

# Consistency of Thyroid Hormone Measurements on the Abbott ARCHITECT® System Over an Extended Period of Time

W. Leonard, C. Villalobos, G. Chan and S. Pearce; Abbott Diagnostics, Abbott Park, IL

American Association for Clinical Chemistry Annual Meeting • Chicago, Illinois • July 23 – 27, 2006

## Abstract (revised)

**Background:** Thyroid disease is common, and many thyroid disorders require life-long treatment and monitoring. Three of the most common tests used by physicians to assess the thyroid status of their patients are serum thyroid stimulating hormone (TSH), free thyroxine (FT4) and free tri-iodothyronine (FT3). Because these tests are often used to follow patients over time, reliable assay performance across multiple reagent lots is important for appropriate patient management. The purpose of our study was to evaluate the consistency of TSH, FT4 and FT3 measurements on the Abbott ARCHITECT over an extended period of time.

**Materials and Methods:** Assays were run according to the manufacturer's instructions. Assay imprecision was monitored over time (>23 months) using a series of human serum panels (different for each assay) which had been aliquoted and stored frozen (-10°C), as well as with the manufacturer's controls (different control lots were used throughout the study). The following testing was performed for each reagent lot and assay evaluated: TSH = 1 instrument, 1 run, 12 replicates per panel/control; FT4 = 2 instruments, 2 runs per instrument, 15 replicates per panel/control; FT3 = 2 instruments, 2 runs/instrument, 12 replicates per panel/control. During the length of the study, >10 different instruments were used for testing. Data for the manufacturer's controls (not shown) were similar to those seen for the human serum panels. For TSH, serum panel 3 ("B") was depleted after testing 17 reagent lots. A new panel "B" lot was prepared, and used to test the remaining 11 lots of TSH reagent. Summarized data for the human serum panels are shown below:

Assay	Reagent Lots (N)	Serum Panel		
		Panel 1	Panel 2	Panel 3
TSH (µIU/mL)	28	0.4224, 6.6%	1.02, 4.2%	15.59, 2.9% (N = 17 lots) 18.08, 2.6% (N = 11 lots)
FT4 (ng/dL)	19	1.34, 1.5%	1.08, 1.8%	2.98, 2.3%
FT3 (pg/mL)	23	1.98, 3.4%	4.18, 2.2%	7.27, 2.7%

**Conclusions:** Based on our data, we conclude that the ARCHITECT TSH, FT4 and FT3 assays provide consistent performance over an extended period of time across multiple reagent lots and instruments. Reliable assay results are important as they help physicians make better informed clinical decisions and contribute to better patient management.

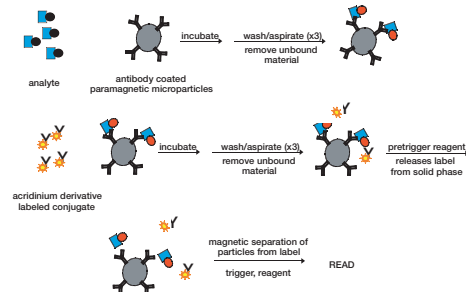
## Introduction

- Measurement of serum levels of thyroid stimulating hormone (TSH), free thyroxine (FT4) and free tri-iodothyronine (FT3) plays an important role in the diagnosis, treatment, and monitoring of thyroid disease.
- Because many thyroid conditions require life-long treatment and monitoring, reliable measurement of thyroid hormone levels over extended periods of time is needed for optimal patient management.
- The objective of our study was to evaluate the consistency of TSH, FT4, and FT3 measurements on the Abbott ARCHITECT system over multiple reagent lots and an extended period of time.

### ARCHITECT TSH Assay Design

The ARCHITECT TSH assay is a double-monoclonal assay that follows a two-step assay protocol as described below:

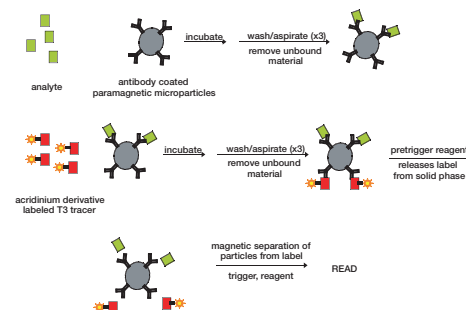
- STEP 1: paramagnetic particles coated with a monoclonal antibody specific for the TSH β subunit are incubated with the sample.
- STEP 2: after washing, conjugate is added. The conjugate is a monoclonal antibody (against the α subunit of TSH) which has been labeled with a sulfopropyl acridinium carboxamide. After incubation and washing, the light generating reaction is initiated by the addition of pre-trigger and trigger reagents.
- The resulting light is measured by a photomultiplier tube, with the amount of light generated being directly proportional to the TSH level in the sample.



