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An Evaluation of the Boditech i-CHROMA™ Thyroid-Stimulating Hormone (TSH) Method: Precision and Accuracy

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Abstract

The objective of this study was to evaluate the precision and accuracy of the Boditech i-CHROMA™ TSH method. In this study, the inter and intra assay precision was < 10% and there was very good correlation (r^2>0.97) between the Boditech i-CHROMA™ TSH method and the following methods: Abbott Architect, BioMerieux Vidas TSH, BioMerieux Vidas TSH3 Ultrasensitive, Roche COBAS® 6000/8000, Siemens Centaur XP/XPT/Classic, Siemens Centaur XP/XPT/Classic 3rd generation, Siemens Centaur XP/XPT/Classic TSH3 Ultra, Siemens Dimension, Siemens Immulite, Siemens Immulite 1000, Beckman DXI 600/800 Fast TSH, Beckman DXI 600/800 Hyper TSH, Roche Elecsys, DiaSorin Liaison, Monobind Inc ELISA/CLIA, Roche COBAS® 4000/e411, Roche Modular E-170, Beckman Access/ LXi725 hyper TSH 3rd generation, Tosoh, Ortho Vitros 3600/5600/ECi. The Boditech i-CHROMA™ TSH method was negatively biased compared to the other methods, with a range between -0.6 uIU/mL and -3.25 uIU/mL with an average of -1.93 uIU/mL. In addition, the Boditech i-CHROMA™ method identified 18/18 (100%) all the samples grouped as TSH <0.4 uIU/mL and 0.4 – 4.0 uIU/mL. However, the Boditech i-CHROMA™ method was only able to identify 15/18 (83%) of the samples with >4 uIU/mL. In conclusion, the Boditech i-CHROMA™ TSH method which is a quantitative method showed very good precision and reasonable accuracy with the other laboratory methods and therefore useful for the diagnosis and management of primary hypothyroidism.

Keywords: TSH; POCT; Boditech i-CHROMA™; RIQAS

Introduction

Since the 1970s there have been technological advances in radioimmunoassays [1-3], immunometric assay [4,5] and liquid chromatography-tandem mass spectroscopy (LC-MS/MS) [6,7] for the measurement of TSH. Over the last 10 years there has been an increased demand for reliable automated TSH assays. Point-of-care testing (POCT) is carried out by the patient's bedside and allows for rapid turnover, enabling clinicians to support the timely diagnosis, monitoring and treatment of patients [8]. There are several POCT tests for TSH such as Thyrotest Rapid TSH testing kits (Wampole Laboratories, LLC), ThyroChek Thyroid Testing (Screening Devices Canada, Inc), Home Test Thyroid – TSH (Prima), Rapid Response Thyroid TSH Test Kit (BTNX Inc), ThyroScreen (Personal Diagnostics). All these tests kits use a lateral flow chromatographic immunoassay designed to identify TSH at concentrations >5 mU/L or 10 mU/L, using a finger prick sample with the result produced after 10 minutes. A positive result is indicated by a line seen in both the control and test area [9]. Most of these tests are qualitative and therefore may only be useful in detecting hypothyroidism. There are very few quantitative TSH methods such as the Boditech i-CHROMA™ TSH method on the market. This is a fluorescence immunochip TSH assay method which was developed and adapted for a lateral flow immunochromatographic technology. It was shown to have an analytical recovery of control of 97.6% within the working range and intra and inter-assay coefficient of variation (CV%) of less than 10%, with significant correlation (r^2=0.989, p<0.001) between the method and the Beckman Coulter Access 2 TSH method [10]. The aim of this article was to assess the performance (precision and accuracy) of the Boditech i-CHROMA™ TSH method.

Materials and Methods

Boditech i-CHROMA™ TSH method Principle

Boditech i-CHROMA™ TSH method uses a sandwich immuno-detection principle, such that the fluorescence-labelled detector antibody binds to the target protein in the sample. The sample is then applied onto a test strip and the fluorescence labelled antigen-antibody complex is captured by a second antibody embedded in the solid phase. The signal intensity of fluorescence of the captured complex is directly proportional to the amount of TSH present and thus allows for

the calculation of sample TSH concentration and the result is displayed on the reader as uIU/mL.

