
| Median of RIA Group | | | | | 5.4 | | | | | | 6.9 | | | | | |
| Range of RIA Group | | | | | 4.9 - 6.3 | | | | | | 6.1 - 7.6 | | | | | |
| Robust mean of RIA Group | | | | | 5.5 (n = 8) | | | | | | 6.8 (n = 8) | | | | | |
| Robust SD of RIA Group | | | | | 0.54 | | | | | | 0.55 | | | | | |
| CV of RIA Group | | | | | 9.8% | | | | | | 8.1% | | | | | |
| | | | | | | | | | | | | | | | | |
| 檢驗單位 <代碼> | 確診醫院 <代碼> | 回報 天數 | 檢體方 法編碼 | 檢體試 劑編碼 | 檢體 S1 | | | | | | 檢體 S2 | | | | | |
| | | | | | (µg/dL) | D | D% | z | SDI | Da% | (µg/dL) | D | D% | z | SDI | Da% |
| RH01a | RH01 | 3 | 4 | 9 | 5.8 | -0.5 | -7.9 | -1.0 | -0.6 | -33 | 7.8 | -0.2 | -2.5 | -0.3 | 0.2 | -10 |
| RH02c | RH02 | 3 | 4 | 1 | 6.1 | -0.2 | -3.2 | -0.4 | 0.3 | -13 | 7.3 | -0.7 | -8.8 | -1.1 | -0.7 | -36 |
| RH06 | RH06 | 2 | 4 | 9 | 6.5 | 0.2 | 3.2 | 0.4 | 1.4 | 13 | 9.4 | 1.4 | 17.5 | 2.2 | 2.9 | 73 |
| RH07a | RH07 | 1 | 4 | 2 | 6.3 | 0.0 | 0.0 | 0.0 | 0.8 | 0 | 7.3 | -0.7 | -8.8 | -1.1 | -0.7 | -36 |
| RH12 | RH12 | 4 | 4 | 2 | 5.4 | -0.9 | -14.3 | -1.8 | -1.7 | -60 | 6.8 | -1.2 | -15.0 | -1.9 | -1.6 | -63 |
| RH14 | RH14 | 4 | 4 | 14 | 6.0 | -0.3 | -4.8 | -0.6 | 0.0 | -20 | 7.5 | -0.5 | -6.3 | -0.8 | -0.3 | -26 |
| RH19 | RH19 | 2 | 4 | 2 | 6.0 | -0.3 | -4.8 | -0.6 | 0.0 | -20 | 7.2 | -0.8 | -10.0 | -1.3 | -0.9 | -42 |
| RH20 | RH20 | 4 | 4 | 7 | 5.8 | -0.5 | -7.9 | -1.0 | -0.6 | -33 | 7.8 | -0.2 | -2.5 | -0.3 | 0.2 | -10 |
| CL005 | CL005 | 7 | 4 | 9 | 7.0 | 0.7 | 11.1 | 1.4 | 2.8 | 47 | 8.4 | 0.4 | 5.0 | 0.6 | 1.2 | 21 |
| CL006a | CL006 | 7 | 4 | 7 | 6.0 | -0.3 | -4.8 | -0.6 | 0.0 | -20 | 7.6 | -0.4 | -5.0 | -0.6 | -0.2 | -21 |
| CL008 | CL008 | 7 | 4 | 2 | 6.1 | -0.2 | -3.2 | -0.4 | 0.3 | -13 | 7.5 | -0.5 | -6.3 | -0.8 | -0.3 | -26 |
| CL011 | CL011 | 1 | 4 | 13 | 6.2 | -0.1 | -1.6 | -0.2 | 0.6 | -7 | 7.7 | -0.3 | -3.8 | -0.5 | 0.0 | -16 |
| CL013 | CL013 | 3 | 4 | 2 | 5.6 | -0.7 | -11.1 | -1.4 | -1.1 | -47 | 8.4 | 0.4 | 5.0 | 0.6 | 1.2 | 21 |
| Median of CLIA Group | | | | | 6.0 | | | | | | 7.6 | | | | | |
