

# ANALYTICAL PERFORMANCE OF TWO THYROGLOBULIN ASSAYS IN THE LOW RANGE: IMPACT ON CLINICAL DECISION



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**Introduction:** Thyroglobulin (Tg) determination is used for follow-up and monitoring of patients with differentiated cancer of the thyroid. In these patients, Tg levels drop to undetectable (or very low) levels after total or near-total thyroidectomy and successful treatment with radio-labelled iodine. If a rise in Tg levels is observed during the follow-up, it can indicate a recurrence of the cancer. Thus, analytical performance of the different available Tg assays in the lower range of measurement is of importance. Unfortunately, this has been evaluated in very few studies.

**Material and methods:** We used two Tg automated methods:

*-Beckman-Coulter Access*

*-Roche Modular*

These methods are claimed to be *calibrated against the same material (CRM457)*.

Roche claims a limit of detection (LOD) <0.1 ng/mL and a functional sensitivity (FS) <1 ng/mL.

Beckman also claims a LOD of 0.1 ng/mL but is less clear on the FS, even if they claim a CV<10% for concentrations >1 ng/mL.

We thus defined the LOD (value significantly different from zero with a probability of 99.7%) and the FS (lowest value who gave a CV of 20% when low values samples were assayed in triplicates on 5 different days) of the two assays.

Then we defined the beta-expectations tolerance limits for 5 samples free of anti-Tg antibodies ranging from about 0.2 to 2 ng/mL by running them on triplicate during 5 different days.

Finally, we focused on 36 patients presenting low Tg levels (with no anti-Tg antibodies) to compare the results obtained with the two assays.

**Conclusion:**

The performance of the 2 instruments is acceptable in the lower range of Tg assays, but Access presents more robust results.

There is also a calibration problem with the Roche assay, even if claimed to be calibrated against CRM457. The first of the two calibrators used to fit to the Master curve of the instrument is probably too high (around 4 ng/mL) whereas Access uses four calibrators, the first around 1 ng/mL. Results obtained with the 2 methods are not transposable.

	Roche Modular	Beckman-Coulter Access
Limit of Detection (ng/mL)	0.10	0.14
Functionnal Sensitivity (ng/mL)	0.31	0.26
	Mean (upper-lower) beta-expectation tolerance limits (ng/mL)	
Pool 1	0.22 (0.08-0.36)	0.22 (0.19-0.26)
Pool 2	0.40 (0.24-0.57)	0.30 (0.25-0.35)
Pool 3	0.86 (0.70-1.02)	0.47(0.42-0.51)
Pool 4	1.26 (1.04-1.48)	0.74 (0.69-0.78)
Pool 5	1.71 (1.57-1.86)	0.89 (0.80-0.98)

***In other words, a patient presenting a Tg value of 0.30 with the Access could either range fro 0.25 to 0.35 with less than 5% of probability to fall out of this range. Run on Modular, this patient would have a value that could range from 0.24 to 0.57 with a chance greater than 5% to fall out of this range.***