

# FREND™ Thyroid Duo: a new way of Helping patients with subclinical thyroid dysfunction

Sunmi Han, Hyejin Lee, Jesik Jeong, Jihyun Seong, Changseop Lee, and Chanil Chung  
Research & Development Division, NanoEnTek Inc. Seoul 08389, South Korea

## OBJECTIVES

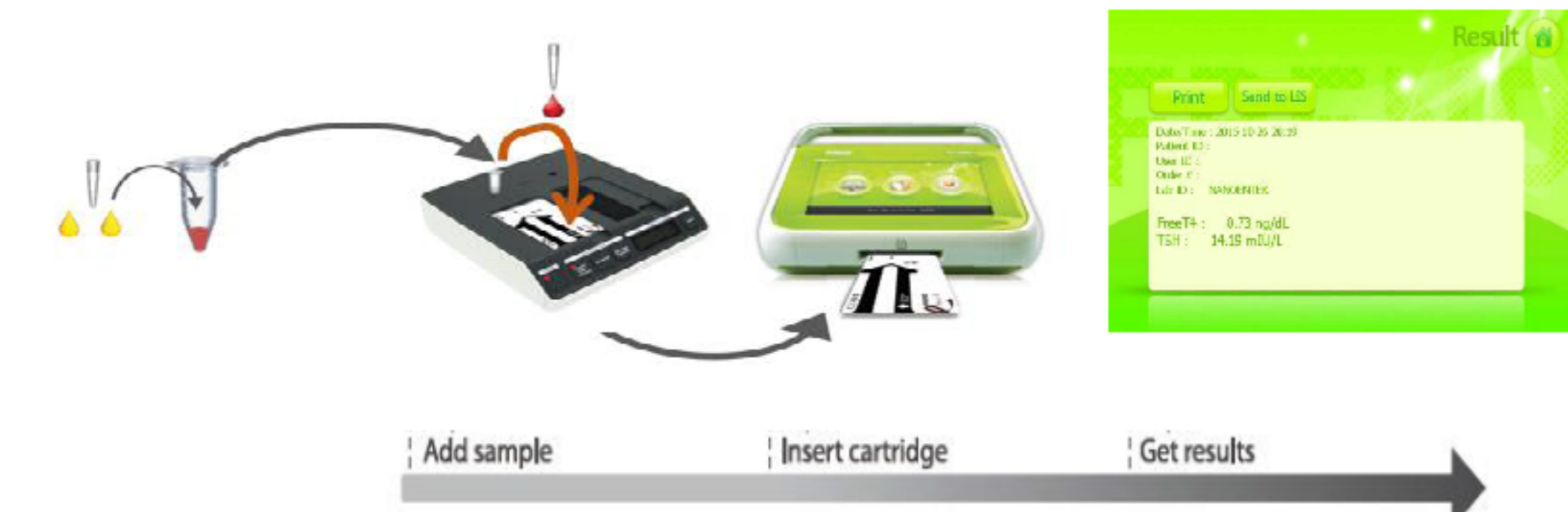
To evaluate the analytical performance a FREND™ Thyroid Duo immunoassay on FREND™ system

### FREND™ System

Accurate, automated testing procedure – simple 3-step operation  
No need to batch your sample – run when you are ready

- Controls: Minimum once a month two level liquid controls
- Electronic code chip calibration – no need to run liquid
- Daily electronic system QC control – takes only 1.5 minutes
- Stores 500 test results

### Test procedure



## METHODS

The analytical performance studies (sensitivity, precision, linearity, interference and accuracy) were performed according to the CLSI protocols (EP17, EP05, EP06, EP07 and EP09). For the method comparison, serum TSH and free T4 were assayed by FREND™ and Architect i1000 (Abbott Diagnostics, Abbott Park, IL).

## RESULTS

The FREND™ Thyroid Duo demonstrated acceptable imprecision of %CV (<10%) in low, intermediate, and high level samples for both analytes. The linearity of the assay was found to be acceptable in the range of 0.06~25 mIU/L for TSH and 0.4~6 ng/dL for FT4. Method comparisons between Abbott Architect's assays and NanoEnTek's FREND Thyroid Duo assay were made and no significant deviation from linearity was found. No significant interference was observed for both analytes from bilirubin, Intra-lipid and total protein up to concentrations of 20 mg/dL, 3 g/dL, and 12 g/dL respectively.

