

Evaluation of the Point-of-Care Lateral Flow Thyrotest TSH Utilizing the Holomic Android “Smartphone” Reader Versus the Centaur XP TSH: Whole Blood Versus Plasma

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As technology continues to improve, the feasibility of performing complex laboratory tests on commonly available “smartphone” mobile devices has become a potentially attractive option for point-of-care testing. Indeed, for some time now, complex immunoassays for various hormones and infectious diseases have become commercially available. These lateral flow methods employ visual detection with built in controls and, to a limited extent, provide useful semiquantitative results suitable for screening purposes only. However, part of the lack of reliability of these screening tests is the fact that visually read results lack reproducibility, accuracy, and most importantly, analytical sensitivity at the low end of detection. Indeed, the analytical sensitivity of lateral flow methods is largely determined by the ability of the analyst to discern the presence of a faint band on the device. To address this concern, we have evaluated the “Smartphone Lab” Holomic Android HRDR-200 cell phone (Holomic, Los Angeles, CA) device to read the lateral flow Thyrotest (Thyrometrix, Hatfield Pt., NB E5T 2P8 Canada) for the measurement of thyroid stimulating hormone (TSH). The Holomic lateral flow test device detects TSH as low as 2 mIU/L, well before the visible line appears at 5 mIU/L. We collected whole blood and plasma and compared Holomic Thyrotest (HT) read TSH results on plasma versus whole blood ($\text{Plasma HT-TSH} = 0.67 * \text{WB-HT-TSH} + 0.43$; $R^2 = 0.94$, $n=16$). On comparison of Holomic plasma read TSH versus plasma on the Centaur XP, we obtained the following regression line: $\text{HT-TSH} = 0.54 * \text{Centaur-TSH} + 0.12$, $R^2 = 0.97$, $n=16$; on comparing whole blood with the Centaur, we obtained: $\text{WB-HT-TSH} = 0.37 * \text{Centaur-TSH} + 0.70$, $R^2 = 0.86$, $n=16$. Using our Centaur cutoff for confirmation of primary hypothyroidism of 10 mIU/L, the HT TSH levels showed 100 percent diagnostic agreement with our Centaur TSH method. We conclude that the Holomic device may immerge as a reasonably reliable tool for the assessment of the Thyrotest TSH lateral flow method...especially at low TSH levels where visual detection may be limited.

