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Performance characteristics of the Beckman Coulter UniCel DxI 800 TSH (3rd IS) assay

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ABSTRACT

Introduction: Beckman Coulter recently reformulated their commercial TSH assay with primary calibration to the World Health Organization 3rd TSH international standard. An extensive evaluation of the performance characteristics for this assay was completed.

Methods: Intra-day and inter-day precision was evaluated using 3 concentrations of commercial quality control material. Linearity, reportable range, stability, sensitivity and susceptibility to common inferences were determined using pooled patient specimens. Inter-assay variability was assessed across 5 different platforms (n = 47 patient specimens).

Results: Intra-day and inter-day CVs were < 10% at all concentrations evaluated. The LOQ, LOD and LOB were 0.0047 μIU/ml (10% CV), 0.0012 μIU/ml and 0.0005 μIU/ml, respectively. Variable bias was observed for the TSH3 assay when evaluated against the previous generation assay and other platforms, but overall TSH3 gave comparable results.

Conclusions: The TSH3 assay for UniCel DxI 800, is precise, highly sensitive and comparable to the previous generation assay. The assay is acceptable for clinical testing.

1. Introduction

Thyroid stimulating hormone (TSH) regulates the secretion of thyroid hormones, which play an important role in growth, development, and metabolism. Moreover, TSH is the first line marker for the evaluation of thyroid function and is used to screen for and monitor thyroid disease [1,2]. Current practice guidelines state that TSH, in conjunction with thyroid hormone measurements, can be used for the evaluation of hyper and hypothyroidism, and to monitor the suppression of the thyroid gland in specific thyroid cancers [3–5]. TSH is quantified using immunoassays, which are rapid and automated; TSH is one of the highest volume immunoassays preformed in the clinical laboratory.

TSH assays lack standardization and/or harmonization, making the comparison of results between assays and laboratories challenging. Standardization of assays requires either pure substance reference material and/or a reference measurement procedure, neither of which currently exist for TSH [5,6]. Harmonization is a more realistic goal, but requires traceability to a reference material [5]. One problematic feature of traceable reference material is non-commutability, which causes the same patient sample to yield different TSH results on different platforms. Thus, transition from one assay to another requires extensive assessment [2,7,8]. Several recommendations associated with TSH harmonization have been made to address commutability of TSH reference material. These recommendations include mathematical correction and recalibration using specialized human specimens [6,9].

Beckman Coulter recently reformulated their commercial TSH assay. Perhaps the most important modification was primary calibration to the World Health Organization 3rd TSH international standard (IS, International Reference Preparation 81/565). The major difference between WHO 3rd IS and WHO 2nd IS is the use of less TSH in the preparation (2 vs 7.5 μg) [10]. Use of this new reference material could lead to dis-harmonization between assay platforms since other manufactures have not yet re-formulated their product using the new reference material.

The performance characteristics of TSH3 were recently evaluated

Abbreviations: TSH3, access TSH 3rd IS; WHO 3rd IS, World Health Organization 3rd TSH international standard

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Table 1
Intra- and inter-day precision was assessed at 3 different institutions (A, B and C) on a total of six different instruments. Each institution has two Beckman Coulter DxIs which were arbitrarily assigned a number (1 or 2). Three different concentrations of commercially available quality control (QC) material were used with peer group means of 0.05 μIU/ml (C1), 0.65 μIU/ml (C2) and 25.92 μIU/ml (C3).

			Intra-day precision			Inter-day precision		
			C1	C2	C3	C1	C2	C3
Institution A	1		(n = 20)			(n = 79)	(n = 80)	(n = 79)
		Mean (μIU/ml)	0.051	0.642	24.2	0.051	0.638	24.5
		SD (μIU/ml)	0.001	0.013	0.596	0.002	0.023	1.08
		CV (%)	1.70	1.96	2.47	3.41	3.66	4.42
	2		(n = 20)			(n = 44)	(n = 44)	(n = 45)
		Mean (μIU/ml)	0.053	0.657	25.6	0.053	0.650	25.5
		SD (μIU/ml)	0.002	0.017	1.02	0.002	0.028	1.22
		CV (%)	2.95	2.56	3.99	3.09	4.30	4.78
Institution B	1		(n = 20)			(n = 20)		
		Mean (μIU/ml)	0.045	0.658	26.0	0.046	0.645	26.3
		SD (μIU/ml)	0.002	0.021	1.15	0.004	0.023	1.52
		CV (%)	3.96	3.13	4.43	7.82	3.58	5.80
	2		(n = 20)				(n = 20)	
		Mean (μIU/ml)	0.045	0.652	26.6	0.046	0.633	26.1
		SD (μIU/ml)	0.002	0.021	1.64	0.004	0.025	1.21
		CV (%)	3.54	3.25	6.15	8.08	3.95	4.64
Institution C	1		(n = 20)			(n = 61)	(n = 61)	(n = 72)
		Mean (μIU/ml)	0.047	0.638	24.8	0.046	0.644	25.9
		SD (μIU/ml)	0.002	0.013	0.575	0.002	0.019	0.943
		CV (%)	3.22	1.97	2.32	3.24	2.91	3.64
	2		(n = 20)			(n = 61)	(n = 71)	(n = 78)
		Mean (μIU/ml)	0.046	0.633	24.6	0.047	0.649	25.3
		SD (μIU/ml)	0.001	0.015	0.658	0.001	0.015	0.752
		CV (%)	2.60	2.43	2.67	2.55	2.38	2.98