### PRECISION

TSH	Mean (mIU/L)	Repeatability		Between-run		Between-day		Within-laboratory	
		SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)
Low	0.49	0.038	7.6	0.020	4.0	0.012	2.4	0.045	8.9
Med	5.07	0.247	5.0	0.031	0.6	0.038	0.8	0.252	5.1
High	20.11	1.144	5.7	0.513	2.6	0.121	0.6	1.259	6.3

Free T4	Mean (ng/mL)	Repeatability		Between-run		Between-day		Within-laboratory	
		SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)
Low	0.77	0.047	6.0	0.029	3.6	0.010	1.3	0.056	7.1
Med	1.84	0.079	4.4	0.008	0.4	0.048	2.7	0.093	5.2
High	4.05	0.188	4.7	0.056	1.4	0.057	1.4	0.205	5.1

### INTERFERENCE

	% Recovery							
	Hemoglobin		Bilirubin		Triglycerides		Total Protein	
	TSH	Free T4	TSH	Free T4	TSH	Free T4	TSH	Free T4
Low	96.2	101.2	99.4	102.9	98.7	103.0	101.9	100.0
Med	102.4	97.0	103.8	95.3	104.6	97.4	100.4	95.4
High	99.9	100.2	106.1	98.9	95.6	98.2	99.1	104.5

