

THYROCHEK®

OFF SITE VALIDATION WITH SERUM

Vendors and their clinical customers may want to compare ThyroChek with laboratory standards. In order to facilitate this activity, follow the guidelines below. This guideline is not intended to replace FDA instructions on how to perform ThyroChek in daily practice. ThyroChek is designed to perform with fresh whole blood from a finger stick or blood from a venous draw, preferably using a tube with no additives, the red cap tube. Any chemistry analyzer may be used for validation.

Perform ThyroChek as Directed, using finger stick blood according to FDA approved instructions included with the kit. The result will be positive or negative, indicated by the presence or absence of lines, indicating TSH value greater or less than 5mIU/L.

To validate ThyroChek result using Whole Blood:

The fresh venous blood may be drawn into a collection tube containing common anti coagulants, specifically Heparin or EDTA, tubes with either lavender (purple) or green caps. Any other additives may limit the performance of ThyroChek. Red caps may be used if the blood is used immediately as no preservatives are present. Use one blood drop to perform ThyroChek according to FDA approved instructions.

Send remainder of blood draw to an accredited laboratory for TSH value. A positive result (all lab values over 5mIU/L) will be indicated by 2 lines on ThyroChek. A negative test result, (all lab values below 5mIU/L) will be indicated by 1 line.

To Validate ThyroChek result using Serum:

Serum used must be prepared from a red cap tube only or a source that can be verified to have had no previous additives.

To perform a clinical assessment of ThyroChek using serum:

A graduated pipette is required to perform this assessment.

1. All material must be at room temperature
2. Human serum samples must be prepared as described above
3. Add 20 µl serum (*Note: this is less than half the amount of blood required in daily practice*)
4. Wait 90 seconds
5. Add 4 drops of buffer included with test
6. Read result at 10 minutes

Screening Devices Canada, Inc., manufacturer of ThyroChek, contracts an independent laboratory to assess the visual performance of each production lot against known value human TSH serum samples. Digital images of each tested lot are available on request. Clinical assessment may be performed with any commercial human TSH serum samples.

For further information, contact scunningham@sdcanada.com.

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