| Range of CLIA Group | | | | | 5.4 - 7.0 | | | | | | 6.8 - 9.4 | | | | | |
| Robust mean of CLIA Group | | | | | 6.0 (n = 13) | | | | | | 7.7 (n = 13) | | | | | |
| Robust SD of CLIA Group | | | | | 0.36 | | | | | | 0.58 | | | | | |
| CV of CLIA Group | | | | | 6.0% | | | | | | 7.5% | | | | | |
| | | | | | | | | | | | | | | | | |
| Median of All Labs | | | | | 6.0 | | | | | | 7.3 | | | | | |
| Range of All Labs | | | | | 4.9 - 7.0 | | | | | | 6.1 - 9.4 | | | | | |
| Robust mean of All Labs | | | | | 5.8 (n = 21) | | | | | | 7.4 (n = 21) | | | | | |
| Robust SD of All Labs | | | | | 0.50 | | | | | | 0.70 | | | | | |
| CV of All Labs | | | | | 8.6% | | | | | | 9.5% | | | | | |
| | | | | | | | | | | | | | | | | |
| Certified assigned value (X _a) (µg/dL) | | | | | 6.3 | | | | | | 8.0 | | | | | |
| Expanded uncertainty (U _a) | | | | | 0.06 | | | | | | 0.09 | | | | | |
| Relative expanded uncertainty | | | | | 1.0% | | | | | | 1.1% | | | | | |
| Coverage factor k | | | | | 2.6 | | | | | | 2.6 | | | | | |
| Effective degrees of freedom v _{eff} | | | | | 5 | | | | | | 5 | | | | | |
| SD for proficiency assessment (σ _p) | | | | | 0.50 | | | | | | 0.64 | | | | | |
| | | | | | | | | | | | | | | | | |
| 1. 設定值 (X _a) 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。 2. D 值為檢驗值 (X) 與設定值 (X _a) 之差距。【D = X - X _a 】。 3. D% 為 D 值與設定值 (X _a) 之比值，以百分比表示。【D% = (D / X _a) x 100%】。 4. z score 為檢驗值差距 (D) 與評定標準差 (σ _p) 之比值。【z score = D / σ _p 】。 5. SDI 為檢驗值 (X) 與同儕群體平均值之差距與同儕群體標準差之比值。【SDI = (X - Mean) / SD】。當 SD 值為 0 時，SDI 不予統計。 6. Da% 為 D 值與最大允許偏差值 (MAD) 之比值，以百分比表示。【Da% = D / (X _a x MAD) x 100%】。 7. Acceptable: z ≤ 2; Caution: 2 < z ≤ 3; Unsatisfactory: z > 3。 8. 檢驗方法 2: Radioimmunoassay (Competitive-type); 4: Chemiluminescent Immunoassay (Competitive-type)。 9. 平均值 (Mean) 與群體標準差 (SD) 採用穩健 (Robust) 統計方法計算 (依據 ISO 13528:2005 指引，使用 Algorithm A 演算法)。 10. 評定標準差 (σ _p) 為 8% x X _a 。 11. 最大允許偏差 (Maximum Allowable Deviation; MAD) 為 3 x (σ _p / X _a) x 100%。 | | | | | | | | | | | | | | | | |