TSH Concentration estimation

The assay was performed following the manufacturer's instructions:

1. Draw 150 µL of sample (serum, plasma, control) to tube containing sample mixing buffer.
2. Add 75 µL of detection buffer to sample mixing tube.
3. Mix sample by shaking 10 times.
4. Transfer 75 µL of sample mixture into sample well on test cartridge.
5. Leave the test cartridge on flat surface at room temperature for 12 minutes.
6. Insert cartridge into cartridge holder of Boditech i-CHROMA™ reader.
7. Press 'Select' to start scanning process.
8. Read the test result on the display screen of the Boditech i-CHROMA™ reader.

Part I

The precision studies were carried out using an Internal Quality Control (IQC) provided by the manufacturer and Pooled human serum constituted in the laboratory. The inter and intra-assay coefficient of variation percent (CV%) performance of the Boditech i-CHROMA™ TSH assay system was evaluated by 3 operators. The IQC samples were reconstituted and analysed for TSH using the Boditech i-CHROMA™ TSH method on 22 separate days (operator 1) and 10 times in one day (operator 2). The mean, standard deviations (SD's) and coefficient variation percent (CV%) were estimated. In addition, pooled human serum was analysed using the Boditech i-CHROMA™ TSH method on 22 separate days (operator 3).

Part II

The accuracy studies were carried out with the external quality control assurance (EQA) samples 1-12 of cycles 38, 40 and 41 purchased from the Randox International External Quality Assessment Scheme (RIQAS). These samples (36) were analysed using the Boditech i-CHROMA™ TSH assay system method described earlier on and compared with the mean results of 20 laboratory methods that were registered with the scheme and had made more returns on more than 25 out of the 36 samples: Abbott Architect (n=36), BioMerieux Vidas TSH (n=36), BioMerieux Vidas TSH3 Ultrasensitive (n=36), Roche COBAS® 6000/8000 (n=36), Siemens Centaur XP/XPT/Classic (n=36), Siemens Centaur XP/XPT/Classic 3rd generation (n=26), Siemens Centaur XP/XPT/Classic TSH3 Ultra (n=36), Siemens Dimension (n=34), Siemens Immulite 2000/2500 (n=36), Siemens Immulite 1000 (n=36), Beckman DXI 600/800 Fast TSH (n=36), Beckman DXI 600/800 Hyper TSH (n=36), Roche Elecsys (n=36), DiaSorin Liaison (n=35), Monobind Inc ELISA/CLIA (n=36), Roche COBAS® 4000/e411 (n=36), Roche Modular E-170 (n=36), Beckman Access/LXi725 hyper TSH 3rd generation (n=36), Tosoh (n=26), Ortho Vitros 3600/5600/ECi (n=36).

The results obtained from the RIQAS samples 1-12 of cycles 38, 40 and 41 using the Boditech i-CHROMA™ TSH assay system were compared with the corresponding mean results of the other registered laboratory methods in the RIQAS and the correlation, bias, bias percent and paired T test were derived.

TSH range grouping (<0.4 uIU/mL, 0.4 – 4.0 uIU/mL) and >4 uIU/mL) was carried out on the mean results of the 17 registered laboratory methods that had made returns on all the 36 samples (RIQAS samples 1-12 of cycles 38, 40 and 41) including the results of the Boditech i-CHROMA™ method. The 16 laboratory methods were: Abbott Architect, BioMerieux Vidas TSH, BioMerieux Vidas TSH3 Ultrasensitive, Roche COBAS® 6000/8000, Siemens Centaur XP/XPT/Classic, Siemens Centaur XP/XPT/Classic TSH3 Ultra, Siemens Immulite 2000/2500, Siemens Immulite 1000, Beckman DXI 600/800 Fast TSH, Beckman DXI 600/800 Hyper TSH, Roche Elecsys, Monobind Inc ELISA/CLIA, Roche COBAS® 4000/e411, Roche Modular E-170, Beckman Access/LXi725 hyper TSH 3rd generation, Ortho Vitros 3600/5600/ECi.

Results

Part I

The Boditech i-CHROMA™ TSH results obtained by operator 1 ranged between 3.11 and 3.76 uIU/mL, with a mean of 3.45 uIU/mL, an SD of 0.08 uIU/mL and a CV% of 5.3% and by operator 2 ranged between 3.09 uIU/mL and 3.37 uIU/mL, with a mean of 3.22 uIU/mL, an SD of 0.08uIU/mL and a CV% of 2.5% using the IQC. For operator 3, the Boditech i-CHROMA™ TSH results of the pooled human serum ranged between 1.37 uIU/mL and 1.83 uIU/mL, with a mean of 1.59 uIU/mL, an SD of 0.15 uIU/mL and a CV% of 9.2% (**Table 1**).