### ARCHITECT Free T4 and Free T3 Assay Designs

The ARCHITECT Free T4 and Free T3 assays follow a two-step assay protocol as described below:

- STEP 1: paramagnetic particles coated with antibody specific for T4 (sheep polyclonal) or T3 (sheep monoclonal) are incubated with the sample.
- STEP 2: after washing, tracer is added. The tracer is T3 labeled with a sulfopropyl acridinium carboxamide. After incubation and washing, the light generating reaction is initiated by the addition of pre-trigger and trigger reagents.
- The resulting light is measured by a photomultiplier tube, with the amount of light generated being inversely proportional to the Free T4 or Free T3 level in the sample.



# Methods

- Human serum-based panels were used to monitor assay performance. Panel composition is shown in the table below. Panels were aliquoted, and stored at  $-10^{\circ}\text{C}$ .
- The following testing was performed for each reagent lot evaluated:
  - TSH: 1 instrument, 1 run, 12 replicates per panel. A total of 28 reagent lots were evaluated over a period of 24 months; 15 different instruments were used in this study. For panel "B", volume was depleted after testing 17 reagent lots. A new panel lot was prepared (with a higher concentration), and used to test the subsequent 11 reagent lots.
  - Free T4: 2 instruments, 2 runs per instrument, 15 replicates per panel. A total of 19 reagent lots were evaluated over a period of 24 months; 16 different instruments were used in this study.
  - Free T3: 2 instrument, 2 runs per instrument, 12 replicates per panel. A total of 23 reagent lots were evaluated over a period of 23 months; 13 different instruments were used in this study.
- These data were then used to calculate the mean and standard deviation for each reagent lot, as well as a mean value and total percent coefficient of variation (CV) across all reagent lots. Mean values (error bars represent  $\pm 2\text{SD}$  values) were then plotted versus the reagent lot number.

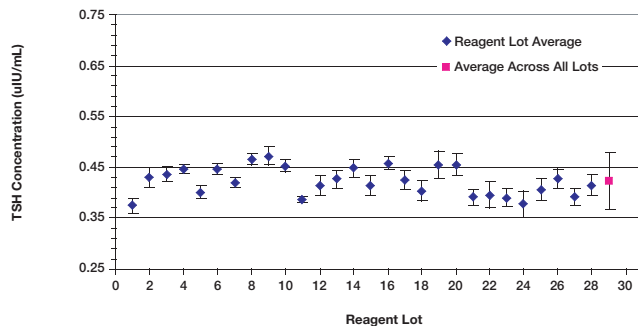
	Matrix*	Hormone Added*
<b>TSH (<math>\mu\text{IU/mL}</math>)</b>		
Panel H2	SHS	Human TSH
Panel N	NHS	None
Panel B	SHS	Human TSH
<b>Free T4 (ng/dL)</b>		
Panel O	SHS	T4 (if needed)
Panel N	NHS	None
Panel R	NHS	T4
<b>Free T3 (pg/mL)</b>		
Panel – Low	NHS	None
Panel – High	SHS	T4/T3
Panel – Very High	SHS	T4/T3

\* SHS = Stripped human serum; NHS = Normal human serum.

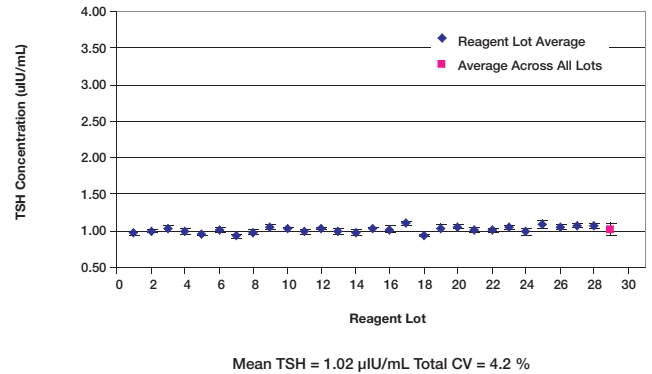
\* T4 and T3 stocks prepared using HPLC grade material.

