

BLOOD SPOT TEST SPECIFICATIONS

Insulin

Clinical Information

High fasting insulin levels are a good indicator of insulin resistance, whether or not the patient shows glucose intolerance. Insulin resistance occurs when the cellular response to the presence of insulin is impaired, resulting in a reduced ability of tissues to take up glucose for energy production. Chronically high insulin levels are seen as the body attempts to normalize blood sugar levels. The normal range for fasting insulin is 1 – 15 $\mu\text{IU/mL}$, but levels between 1 and 8 $\mu\text{IU/mL}$ are optimal. Blood levels of insulin 2 hours after a meal are now becoming an important indicator of both diabetes progression and cardiovascular disease risk. In non-diabetics, elevated postprandial insulin may be a better marker of cardiovascular disease risk than fasting insulin. In individuals with diabetes, postprandial levels become lower as diabetes progresses and beta-cell responsiveness deteriorates, indicating worsening of blood sugar control. In non-diabetics, whose pancreatic beta cell function is normal, insulin levels usually return to normal (1-15 $\mu\text{IU/mL}$) within 2 hours after eating a typical breakfast meal. Elevated postprandial insulin levels have been strongly linked with coronary artery disease risk in non-diabetics.

References:

Kapur S, Kapur S, Zava D. Cardiometabolic risk factors assessed by a finger stick dried blood spot method. *J Diabetes Sci Technol* 2008; 2:236-241.

Butter NL, Hattersley AT, Clark PM. Development of a blood spot assay for insulin. *Clin Chim Acta*. 2001;310:141-150.

Shim WS, Kim SK, Kim HJ, et al. Decrement of postprandial insulin secretion determines the progressive nature of type-2 diabetes. *Eur J Endocrinol* 2006;155:615-22.

Karabulut A, Iltumur K, Toprak N, et al. Insulin response to oral glucose loading and coronary artery disease in nondiabetics. *Int Heart J* 2005;46:761-70.

Baltali M, Korkmaz ME, Kiziltan HT, et al. Association between postprandial hyperinsulinemia and coronary artery disease among non-diabetic women: a case control study. *Int J Cardiol* 2003;88:215-21.

Albarak AI, Luzio SD, Chassin LJ, et al. Associations of glucose control with insulin sensitivity and pancreatic beta-cell responsiveness in newly presenting type 2 diabetes. *J Clin Endocrinol Metab* 2002;87:198-203.

Assay Method: ELISA

Intra-assay Precision

Intra-assay precision was determined by choosing three samples spanning the reference range, and analyzing them multiple times within the same run. Results are shown below:

Mean Insulin Concentration ($\mu\text{IU/ml}$)	Standard Deviation	Coefficient of Variation (C.V. %)
5.05	0.37	7.37
10.36	1.05	10.15
13.77	1.34	9.76

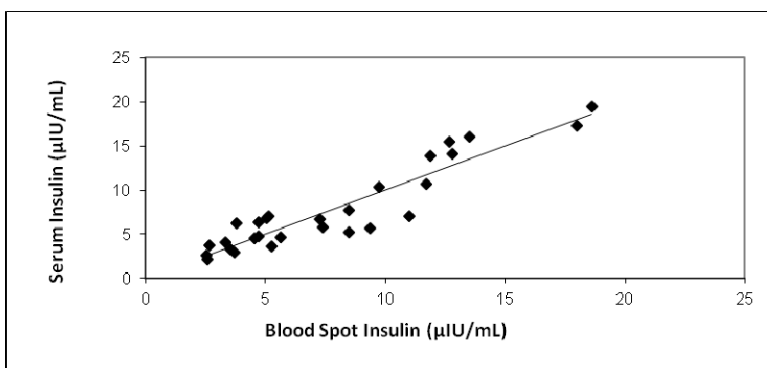
Inter-assay Precision

Inter-assay precision was determined by choosing three samples spanning the reference range, and analyzing them multiple times throughout different runs. Results are shown below:

Mean Insulin Concentration ($\mu\text{IU/ml}$)	Standard Deviation	Coefficient of Variation (C.V. %)
3.7	0.34	9.1
5.5	0.46	8.5
23.0	3.68	16.0

Accuracy

To test the accuracy of the dried blood spot assay for insulin, dried blood spot samples collected at the same time as corresponding serum samples were analyzed by linear regression. Resulting correlation data are shown below ($R = 0.93$):



Analyte Stability

The dried blood spot samples are stable for more than 1 month at room temperature.

Specimen Collection

Kits for blood spot collection contain a filter paper collection card, finger lancets, an alcohol prep pad, sterile gauze, a band-aid, easy-to-follow instructions, and a mailer to return the sample for analysis.