Table 1 Mean, SD and CV% values for TSH estimations.

Variable	Internal quality control mean 3.45 uIU/mL (Operator 1) N=22	Internal quality control mean 3.45 uIU/mL (Operator 2) N=10	Pooled human sample mean TSH 1.56 uIU/mL (Operator 3) N=22
Mean	3.45	3.22	1.59

SD	0.18	0.08	0.15
CV%	5.3	2.5	9.2

Part II

Correlations: There was a very good correlation with the Boditech i-CHROMA™ TSH method and the 20 methods registered: Abbott Architect (r2=0.98), BioMerieux Vidas TSH (r2=0.97), BioMerieux Vidas TSH3 Ultrasensitive (r2=0.97), Roche COBAS® 6000/8000 (r2=0.98), Siemens Centaur XP/XPT/Classic (r2=0.97), Siemens Centaur XP/XPT/Classic 3rd generation (r2=0.98), Siemens Centaur XP/XPT/Classic TSH3 Ultra (r2=0.97), Siemens Dimension (r2=0.98), Siemens Immulite 2000/2500 (r^2=0.98), Siemens Immulite 1000 (r^2=0.98), Beckman DXI 600/800 Fast TSH (r^2=0.97), Beckman DXI 600/800 Hyper TSH (r^2=0.97), Roche Elecsys (r^2=0.98), DiaSorin Liaison (r^2=0.96), Monobind Inc ELISA/CLIA (r^2=0.98), Roche COBAS 4000/e411 (r^2=0.98), Roche Modular E-170 (r^2=0.98), Beckman Access/LXi725 hyper TSH 3rd generation (r^2=0.97), Tosoh (r^2=0.98), Ortho Vitros 3600/5600/ECi (r^2=0.98) (**Table 2**).

Bias: The Boditech i-CHROMA™ TSH method estimations were lower than all 20 methods. The method bias ranged between -0.6 uIU/mL (-13.45%) and -3.25 uIU/mL (-72.92%) with an average of -1.93 uIU/mL with the methods. The bias difference of the methods as: Abbott Architect (-0.70 uIU/mL), BioMerieux Vidas TSH (-1.81 uIU/mL), BioMerieux Vidas TSH3 Ultrasensitive (-0.94 uIU/mL), Roche COBAS® 6000/8000 (-1.22 uIU/mL), Siemens Centaur XP/XPT/Classic (-1.43 uIU/mL), Siemens Centaur XP/XPT/Classic 3rd generation (-1.04 uIU/mL), Siemens Centaur XP/XPT/Classic TSH3 Ultra (-1.15 uIU/mL), Siemens Dimension (-1.29 uIU/mL), Siemens Immulite 2000/2500 (-1.36 uIU/mL), Siemens Immulite 1000 (-1.29 uIU/mL), Beckman DXI 600/800 Fast TSH (-0.60 uIU/mL), Beckman DXI 600/800 Hyper TSH (-0.95 uIU/mL), Roche Elecsys (-1.29 uIU/mL), DiaSorin Liaison (-2.3 uIU/mL), Monobind Inc ELISA/CLIA (-1.96 uIU/mL), Roche COBAS® 4000/e411 (-1.28 uIU/mL), Roche Modular E-170 (-1.22 uIU/mL), Beckman Access/LXi725 hyper TSH 3rd generation (-1.02 uIU/mL), Tosoh (-2.11 uIU/mL), Ortho Vitros 3600/5600/ECi (-3.25 uIU/mL) (**Table 2**).

T-Tests: Paired T-Test were carried out to see if there was a significant difference between the two sets of data being measured; the Boditech i-CHROMA™ TSH method and all other tested RIQAS TSH methods. All p values were greater than 0.05, concluding that there was no significant difference between the estimations of the respective method when compared to the Boditech i-CHROMA™ TSH method (**Table 2**).

Table 2 Correlation (r^2), bias, bias% and paired T-Test for TSH methods.

