

Analytical and clinical evaluation of the new VIDAS® FT4 method for free thyroxin measurement

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Background

The measurement of FT4 is an important tool for the diagnosis and monitoring of thyroid diseases.

Recently, bioMérieux (Marcy l'Etoile, France) has redeveloped its FT4 test on the VIDAS instrument. The new test (VIDAS FT4-ref 30459) has been evaluated in our laboratory (G. Monasterio Foundation, Laboratory Medicine and IFC-CNR, Cardiovascular Endocrinology and Metabolism, Pisa, Italy). The method is based on the technique Enzyme Linked Fluorescent Assay (ELFA). All of the assay steps are performed automatically by the instrument.

Materials and Methods

We evaluated 71 routine serum samples: 11 normal subjects, 9 hyperthyroid, 9 hypothyroid, 7 low-T3 syndrome, 4 subclinical hyperthyroid, 5 renal failure and 4 liver cirrhosis patients, plus 12 pregnant women and 10 paediatric patients undergoing cardiac surgery. Moreover, control samples from an External Quality Assessment (EQA) scheme (QualiMedLab/CNR, Pisa Italy) were measured.

For comparison, in addition to VIDAS FT4, all samples were tested on Cobas-Roche FT4 and AIA-Tosoh FT4 immunoassay techniques.

Results

Results of measurements performed using the VIDAS FT4 test on 71 samples from healthy subjects and patients enrolled are shown in **Figure 1**.

Regression analysis between VIDAS FT4 and the two compared methods **Figure 3-4** [VIDAS FT4 = 1.24 Cobas - 0.62, n = 70, r = 0.974; VIDAS FT4 = 1.27AIA - 0.44, n = 71, r = 0.986] indicates that results produced by VIDAS are slightly higher but well correlated with those of the other two techniques. In addition, the results of the control samples obtained by the EQA in laboratories using VIDAS, Cobas and AIA (including our lab) confirms the trend obtained on patient samples.

