Black Country Pathology Services

Different thyroid assays may substantially affect the diagnosis and management of hypothyroidism

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Introduction:

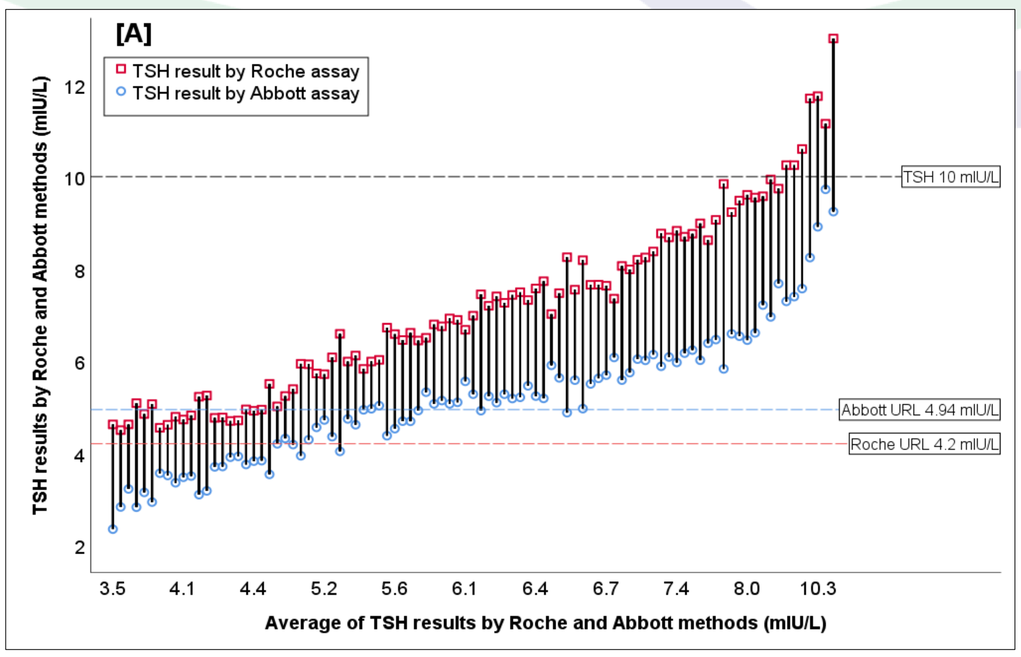
We assessed the commutativity of Roche and Abbott TSH and fT4 assays (used by 75% of clinical laboratories in the UK) in the diagnosis and management of subclinical hypothyroidism (SCH) and primary hypothyroidism on adequate levothyroxine.

Subclinical hypothyroidism discordance study:

- Consecutive SCH patient samples (a raised TSH <10mIU/L and a normal fT4) were identified from primary care from two neighbouring hospital laboratories over 10 days.
- Exclusion criteria: pituitary disease, pregnant women, children (<18 years), and patients taking levothyroxine or anti-thyroid drugs.
- Samples were analysed using a Roche cobas e801 in one laboratory and an Abbott Architect i2000 SR in the other laboratory. Manufacturer provided assay-specific reference intervals were applied for the interpretation of results.
- 93 SCH patients were identified, 40 using the Abbott assay and 53 using the Roche assay over 10 working days.
- Roche TSH and fT4 results were respectively 40±15% and 16±7% higher (p<0.001) compared to the Abbott results.
- Of the total 93 patients, only 41 (44%) were concordant for SCH on both the methods.
- The diagnosis and management of subclinical hypothyroidism is strikingly different when using TSH and fT4 assays provided by Abbott Laboratories and Roche Diagnostics.

Table 1: Comparison of the Roche cobas and Abbott Architect thyroid assays in the diagnosis of subclinical hypothyroidism.

Subclinical hypothyroidism on Roche assays	Analysed using Abbott Assays		
	Normal Thyroid function	Subclinical hypothyroidism	Biochemical indication for thyroxine replacement
n=53	40 (75.5%)	13 (24.5%)	0 (0.0%)
Subclinical hypothyroidism on Abbott assays	**Analysed using Roche Assays**		
	Normal Thyroid function	Subclinical hypothyroidism	Biochemical indication for thyroxine replacement
n=40	0 (0.0%)	28 (70.0%)	12 (30.0%)



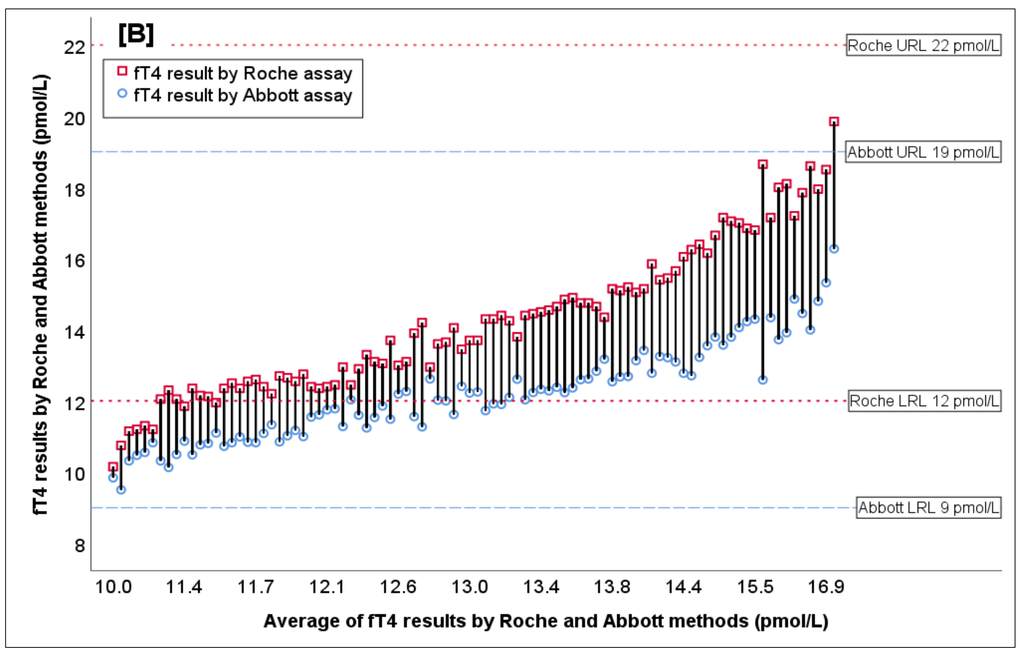


Figure 1: TSH (A) and fT4 (B) results analysed by Roche and Abbott assays on samples with subclinical hypothyroidism on at least one of the two analytical platforms (n=93). URL and LRL are the upper and lower reference limits.

Primary hypothyroidism on adequate levothyroxine replacement discordance study:

- Consecutive samples from primary care patients with primary hypothyroidism and on adequate levothyroxine replacement based on an Abbott Architect i2000 SR TSH were analysed for TSH using a Roche cobas e801.
- A potential 14% difference in levothyroxine replacement decisions in primary hypothyroidism was identified.

Table 2: Comparison of the Roche cobas and Abbott Architect thyroid assays in primary hypothyroidism patients on adequate levothyroxine replacement.

Primary hypothyroidism on adequate levothyroxine on Abbott assays	Analysed using Roche Assays	
	Normal Thyroid function	TSH above the Roche specific upper reference range
n=100	86 (86%)	14 (14%)

Conclusion:

- Between assay differences and variations in manufacturer provided reference ranges significantly affect the diagnosis and management of subclinical hypothyroidism and levothyroxine replacement decisions in primary hypothyroidism.
- The extent of these differences may not be detected by routine method validation studies.