## ARCHITECT TSH Serum Panel Testing

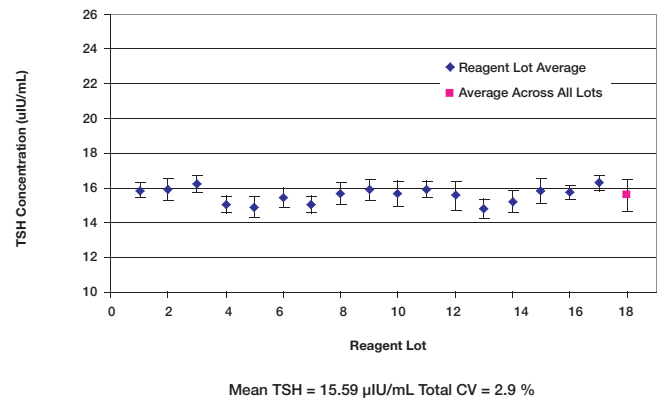
ARCHITECT TSH  
Reagent Lot Versus Panel H2 Concentration



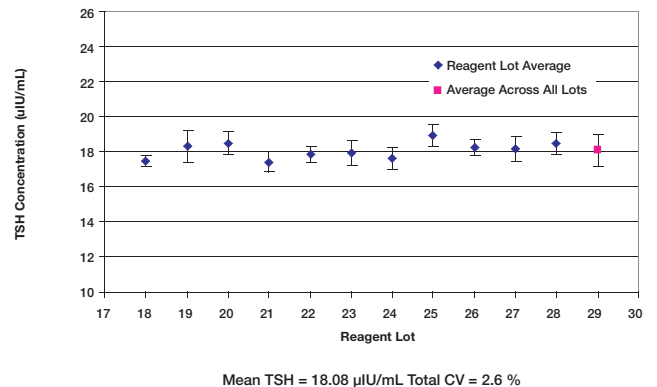
ARCHITECT TSH  
Reagent Lot Versus Panel N Concentration



ARCHITECT TSH  
Reagent Lot Versus Panel B Lot 1 Concentration

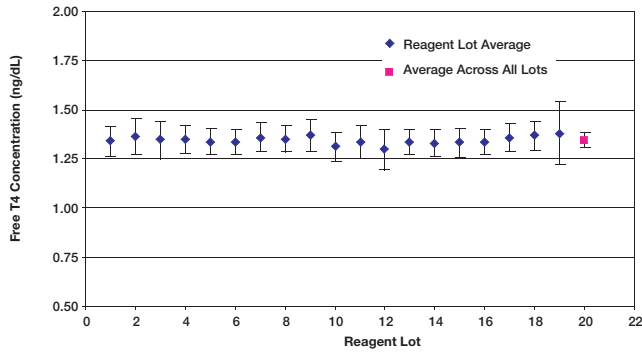


ARCHITECT TSH  
Reagent Lot Versus Panel B Lot 2 Concentration



## ARCHITECT Free T4 Serum Panel Testing

### ARCHITECT Free T4 Panel N Reagent Lot Versus Concentration



## Summary and Conclusion

- Based on our data, we conclude that the ARCHITECT TSH, FT4 and FT3 assays provide consistent results across multiple reagent lots over an extended period of time.
  - For TSH, total imprecision across 28 reagent lots and 15 different instruments ranged from 2.6 – 6.6%. Testing took place over a 24-month period.
  - For FT4, total imprecision across 19 reagent lots and 16 different instruments ranged from 1.5 – 2.3%. Testing took place over a 24-month period.
  - For FT3, total imprecision across 23 reagent lots and 13 different instruments ranged from 2.2 – 3.4%. Testing took place over a 23-month period.
- Reliable laboratory results allow physicians to make more informed decisions and contribute to improved patient management.