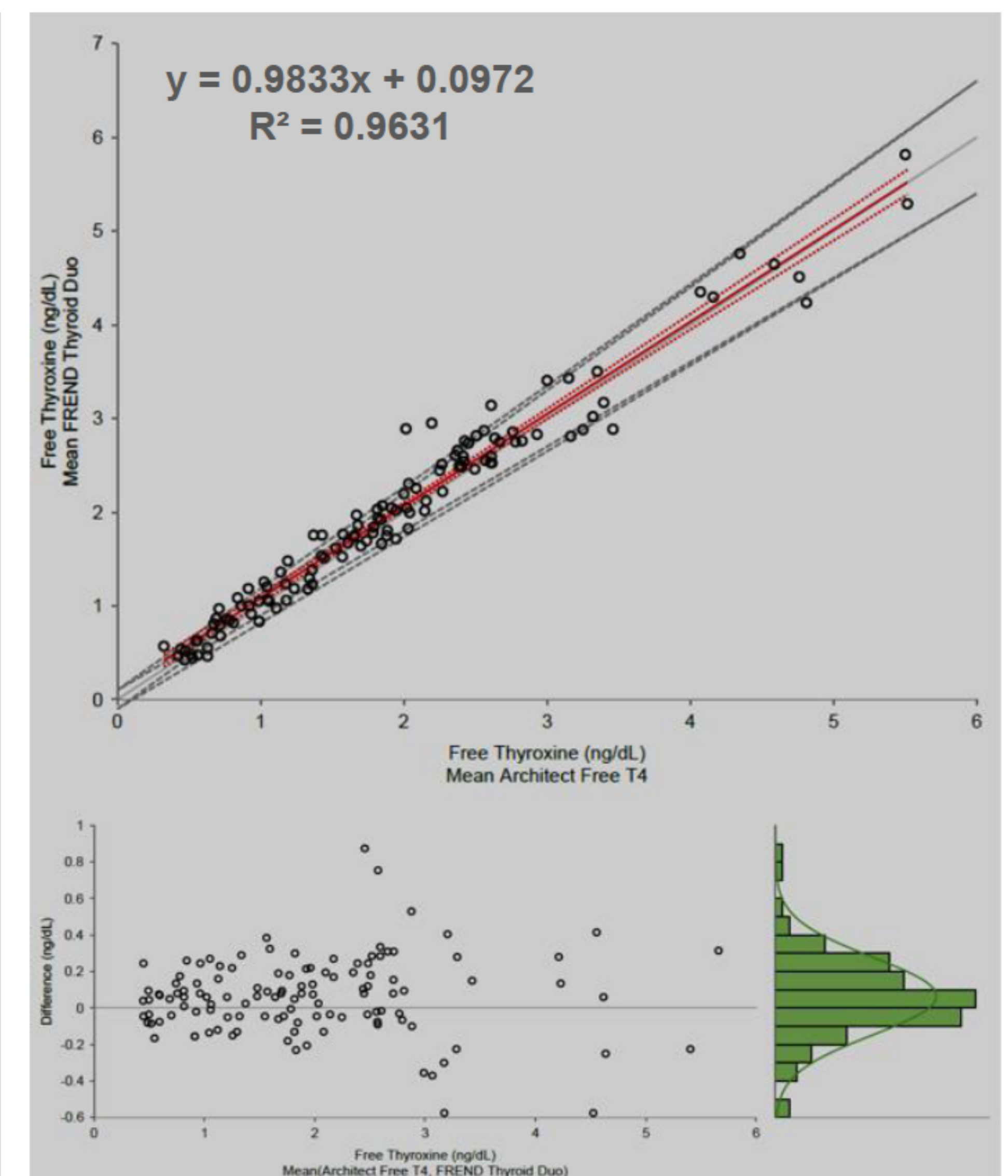
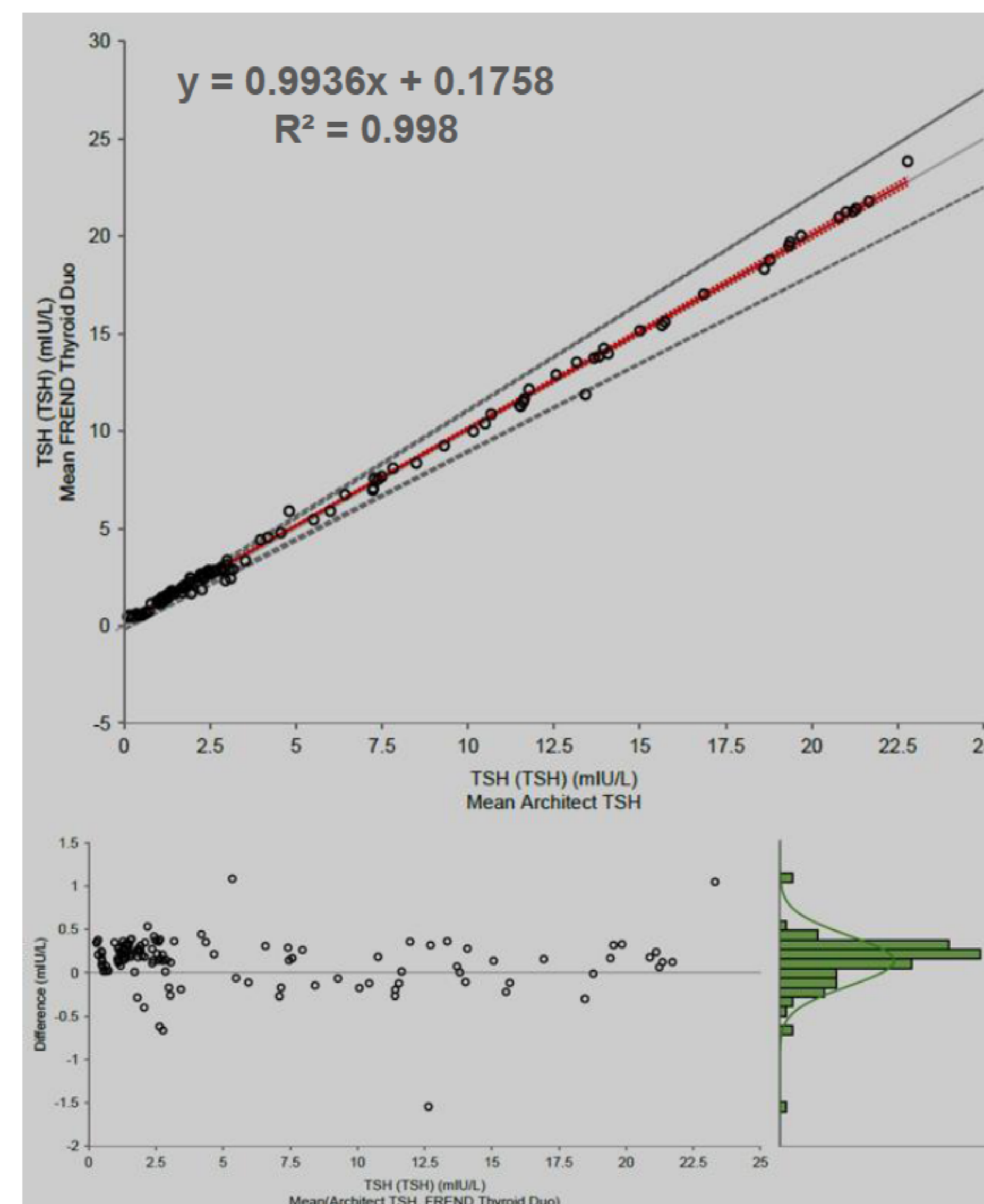
### CROSS-REACTIVITY