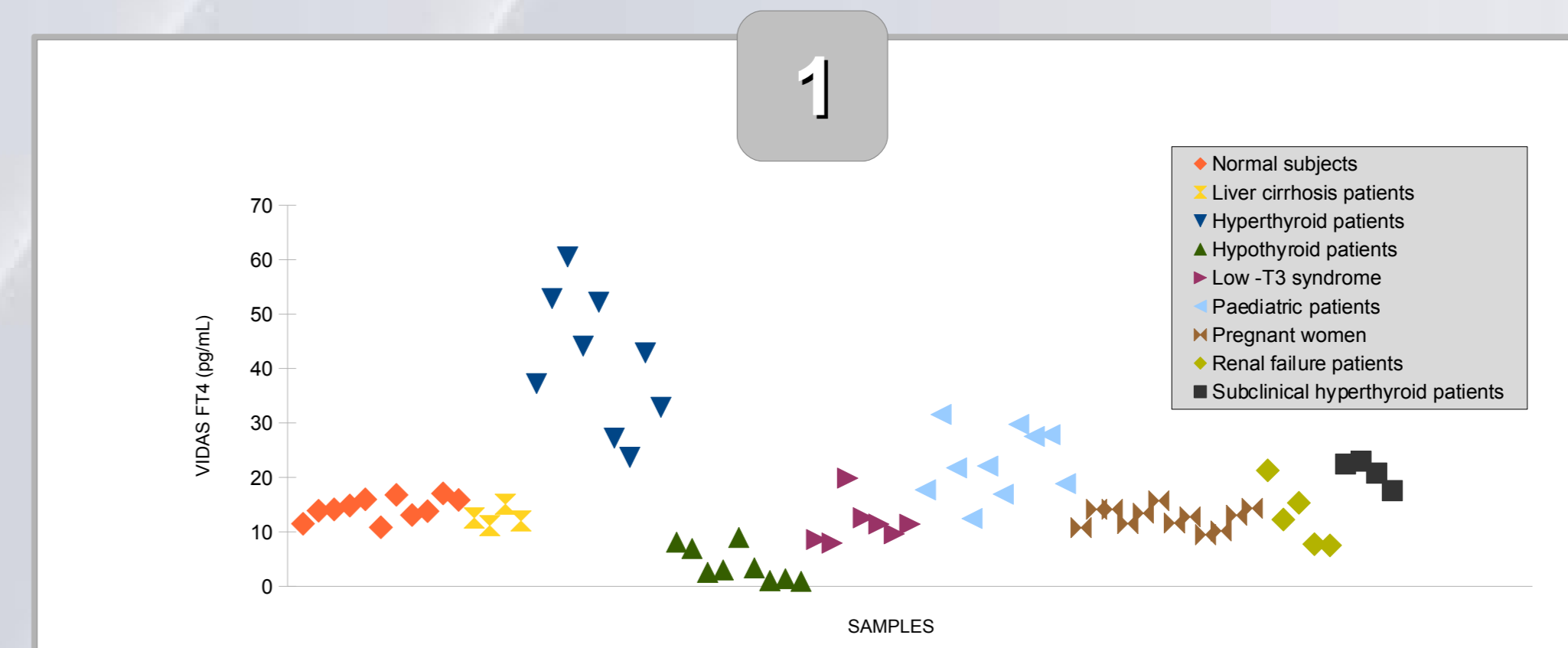


Figure 1. Results of FT4 (pg/mL) obtained for the mini VIDAS method

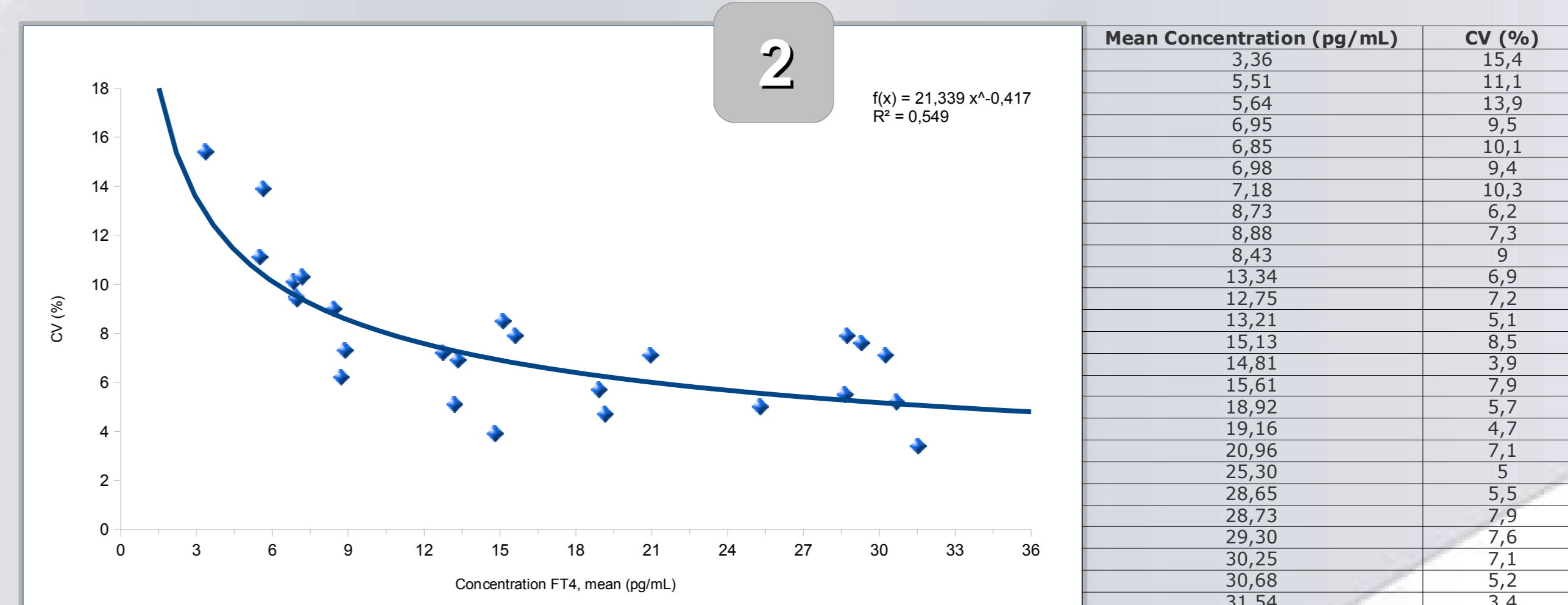


Figure 2. Imprecision profile for the VIDAS FT4N method

Regarding precision, **Figure 2** shows the imprecision profile obtained from the measurements of the 27 control samples. It is clear that the test's inter-assay precision is higher than 10% (CV%) for the samples in the measurement range higher than 5 pg/ml, and lower, as expected, for low concentrations.