Method	Correlation	Bias (uIU/mL)	Bias Difference (%)	p-value
Abbott Architect	0.98	-0.70	-15.66	0.56
BioMerieux, VIDAS TSH	0.97	-1.81	-40.67	0.18
BioMerieux VIDAS TSH3 Ultrasensitive	0.97	-0.94	-21.09	0.43
Siemens Centaur XP/XPT/Classic	0.97	-1.43	-32.13	0.26
Siemens Centaur XP/Classic 3rd Generation	0.98	-1.04	-22.93	0.48
Siemens Centaur XP/Classic TSH3-Ultra	0.98	-1.15	-25.72	0.36
Siemens Dimension	0.98	-1.29	-28.69	0.33
Siemens/DPC Immulite 2000/2500	0.98	-1.36	-30.55	0.28
Siemens/DPC Immulite 1000	0.98	-1.29	-28.88	0.30
Roche COBAS® 4000/e411	0.98	-1.28	-28.81	0.29
Roche Modular E170	0.98	-1.22	-27.46	0.31
Roche Elecsys	0.98	-1.29	-28.83	0.29
Roche COBAS® 6000/8000	0.98	-1.22	-27.48	0.31
Beckman DxI 600/800 Fast TSH	0.97	-0.6	-13.44	0.60
Beckman DXI 600/800 Hyper TSH	0.97	-0.95	-21.24	0.43
Beckman Access/LXi725 hyper TSH 3rd Generation	0.97	-1.02	-22.98	0.40
DiaSorin Liaison	0.96	-2.3	-50.29	0.09
Monobind Inc ELISA/CLIA	0.98	-1.96	-44.08	0.14

Tosoh	0.98	-2.11	-39.06	0.21
Ortho Vitros 3600/5600/ECi	0.98	-3.25	-72.91	0.05

TSH grouping: The mean results of the EQA sample 1–36 from the 16 methods including the Boditech i-CHROMA™ method were grouped into 3 groups: Group 1 with results <0.4 uIU/mL, Group 2 with results 0.4–4.0 uIU/mL (normal range) and Group 3 with results >4 uIU/mL (**Table 2**). All (17/17) of the laboratory methods including the Boditech i-CHROMA™ method identified the TSH estimations in samples 1,9,13,24,25,36 as being <0.4 uIU/mL. All (17/17) of the laboratory methods including the Boditech i-CHROMA™ method identified the TSH estimations in samples 2,5,7,11,15,18,21,22,26,29,31,32 as being between 0.4–4.0 uIU/mL. All the laboratory methods including the Boditech i-CHROMA™ method identified the TSH estimations in samples 3,4,6,8,10,12,14,16,19,20,23,28,34,35 and 36 as >4.0 uIU/mL. The TSH estimations in samples 17, 30 and 33 were estimated as >4.0 uIU/mL by all the laboratory methods but were estimated as between 0.4–4.0 uIU/mL by Boditech i-CHROMA™ method (**Tables 3 and 4**).

Table 3 Showing samples, the total number of methods with majority group and the methods not consistent with the majority.

Sample	Grouping	Total no. of methods that estimation fell into respective group	Method that estimation was inconsistent with group
1	<0.4	17/17	
2	0.4 - 4.0	17/17	
3	>4.0	17/17	
4	>4.0	17/17	
5	0.4 - 4.0	17/17	
6	>4.0	17/17	
7	0.4 - 4.0	17/17	
8	>4.0	17/17	
9	<0.4	17/17	
10	>4.0	17/17	
11	0.4 - 4.0	17/17	
12	>4.0	17/27	
13	<0.4	17/17	
14	>4.0	17/17	
15	0.4 - 5.0	17/17	
16	>4.0	17/17	
17	>4.0	16/17	Boditech i-CHROMA™
18	0.4 - 4.0	17/17	
19	>4.0	17/17	
20	>4.0	17/17	
21	0.4 - 4.0	17/17	
22	0.4 - 4.0	17/17	
23	>4.0	17/17	
24	<0.4	17/17	
25	<0.4	17/17	
26	0.4 - 4.0	17/17	
27	>4.0	17/17	

28	>4.0	17/17	
29	0.4 - 4.0	17/17	
30	>4.0	16/17	Boditech i-CHROMA™
31	0.4 - 4.0	17/17	
32	0.4 - 4.0	17/17	
33	>4.0	16/17	Boditech i-CHROMA™
34	>4.0	17/17	
35	>4.0	17/17	
36	<0.4	17/17	

Table 4 Showing the Boditech i-CHROMA™ TSH estimations of samples 17, 30 and 33 that were not consistent with the other methods of >4.0 uIU/mL.