Cross-Reactants	Final conc.	TSH (% Recovery)			Free T4 (% Recovery)		
		Low	Med	High	Low	Med	High
1. Follicle-stimulating hormone (FSH)	500 mIU/mL	97.0	97.7	105.7	98.0	101.9	102.1
2. Luteinizing hormone (LH)	500 mIU/mL	96.2	102.2	99.9	95.2	101.1	97.1
3. Human chorionic gonadotropin (HCG)	200,000 mIU/mL	102.0	99.6	105.1	101.7	104.1	100.3
4. Diiodothyronine, T2 (20X)	5 µg/dL	99.3	101.0	105.6	96.9	100.7	99.6
5. Tetraiodothyroacetic Acid (20X)	10 µg/dL	102.6	100.6	102.6	94.6	98.7	98.3
6. Triiodothyroacetic Acid (20X)	1 µg/dL	98.7	100.7	102.6	101.6	97.8	93.2
7. Triiodothyropropionic Acid (20X)	5 µg/dL	101.3	99.7	103.8	102.7	99.1	102.5
8. Diiodothyrosine, DiT (20X)	1,000 µg/dL	101.3	101.1	97.8	100.4	96.6	100.5
9. L-Triiodothyronine, T3 (20X)	1 µg/dL	98.7	104.1	98.0	98.0	99.4	97.8
10. Monoiodotyrosine (20X)	1,000 µg/dL	105.2	101.8	98.7	98.8	103.6	104.4
11. Reverse T3 (20X)	10 µg/dL	97.6	100.4	100.1	96.3	103.6	105.4