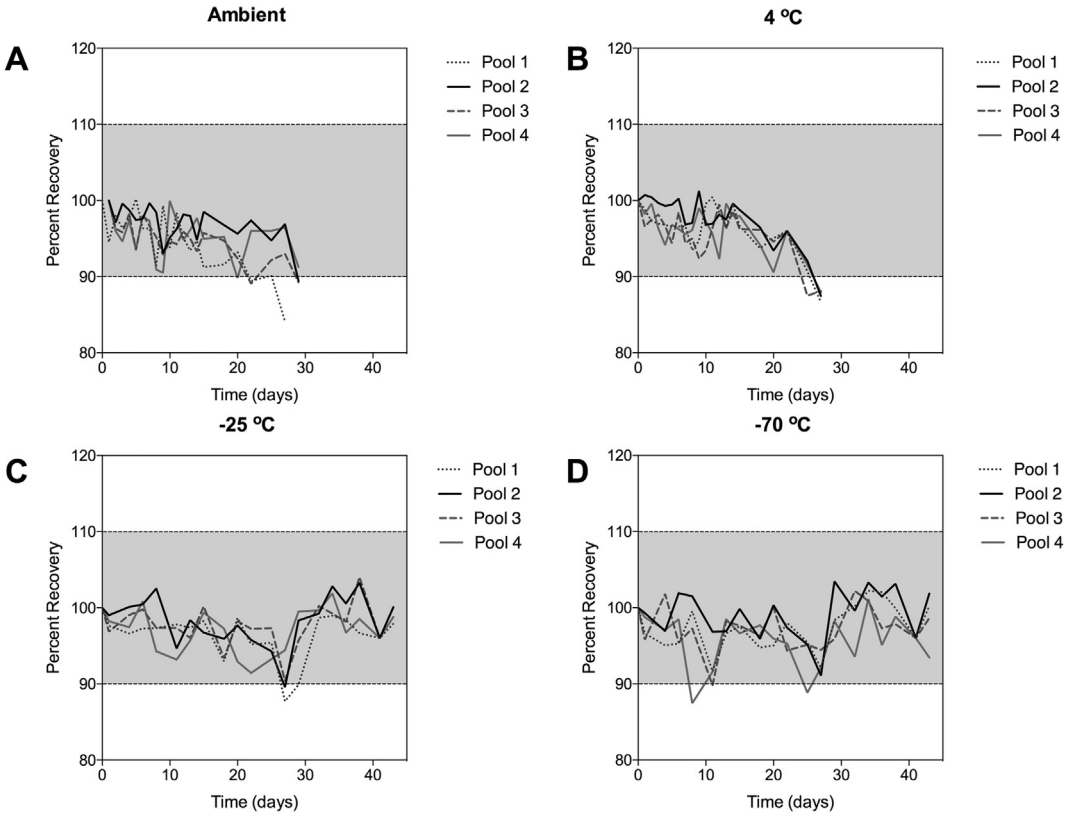

Fig. 1. The stability of TSH was evaluated in 4 separate serum and/or plasma pools stored at ambient temperature (panel A), 4 °C (panel B), − 25 °C (panel C), and − 70 °C (panel D) over 4–6 weeks. The average percent recovery of each pool at the specified temperature is shown.

and compared to the previous generation assay (Access HYPERsensitive hTSH Thyrotropin) by Dittadi et al. [11]. However, this study did not compare the performance of TSH3 to any other manufacturer assay. The study investigated sensitivity and precision, but the primary focus was the establishment of a reference interval using the new assay. No assessment of stability, susceptibility to interferences, or inter-assay comparisons was reported.