Technical Bulletin

Thyrotropin (TSH), DB

Self-Collection and Dried Blood Spot (DBS) Screening System

Performance Characteristics

• Within-Run Precision

Within-run precision was determined by testing dried blood spots containing two concentrations of TSH. Ten DBS samples at each concentration were analyzed ten times within the same run:

Mean TSH (µIU/mL)	Standard Deviation	Coefficient of Variation (%)
1.3	0.07	5.4
5.3	0.24	4.5

• Between-Day Precision (Reproducibility)

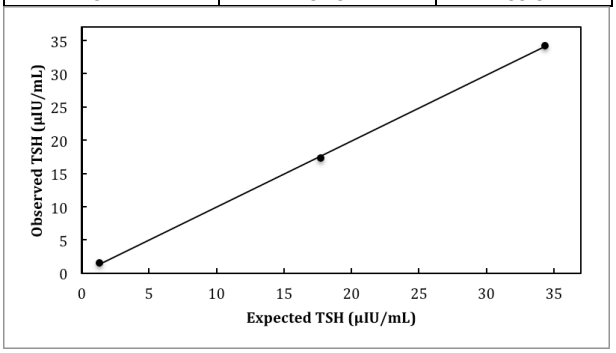
Between-day precision was determined by testing dried blood spots containing two concentrations of TSH. Ten individual DBS samples at each concentration were tested in separate assays during three days:

Mean TSH (µIU/mL)	Standard Deviation	Coefficient of Variation (%)
3.9	0.24	6.2
13.9	0.46	3.3

• Linearity

Whole blood spot containing elevated levels of TSH was diluted with a whole blood spot sample with low levels of TSH. The assay was performed in triplicate:

Observed TSH (µIU/mL)	Expected TSH (µIU/mL)	Recovery (%)
1.4	1.3	107.7
17.3	17.7	97.9
34.2	34.3	99.8



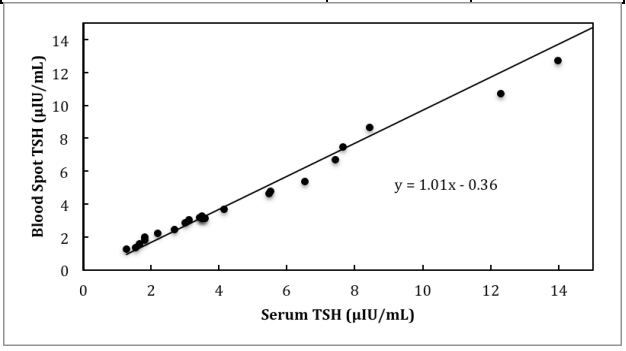
• Dried Blood Spot Sample Stability

Dried blood spot TSH is stable for at least three months when stored at room temperature and for at least one year when stored at -10 °C.

• Accuracy

Paired serum and dried blood spot samples containing varying concentrations of TSH were tested. TSH concentrations observed for the dried blood spot samples versus serum (immunometric method) were statistically analyzed by simple regression:

N=26		
Correlation Coefficient		0.9979
Slope		1.01
Intercept		-0.36
	DBS TSH	Comparable Serum Method
Mean Thyrotropin (TSH)	7.38	7.69
Standard Deviation of Range	9.53	9.46



• Sample Requirements

The COREMEDICA Dried Blood Spot TSH test requires two drops of blood placed on a HemaSpot-HF® blood collection device. The sample is then placed in the return envelope, and mailed to the laboratory for testing.

• Convenience and Simplicity

Simple instructions are provided to the health awareness participant for collection of a blood spot using a finger lancet. The TSH DBS test system requires three simple steps:

1. The collection kit is provided.
2. Participant applies sample onto a HemaSpot-HF® device.
3. Sample is sent to COREMEDICA in provided mailer.

• Test Limitations

The test is performed on a COBAS e411 analyzer using second generation ECL Technology. The detection limit is 0.2 µIU/mL and the method has a functional sensitivity of 0.5 µIU/mL.

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