Sample	Boditech i-CHROMA™ TSH estimation uIU/mL
17	2.89 uIU/mL
30	3.03 uIU/mL
33	3.63 uIU/mL

Discussion

We have previously assessed the performance of the Boditech i-CHROMA™ for precision and accuracy for Prostate Specific antigen (PSA) [11-13], Vitamin D [14], Human Chorionic Gonadotrophin (HCG) [15], Luteinizing Hormone (LH) [15], Follicle Stimulating Hormone (FSH) [14], C-Reactive Protein (CRP) [15] and Microalbumin [15] and found this POCT device quite promising in its performance.

For precision, according to the manufacturer's product leaflet of the Boditech i-CHROMA™ TSH method, the expected CV% for concentrations of 0.5 uIU/mL, 2.0 uIU/mL and 5.0 uIU/mL were 11.5%, 6.10% and 4.61%, respectively. In this study, the inter and intra assay precision of the Boditech i-CHROMA™ TSH method using the IQC with concentration of 3.45 uIU/mL was 5.3% and 2.5%, these results were very good and comparable to the data from the manufacturer. Furthermore, using pooled serum with a TSH concentration of 1.56 uIU/mL the estimated precision was 9.2%, also comparable to the CV% of 11.5% for concentration of 0.5 uIU/mL described in the manufacturer's product leaflet.

For accuracy, there was a very good correlation (r^2>0.97) with the Boditech i-CHROMA™ TSH method and the following methods: Abbott Architect, BioMerieux Vidas TSH, BioMerieux Vidas TSH3 Ultrasensitive, Roche COBAS® 6000/8000, Siemens Centaur XP/XPT/Classic, Siemens Centaur XP/XPT/Classic 3rd generation, Siemens Centaur XP/XPT/Classic TSH3 Ultra, Siemens Dimension, Siemens Immulite 2000/2500, Siemens Immulite 1000, Beckman DXI 600/800 Fast TSH, Beckman DXI 600/800 Hyper TSH, Roche Elecsys, DiaSorin Liaison, Monobind Inc ELISA/CLIA, Roche COBAS® 4000/e411, Roche Modular E-170, Beckman Access/LXi725 hyper TSH 3rd generation, Tosoh, Ortho Vitros 3600/5600/ECi. The method with the least bias of -0.6uIU/mL was the Beckman DxL 600/800 Fast TSH and the method with the most bias of -3.25ng/ml was the Ortho Vitros 3600/5600/ECi. Jeong et al, had previously shown a significant correlation (r^2=0.989, p<0.001) between the Boditech i-CHROMA™ TSH method and the Beckman Coulter Access 2 TSH method 10. In this study, the Boditech i-CHROMA™ TSH method showed a very good correlation with all the Beckman methods participating in the RIQAS: Beckman DXI 600/800 Fast TSH (r^2=0.97), Beckman DXI 600/800 Hyper TSH (r^2=0.97) and Beckman Access/LXi725 hyper TSH 3rd generation (r^2=0.97), with the method with the combined best correlation and bias difference with the TSH Boditech i-CHROMA™ being the Beckman DXI 600/800 Fast TSH (r^2=0.97, bias difference=-13.45%).

When grouping the samples based on the estimated TSH levels, the Boditech i-CHROMA™ method identified all the samples grouped as TSH <0.4 uIU/mL and 0.4–4.0 uIU/mL. However, the Boditech i-CHROMA™ method was only able to identify 15/18 (83%) of the samples with TSH >4.0 uIU/mL, grouping the remaining 3/18 (17%) as having TSH levels 0.4–4.0 uIU/mL. The TSH estimations in the 3 samples: 17, 30 and 33 were lower than the results obtained by the other methods, this is not surprising as the Boditech i-CHROMA™ TSH method in this study when compared to all the other methods had a negative bias on an average of -1.93 uIU/mL.

Conclusion

Most of the current POCT TSH methods on the market are qualitative or semi quantitative, they may be only useful in detecting hypothyroidism, as it would require a method that provides a quantitative result to have a broader application in the monitoring and surveillance of conditions associated with hypothyroidism. This is the first precision and accuracy study of a quantitative POCT TSH method, we found that the Boditech i-CHROMA™ TSH method showed good precision and very good accuracy when compared to a wide range of laboratory methods. In addition, the method was simple to use, and the device required very little maintenance. The Boditech i-CHROMA™ TSH POCT method can be useful in the screening, monitoring and surveillance of conditions associated with hypothyroidism at the point of care.

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