Technical Bulletin

Blood Cotinine, DBS

Self-Collection Capillary Blood Microsample Method.

Performance Characteristics

● Within-Run Precision

Within-run precision was determined by testing microsamples containing two concentrations of Cotinine. Each of the microsamples was tested ten times:

Cotinine (ng/mL)	Standard Deviation	Coefficient of Variation (%)
105.3 13.0	3.2 1.2	3.0 9.1

● Clinical Sensitivity and Specificity

Clinical sensitivity and specificity were determined by testing paired venous samples and capillary blood microsamples from 30 donors and the results evaluated at a cut-off value of 75 ng/mL:

N=30	Capillary Cotinine Positive	Capillary Cotinine Negative
Venous Cotinine Positive Negative	 7 0	 0 23

● Interpretation

A sample that gives a value equal or greater than the Cotinine cut-off value (75 ng/mL) is interpreted as positive. A positive result from the assay only indicates the presence of Cotinine.

A sample that gives a value less than the Cotinine cut-off value (75 ng/mL) is interpreted as negative. In this case, either the sample does not contain Cotinine or Cotinine is present at concentrations below the cut-off value (75 ng/ mL).

● Microsample Stability

Cotinine dried blood microsamples are stable for two weeks when stored at ambient temperature during regular shipping and handling conditions.

● Limitations

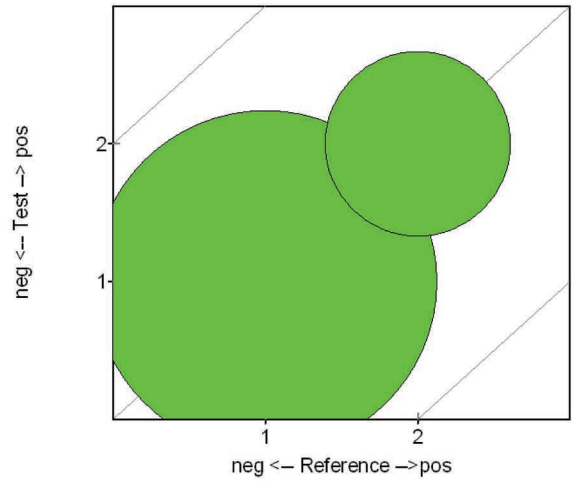
The Cotinine test cannot differentiate between cigarette smoking habits and smoking cessation treatments such as the Nicotine Patch.

● Accuracy

Paired venous samples, and capillary blood microsamples containing varying concentrations of Cotinine, were tested. Cotinine concentration observed for the dried blood microsamples versus venous (homogeneous enzyme immunoassay method) were statistically analyzed using the "score" method.

Agreement	100%
Sensitivity	100%
Specificity	100%
Prevalence*	22.6 %
Negative Predictive Value	100%
Positive Predictive Value	100%

* Prevalence Estimated from Experimental Results



● Sample Requirements

The Cotinine dried blood microsample test requires capillary blood placed into a Microcollection device. The device is then placed in the return box and mailed to the laboratory for analysis.

● Convenience and Simplicity

Simple stepwise instructions are provided to health awareness participants for collection of a Microsample using a finger lancet:

1. The collection kit is provided
2. Participant deposits 5 blood drops into transport device
3. The Microsample is mailed to the laboratory