Research Article

Thyroid-Stimulating Hormone (TSH) Assay: Evaluation of a Rapid Qualitative Immunochromatographic Method

Nasir A. M. Al-Jurayyan*

Department of Pediatrics (39), College of Medicine and King Khalid University Hospital, King Saud University, P.O. Box 2925, Riyadh 11461, Saudi Arabia

*Corresponding author.

Abstract

A rapid self-performing qualitative method to screen for elevations of Thyroid-Stimulating Hormone (TSH) in serum is evaluated. The method can identify serum samples that contain TSH concentrations of more than 5 mU/L using a solid-phase, two-site immunochromatographic assay. The test is sensitive and specific and can be recommended to screen suspicious cases of primary hypothyroidism in an outpatient setting.

Keywords

Hypothyroidism
Immunochromatography
Serum sample

Introduction

Thyroid-stimulating hormone (TSH) elevation is a sensitive indicator of primary hypothyroidism (Andre and Van Herle, 1990). Many methods have been developed for its determination (Dominici et al., 1986; Toressanl and Scherz, 1986; Travis, 1980). Recently, a one-step, rapid qualitative assay, the so-called ThyroChek (Franklin Diagnostic Inc., 140 Hanover Avenue, Cedar Knolls, NJ 07927, U.S.A.) has been introduced which can identify serum samples that contain TSH in a concentration of more than 5 mU/L. The assay uses a mobile phase murine monoclonal antibody with a colloidal gold label that recognizes a unique epitope on the α-β heterodimer and a second stationary phase antibody that recognizes an amino-acid sequence on the β-subunit (Fig. 1). The present report discusses our experience concerning the evaluation of this method against the enzyme-immunological (Boehringer Mannheim Immunodiagnostics, ES 700) method.

Materials and methods

A hundred samples with known TSH concentrations ranging from <0.01-300 mU/L were assayed in a single blind fashion. Four drops (0.1ml) of serum were added to the well-marked S (specimen) at the end of the cassette. Then, the results were interpreted at 10 minutes. The presence of a horizontal pink line at both the T (Test) and C (Control) site in the cassette window indicates that serum TSH > 5 mU/L, while the presence of a single pink line at the C site alone indicates that serum TSH < 5 mU/L. The test is invalid if no pink line appears at the C site in the cassette windows. Since TSH is a glycoprotein and has an α-chain
identical to that found in Luteinizing Hormone (LH), Follicle-Stimulating Hormone (FSH) and Human Chorionic Gonadotrophin (HCG), therefore, to determine the specificity of the test serum samples (10 each) with normal TSH values (0.5-4 mU/L) which demonstrated variable levels of these hormones were also treated.

Fig. 1: Immunochromatographic TSH assay construction

This method is reliable, sensitive and specific for qualitative screening of serum with TSH > 5 mU/L, and requires only minute amounts of blood. Our data confirmed this, as we demonstrated no false negative or positive results at variable concentrations of TSH. Furthermore, no high-dose hook effect has been seen with serum samples containing TSH at a concentration as high as 300 mU/L, nor there any interference with other glycoprotein hormones that have structural homology with TSH such as LH, FSH and HCG.

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References