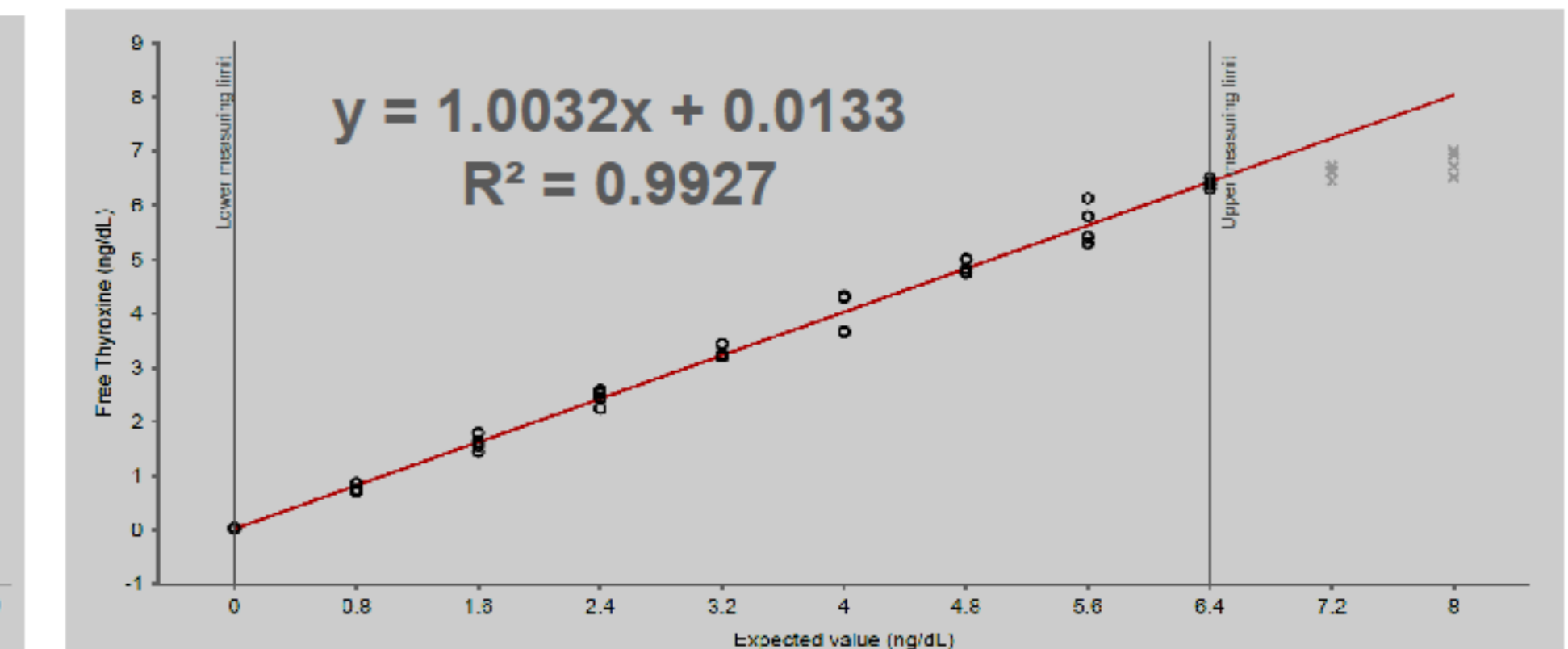
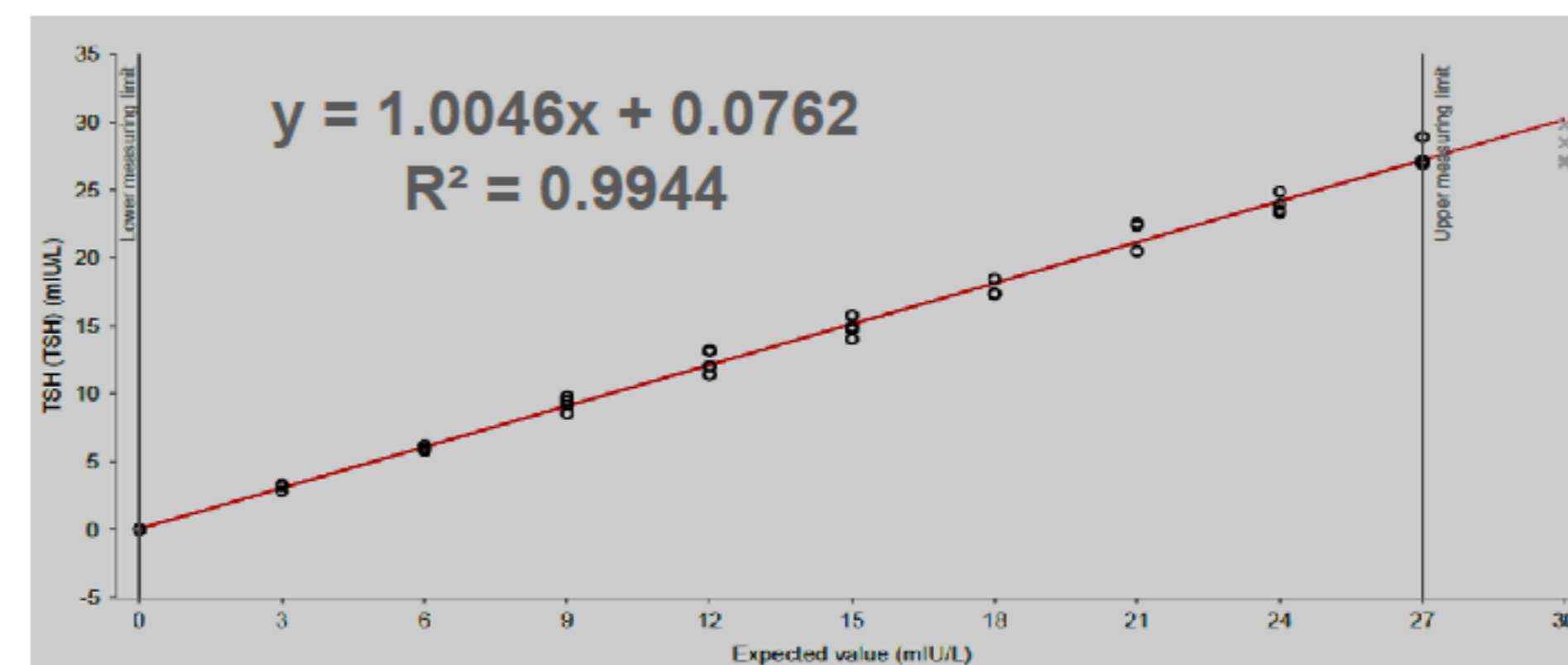
### DETECTION LIMIT

	LoB (Limit of Blank)	LoD (Limit of Detection)	LoQ (Limit of Quantitation)
TSH (mIU/L)	0.03	0.04	0.06
Free T4 (ng/dL)	0.24	0.31	0.40

### METHOD COMPARISON



### LINEARITY



## CONCLUSIONS

**Conclusion:** The NanoEnTek's FREND™ Thyroid Duo assay represents a rapid, accurate and convenient mean of measuring TSH and FT4 quantities in human serum on FREND™ system. The subclinical thyroid dysfunction may be screened or monitored in a clinic or physician's office using this microfluidic 2-in-1 thyroid assay with ease and comfort.

## References

1. Gharib et al., *J. Clin. Endocrinol Metab.* (2005) 90:581-585
2. Astles et al., CLSI guideline EP19, 2nd ed. June 2015.