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Research Article

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

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A b s t r a c t

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.

K e y w o r d s

Hypothyroidism

Immunochromatography

Serum sample

Introduction

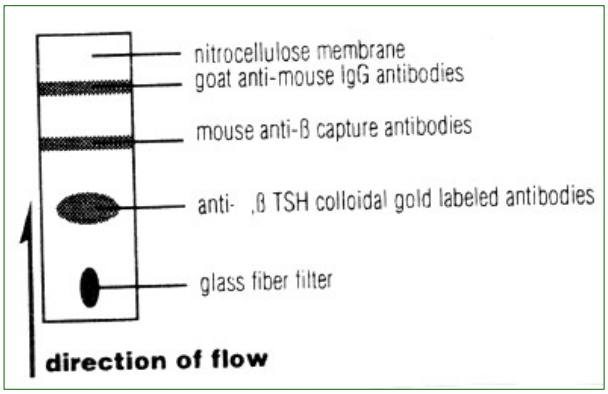
Thyroid-stimulating hormone (TSH) elevation is a sensitive indicator of primary hypothyroidism (Andre and Van Herle, 1990). Many methods have been developed for its determination (Dominici et al., 1986; Toressanl and Scherz, 1986; Travis, 1980). Recently, a one-step, rapid qualitative assay, the so-called 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 discuss 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



Results and discussion

Primary hypothyroidism is a common endocrine disorder affecting all ages. The lack of specific symptoms and signs makes TSH determination the most important tool in the diagnosis and management of thyroid disorders (Andre and Van Herle, 1990; Root, 1993; Daniels and Martin, 1991). During the last two decades, many methods have been developed for TSH determination (Dominici et al., 1986; Toressanl and Scherz, 1986; Travis, 1980).

Logistic and economic considerations, however, make a rapid and self-performing test suitable for screening. The recently introduced method is a rapid, self-performing qualitative assay that uses solid-phase two-site immuno-chromatographic method. When serum is absorbed onto the test strip, it follows through a glass fiber filter onto a nitrocellulose membrane. This exposes the TSH in the serum to the labeled, mobile phase antibody. The serum is wicked laterally by capillary action through pores in the nitrocellulose membrane. Serum passes through the site on the membrane at which the capture antibodies are attached and then continues onto the distal end of the membrane. At this end, ovine antibodies which recognize murine immunoglobulins have been covalently bound to the nitrocellulose membrane. Mobile phase, colloidal gold antibodies bound to TSH will aggregate where they pass through the capture antibodies. This creates a pink line visible to the naked eye in the middle of the membrane. Antibodies not bound to TSH will collect at the distal end of the membrane and be visible as a second pink line. The presence of this line serves as a built-in control and indicates that the immunochromatography has successfully gone to completion.

Use of specific antibody concentrations determines the TSH concentration at which the test is positive, that is the TSH concentration above which the test gives a positive result. Beyond the neonatal period, the normal reference value for TSH is considered to be (0.5-5 mU/L), therefore, cut off concentration of 5 mU/L is used for this assay (Root, 1993; Daniels and Martin, 1991).

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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