IDEXX Catalyst Dx® Chemistry Analyzer for In-house Measurement of Total Thyroxine (TT_4) Concentration in Serum from Dogs and Cats

Authors:

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Introduction

Thyroid disorders are encountered commonly in veterinary practice. As thyroid disorders typically respond well to treatment and carry a good prognosis, it is important for the clinician to routinely screen patients with suspected or potential thyroid disease. We recommend that total T_4 (TT_4) be used as the initial screening test for thyroid disorders. The test is most often used to exclude the diagnosis of hypothyroidism in dogs or to screen for hyperthyroidism in cats. Additionally, regular monitoring of TT_4 concentration is used to assess the efficacy of treatment in both species.

The IDEXX Catalyst® Total T_4 Test comprises a new immunoassay system from IDEXX Laboratories that is designed to measure TT_4 concentrations in serum or lithium heparin plasma samples from dogs (0.5–10 μg/dL; 6.4–128.7 nmol/L) and cats (0.5–20 μg/dL; 6.4–257.4 nmol/L) without the need to dilute the sample. This test uses ELISA technology in a new Catalyst slide format. It is designed to produce prompt, reliable and accurate test results in the veterinary clinic.

The objective of this study was to conduct a comprehensive comparison of TT_4 concentrations determined by the Catalyst® Total T_4 Test, using an IDEXX Catalyst Dx® Chemistry Analyzer, and TT_4 concentrations determined by DRI® Thyroxine (T_4) Assay, a method used by reference laboratories.[1,2] In this study, the DRI Thyroxine (T_4) Assay is deemed to be the reference method.

Method comparison

Materials and Methods: Serum samples were collected from 75 dogs and 74 cats, including a mixture of healthy animal and clinical patients. All samples were analyzed using both the DRI® Thyroxine (T_4) Assay (run on a clinical chemistry analyzer used in veterinary reference laboratories)[3] and the Catalyst® Total T_4 Test (run on the IDEXX Catalyst Dx® Chemistry Analyzer). Each sample was run twice on the reference method and an average was calculated for use in the comparison. Each sample was also run once on three Catalyst Dx analyzers to give a total of three comparisons per sample (a grand total of 447 comparisons).

The IDEXX Catalyst Dx analyzer uses algorithms to suppress results when it encounters problems with either sample quality or the consumable. This is not an automated feature for the reference method. In this study 3 results (0.7% of all comparisons; 2 canine and 1 feline) were suppressed by the Catalyst Dx analyzer and the comparisons were excluded from the analysis.

For each species, correlation plots were constructed with calculation of R-squared (R^2), slope and mean bias. R^2 is a statistical technique that evaluates the relationship between two series of events, and the slope of this correlation directly speaks to the overall bias. In this context, an R^2 of one and a slope of one are considered ideal.

Results: The results are shown in figure 1 (canine) and figure 2 (feline). The comparison of the clinical interpretations is shown in table 1 (canine) and table 2 (feline). There was excellent correlation between the two methods and strong concordance on the clinical interpretation.

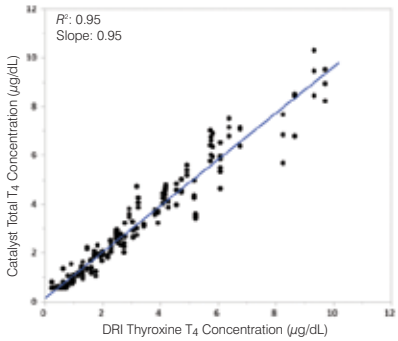

Figure 1. Linear regression graph of pairwise comparisons (n=223) of serum TT_4 concentrations in canine samples measured by the two assays. The line of best fit for the data is indicated in the linear regression graph, with the slope and R-squared (R^2).

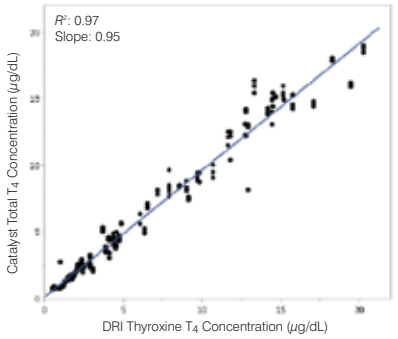

Figure 2. Linear regression graph of pairwise comparisons (n=220) of serum TT_4 concentrations in feline samples measured by the two assays. The line of best fit for the data is indicated in the linear regression graph, with the slope and R-squared (R^2).