| 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 | RH02c, |
| Beckman Coulter Access | 2 | RH07a, RH12, RH19, CL008, CL013, |
| Cisbio RIA-gnost | 3 | RH07b, CL012, |
| Immunotech | 5 | RH01b, CL009, CL010, CL014a, CL015, |
| MP | 6 | RH15, |
| Siemens ADVIA Centaur | 7 | RH20, CL006a, |
| Siemens Immulite 2000 | 9 | RH01a, RH06, CL005, |
| Roche | 13 | CL011, |
| Johnson & Johnson ortho vitros | 14 | RH14, |

[\[Home \]](#)

若有任何疑問,歡迎來電(函)聯繫或指教


財團法人預防醫學基金會
 地址：10699 台北郵政 26-624 號信箱 電話：(02) 2703-6080
 e-mail：cht@pmf.tw 傳真：(02) 2703-6070

updated：2016-07-19

Long Term Observation of CHT (T₄) EQA Survey for Confirmatory Hosp.

Survey No : CHT2016-03 T₄ (in green □△○)

- Total participants' CV result plotted T₄ against surveys

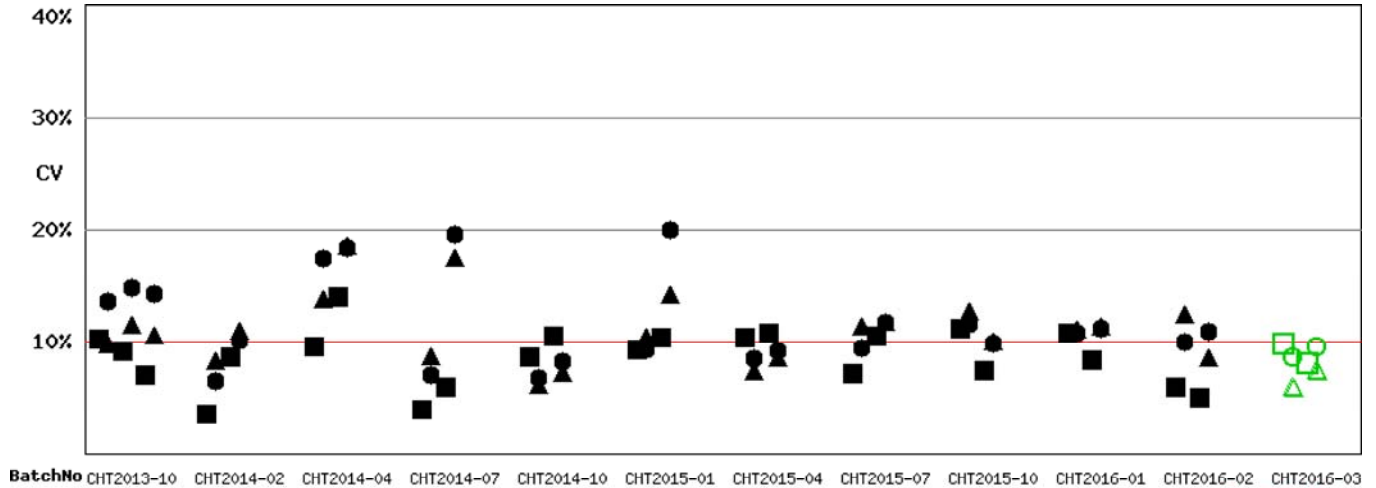


Fig T4-2.1

- Total participants' CV result plotted T₄ against concentration

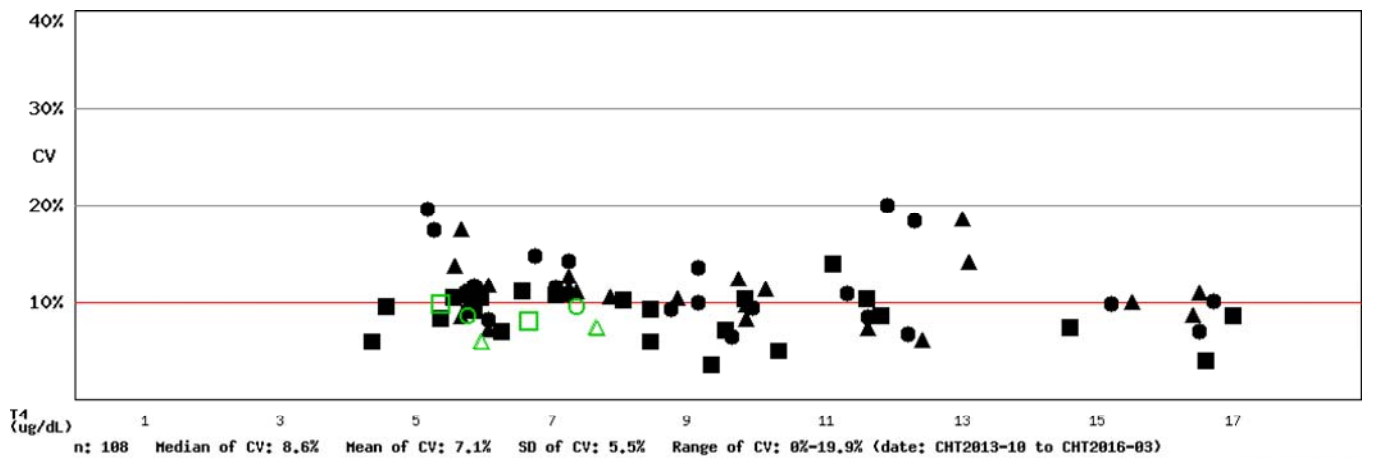


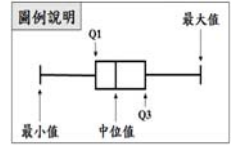
Fig T4-2.2

- 備註：1). ■□ Method 2 , ▲△ Method 4 , ●○ All Method
 2). 品管結果報告刊載於網際網路 <<http://cht.qap.tw>>
 3). 若有任何問題請洽 預防醫學基金會 范美玲小姐。
 10699 台北郵政 26-624 信箱
 電話：(02) 2703-6080 傳真：(02) 2703-6070

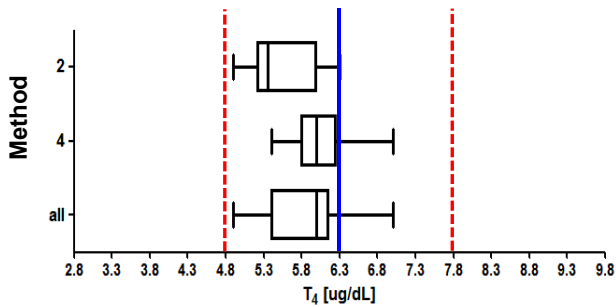