The inter-assay precision of the VIDAS test for 3 concentration levels is shown in **Table 1**. This level of precision is comparable to that observed with the two compared methods.

Sample	Mean concentration (pg/mL)	Standard deviation	CV (%)
Sample A	5.54	1.56	13.5
Sample B	8.31	0.77	8.7
Sample C	21.77	7.23	6.6

Table 1. Evaluation of inter-assay precision for the VIDAS FT4N method

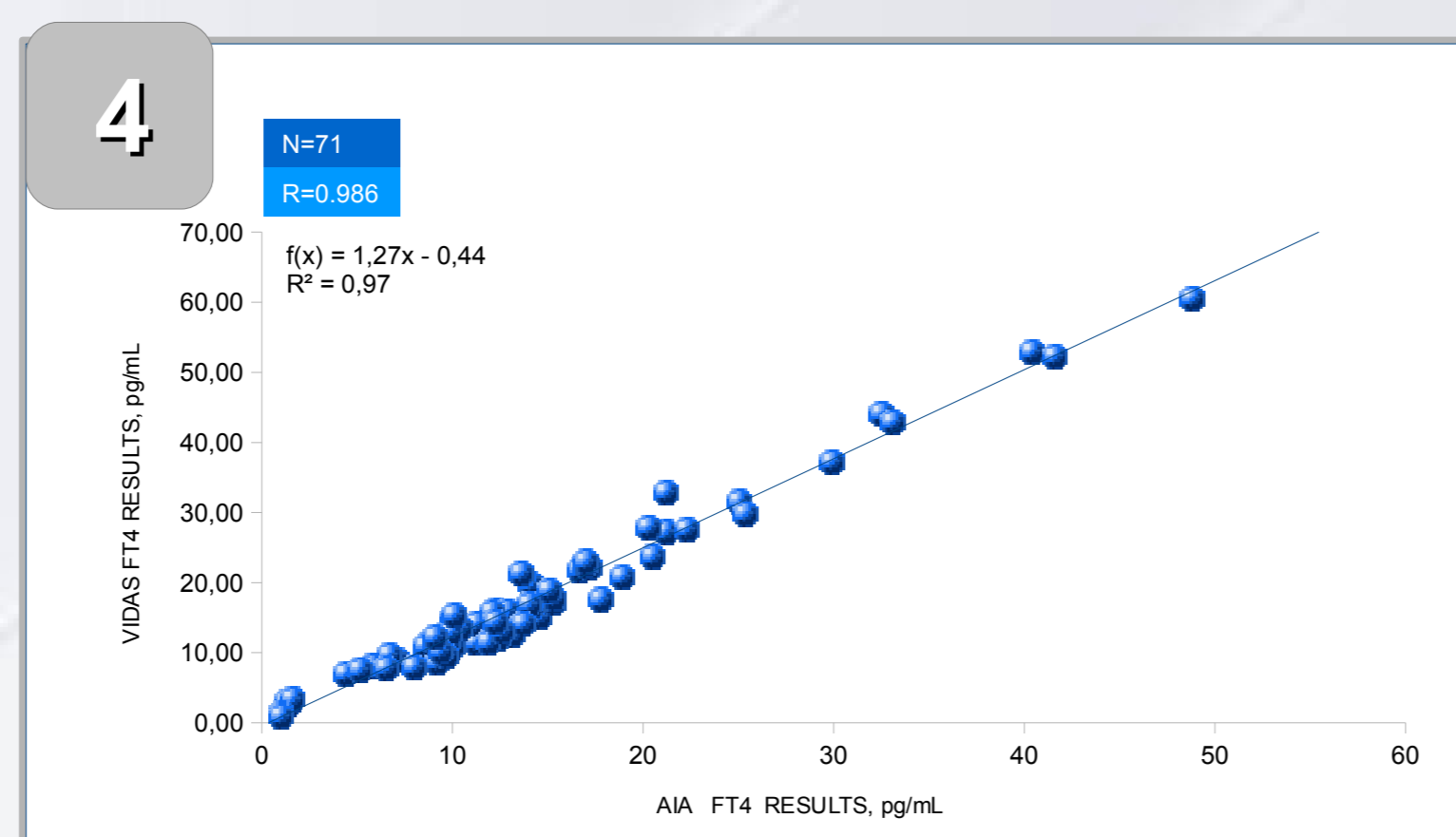
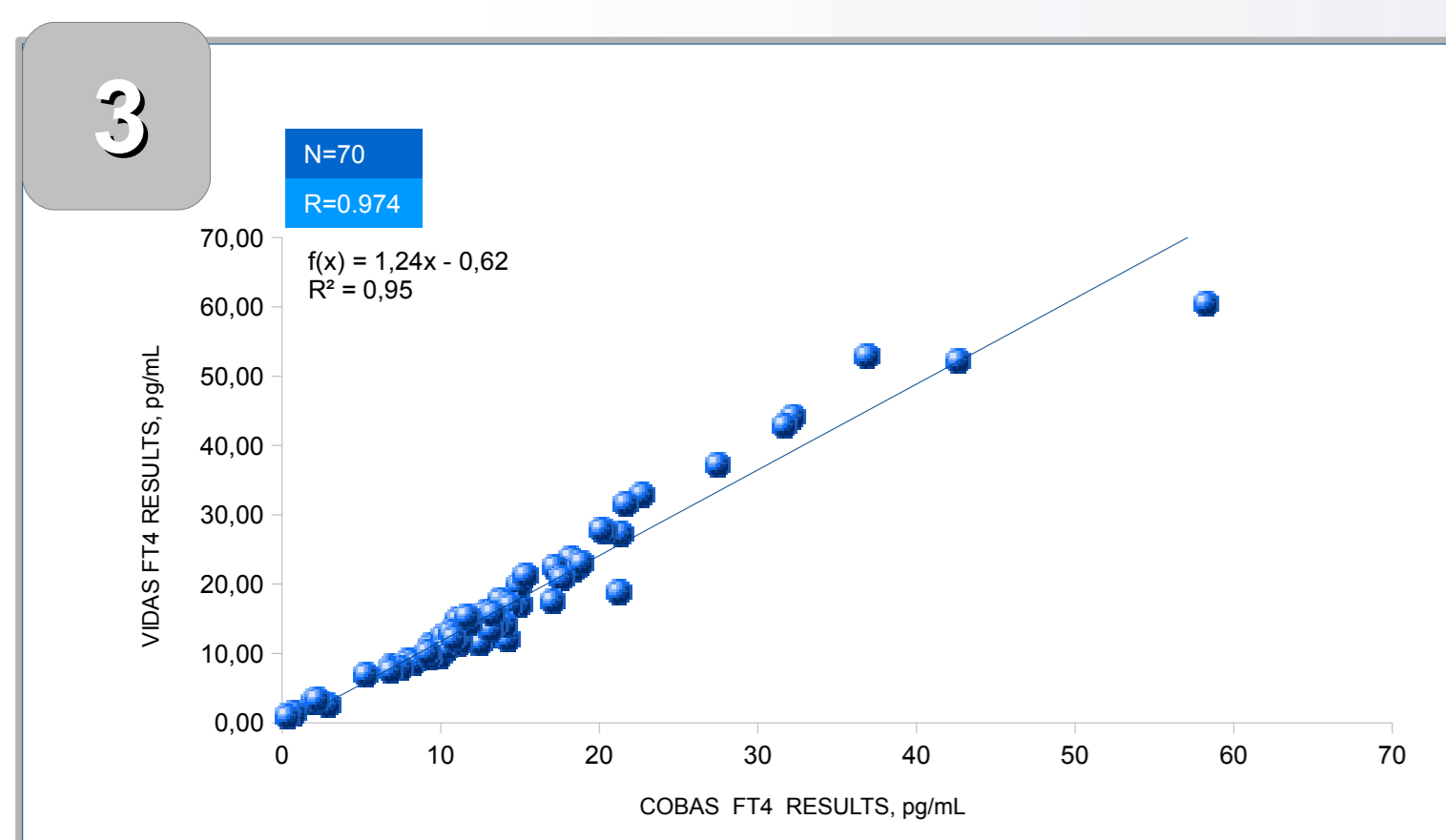
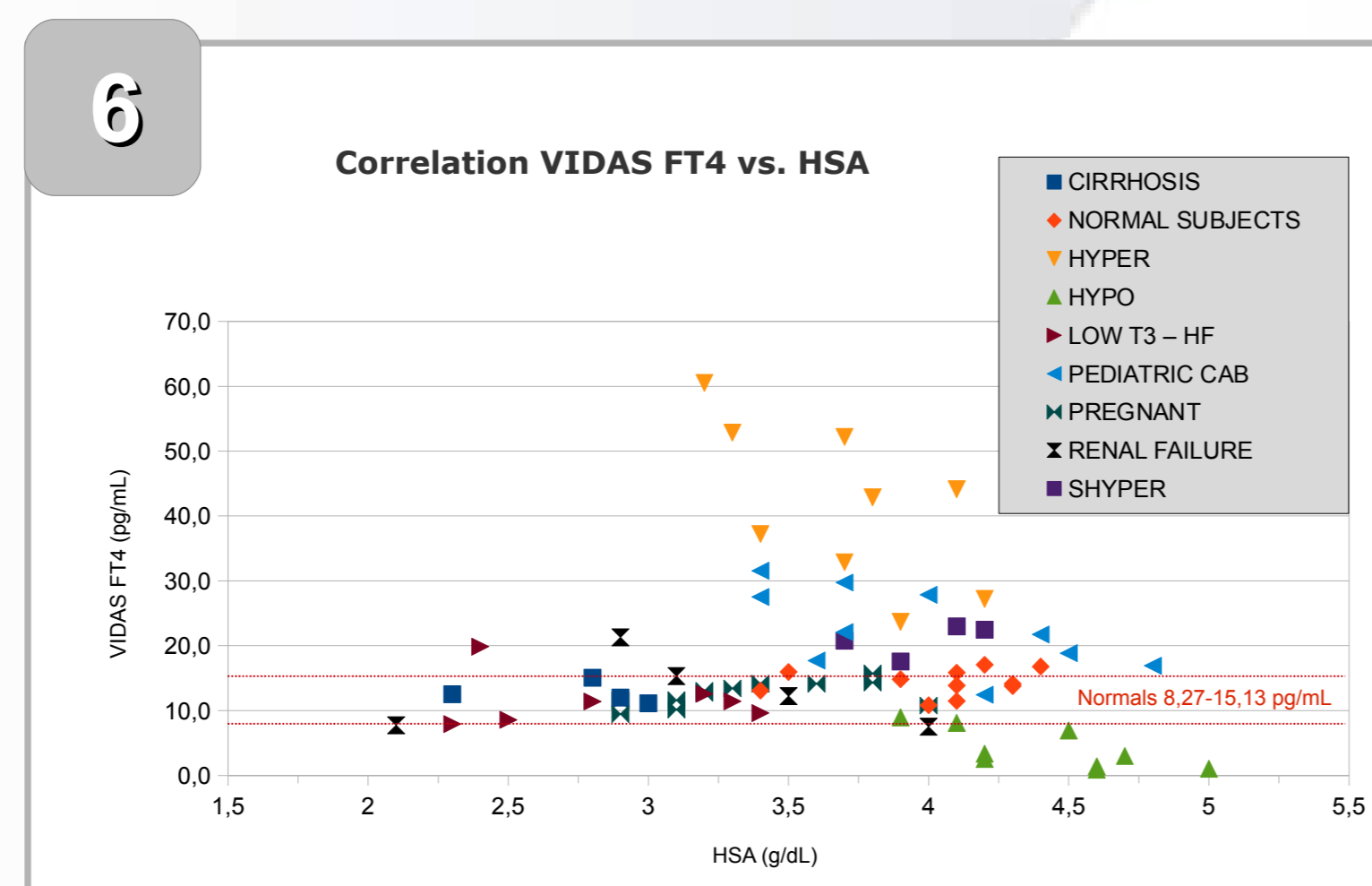
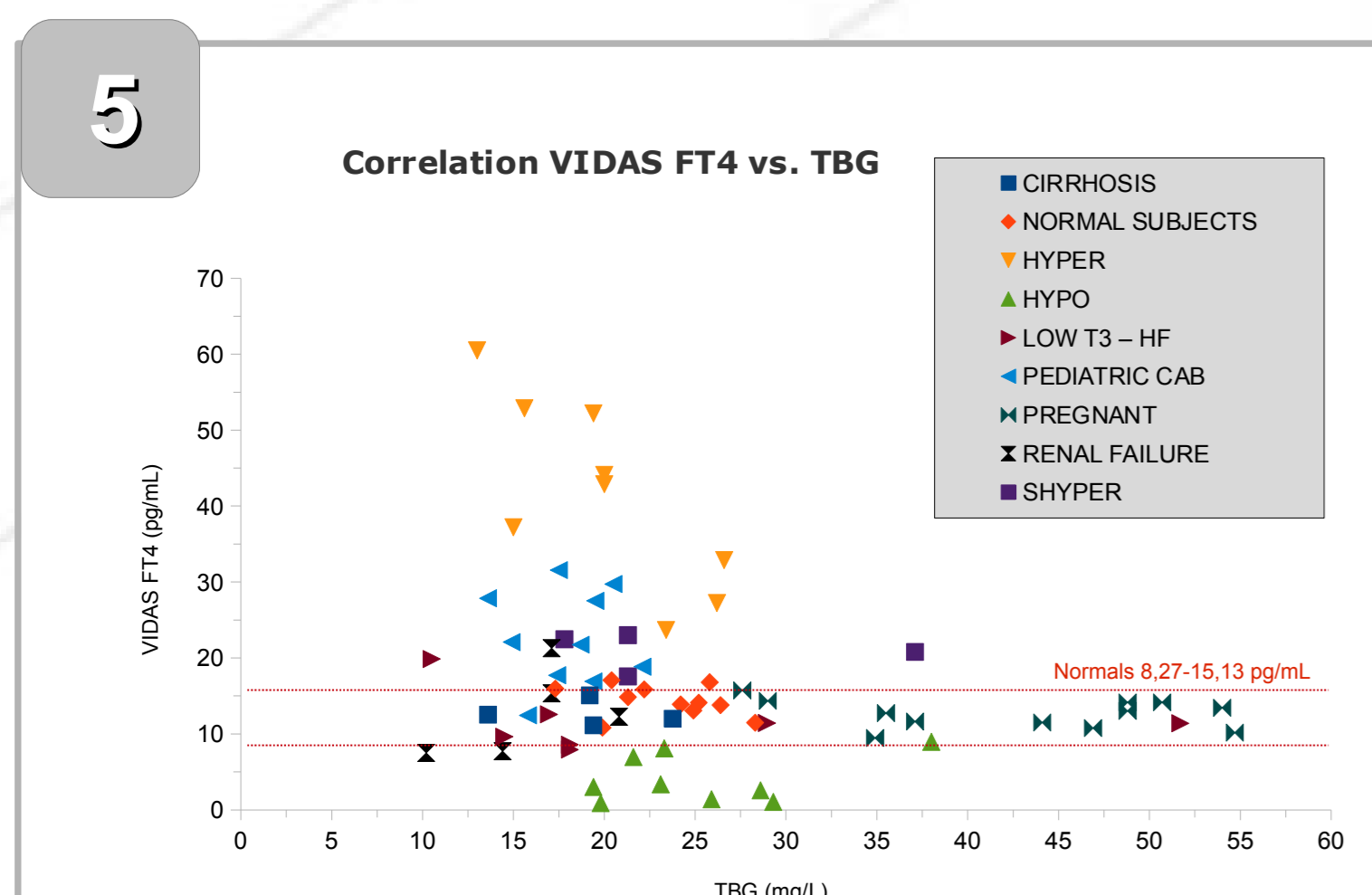


Figure 3-4. Linear regression between the FT4 values measured by:
3 - mini VIDAS and COBAS
4 - mini VIDAS and AIA



The relationship between FT4 measurements and TBG concentration in healthy subjects and patients is shown in **Figure 5**.

The relationship between measurements of FT4 and albumin in healthy subjects and in patients is shown in **Figure 6**. Results confirm good performance when carrier proteins concentrations are altered.

Conclusions

In conclusion, these preliminary data confirm the good analytical and clinical performance of the redeveloped VIDAS-FT4 assay in presence of physiological variations of thyroid hormone binding proteins and in various pathological thyroid conditions.