Method comparison

continued

Canine		DRI® Thyroxine (T_4) Results		
		Low <1.0 µg/dL <13 nmol/L	Normal 1.0–4.0 µg/dL 13–51 nmol/L	High >4.0 µg/dL >51 nmol/L
Catalyst® Total T_4 Results	Low <1.0 µg/dL <13 nmol/L	33	3	0
	Normal 1.0–4.0 µg/dL 13–51 nmol/L	6	124	0
	High >4.0 µg/dL >51 nmol/L	0	2	55

Table 1. Comparison of the clinical interpretation of the canine results based on the guidelines currently used by IDEXX Reference Laboratories.

Feline		DRI® Thyroxine (T_4) Results		
		Low <0.8 µg/dL <10 nmol/L	Normal 0.8–4.7 µg/dL 10–60 nmol/L	High >4.7 µg/dL >60 nmol/L
Catalyst® Total T_4 Results	Subnormal <0.8 µg/dL <10 nmol/L	4	2	0
	Normal 0.8–4.7 µg/dL 10–60 nmol/L	7	128	3
	High >4.7 µg/dL >60 nmol/L	0	7	69

Table 2. Comparison of the clinical interpretation of the feline results based on the guidelines currently used by IDEXX Reference Laboratories.

Precision

Materials and Methods: Precision was assessed according to Clinical and Laboratory Standards Institute (CLSI) EP05-A3 method guidelines.[4] Two levels of control fluid, IDEXX Catalyst® Advanced Control and a low TT_4 control, were assayed on the Catalyst Dx® Chemistry Analyzer. There were two replicates run on three Catalyst Dx instruments in the morning and afternoon for five days, for a total of 20 replicates of each fluid per instrument.

Results: The average CV, across the three Catalyst Dx analyzers, for fluid with a mean concentration of 2.4 µg/dL was 5%. The average CV for fluid with a mean concentration of 4.0 µg/dL was 8%. This new method shows a precision similar to other methods described in the veterinary literature.[5]

Interfering substances study

Materials and Methods:

Interference caused by the presence of hemoglobin, bilirubin or lipids was assessed according to CLSI EP07-A2 method guidelines.[6] Canine serum samples, which were visibly clear of interferents, were collected and pooled. Aliquots of the pooled sample were then prepared and spiked with varying concentrations of the substances shown in table 1. Each aliquot was run in duplicate on five Catalyst Dx analyzers in a random order.

Results: The results of the interfering substances study are shown in table 3. The common interfering substances examined here have a minimal impact on the reported TT_4 concentrations.

Hemolysis		Lipemia		Icterus	
Hemoglobin concentration (mg/dL)	Catalyst Total T_4 average TT_4 concentration (µg/dL)	Intralipid concentration (mg/dL)	Catalyst Total T_4 average TT_4 concentration (µg/dL)	DTB concentration (mg/dL)	Catalyst Total T_4 average TT_4 concentration (µg/dL)
Not spiked	1.3	Not spiked	1.3	Not spiked	1.3
125	1.3	250	1.4	1	1.3
250	1.3	500	1.4	3	1.3
375	1.3	750	1.4	10	1.4
500	1.2	1000	1.4	20	1.3
				30	1.3

Table 3: Impact of interfering substances.

Conclusion

The new Catalyst Total T_4 Test produces accurate results when used to quantify TT_4 in serum samples from dogs and cats. This new immunoassay system demonstrates excellent correlation with the reference method and provides an accurate, reliable and convenient option for veterinarians who wish to diagnose and monitor animals with thyroid disease using their in-house laboratory.

References

1. DRI Thyroxine (T_4) Assay. Manufactured by Microgenics Corporation (part of Thermo Fisher Scientific), Freemont, California, USA.
2. IDEXX Reference Laboratories, Westbrook, Maine, USA (as supplied with results from analysis with the DRI Thyroxine [T_4] Assay).
3. Olympus AU400, Beckman Coulter, Nyon, Switzerland
4. CLSI. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition.* CLSI document EP05-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.
5. Kemppainen RJ, Birchfield JR. Measurement of total thyroxine concentration in serum from dogs and cats by use of various methods. *AJVR*. 2006;67(2).
6. CLSI. *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition*. CLSI document EP07-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.

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