(Report generated at 2016-07-19 17:51:34)

CHT2016-03 批次 T₄ 檢驗院際品管統計分佈圖

送檢批號 : CHT2016-03 檢體寄出日期 : 2016 年 07 月 11 日 報告截止日期 : 2016 年 07 月 18 日
 回收份數(比率) : 21 份 (100%)



Sample S1

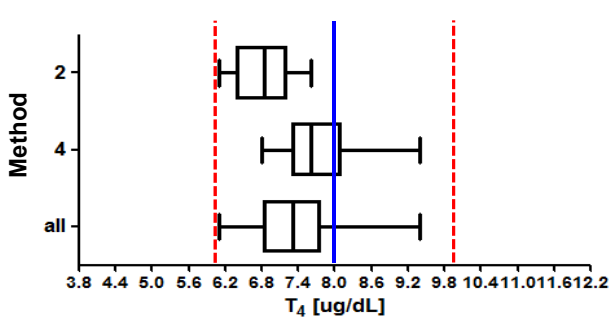


檢體 S1

| Method | 檢驗單位數 | 中位值 (Median) | 平均值 (Mean) | 標準差 (SD) | 變異係數 (CV) |
|--------|-------|--------------|------------|----------|-----------|
| 02 | 8 | 5.4 | 5.5* | 0.54* | 9.8% |
| 04 | 13 | 6.0 | 6.0* | 0.36* | 6.0% |
| All | 21 | 6.0 | 5.8* | 0.50* | 8.6% |
| AEL** | 117 | 6.2 | 6.3 | 0.82 | 13.0% |

Certified assigned value : 6.3 µg/dL

Sample S2



檢體 S2

| Method | 檢驗單位數 | 中位值 (Median) | 平均值 (Mean) | 標準差 (SD) | 變異係數 (CV) |
|--------|-------|--------------|------------|----------|-----------|
| 02 | 8 | 6.9 | 6.8* | 0.55* | 8.1% |
| 04 | 13 | 7.6 | 7.7* | 0.58* | 7.5% |
| All | 21 | 7.3 | 7.4* | 0.70* | 9.5% |
| AEL** | 112 | 7.7 | 7.7 | 0.74 | 9.6% |

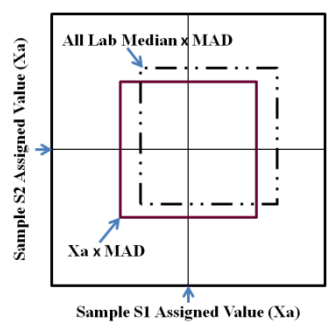
Certified assigned value : 8.0 µg/dL

* Calculated by robust method (ISO 13528 ; Algorithm A)

** All European Laboratories

* — Assigned value , - - - MAD

Youden Plot 圖例說明



- Method 02 (RIA)
- Method 04 (CLIA)
- MAD : Maximum Allowable Deviation

