A comparison of four commercial TSH/FT4 test kits for evaluating thyroid function in Han Chinese pregnant women

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Objective: To assess the detection variations of different TSH/FT4 detection kits for evaluating thyroid function during pregnancy and to establish the corresponding normal reference ranges.

Study Design: A total of 200 pregnant women were recruited according to National Academy of Clinical Biochemistry (NACB) standards. Blood samples were sequentially collected from subjects during the first (T1, 9-12 weeks), second (T2, 16-24 weeks) and third (T3, 32-36 weeks) trimesters to test serum TSH and FT4 levels using four different detection kits.

Results: Similar TSH and FT4 dynamic change trends during pregnancy were detected by different kits, indicating the reliability and consistency of the kits. TSH levels were significantly high while FT4 levels were lower in T2 and T3 compared to T1 (for both TSH and FT4, T1 vs. T2: P<0.0001; T1 vs. T3: P<0.0001). Importantly, the detection values of TSH and FT4 showed significant variations among different kits in each trimester (for both TSH and FT4, Abbott vs. Siemens-I: P<0.0001; Abbott vs. Siemens-C: P<0.0001; Abbott vs. Roche: P<0.0001), indicating that specific normal reference ranges should be established for each kit.

Conclusions: TSH and FT4 measurement using four commercial kits showed similar trimester-dependent dynamic changes. However, the detection values of different kits in the same trimester showed significant differences. This study indicates the necessity for establishing trimester-dependent and detection kit-dependent normal reference ranges of TSH and FT4 for thyroid function evaluation.

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