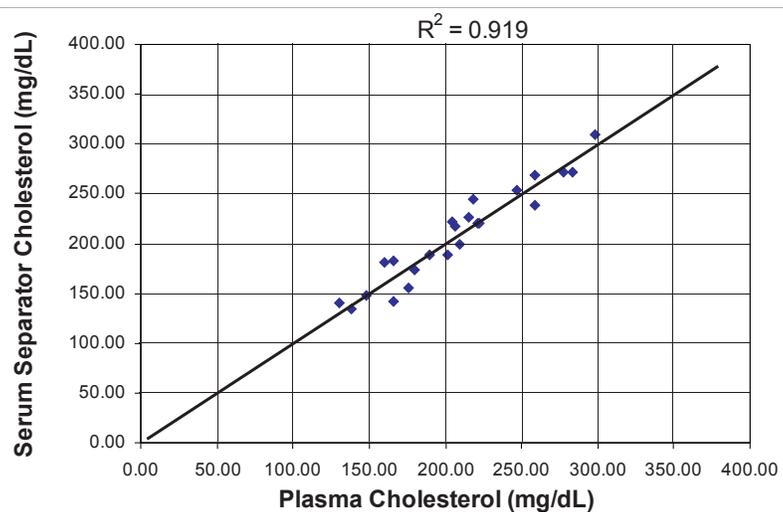


Total Cholesterol Performance Characteristics Using the AdvanceDx 100 Serum Collection Card

Whole Blood collected on the AdvanceDx 100 Serum collection card paired with serum collected by venipuncture were assayed on the Beckman Coulter Synchron CX9 Pro clinical Systemc chemistry analyzer. The amount of the total cholesterol in mg/dL was plotted and the paired concentrations were compared using linear regression analysis.

Correlation Coefficient (R)	0.9586
Slope	1.381
Intercept	3.10



The AdvanceDx 100 collection card is intended for screening purposes for various clinically significant abnormal analytes. This Technical Bulletin pertains to whole blood using the AdvanceDx 100 collection card followed by laboratory testing of the total cholesterol levels.

The Cholesterol blood Test is used to check the levels of the waxy, fatlike substance that is naturally present in cell walls or membranes everywhere in the body. The body uses cholesterol to produce many hormones, vitamin D, and the bile acids that help to digest fat. If the body has too much cholesterol in the bloodstream, the excess may be deposited in the arteries of the heart, which could lead to heart disease.

Reportable Range

When used correctly, the AdvanceDx 100 collection card for cholesterol allows for detection of low concentrations down to 20 mg/dL or as high as 4000 mg/dL.

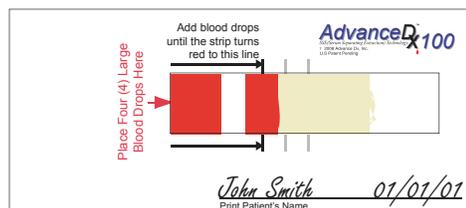
Reference Range

Less than 200 mg/dL

No significant interference by bilirubin, hemolysis or lipemia. In very rare cases gammopathy, in particular, IgM Waldenstrom's Macroglobulinemia may cause unreliable results.

Specimen Requirements

The AdvanceDx 100 collection card requires approximately four (4) drops of capillary blood placed in the clearly marked application point on the collection card. Blood is placed until the red blood cells reach an easy to read mark identified on the card. The card is air dried and then placed in an envelope containing an oxygen scrubber and mailed back to the laboratory. An illustrated instruction guide is included with each AdvanceDx 100 collection card.



Card Stability

The unused AdvanceDx 100 collection card is stable when kept from extremes in humidity and temperature for greater than 2 years.

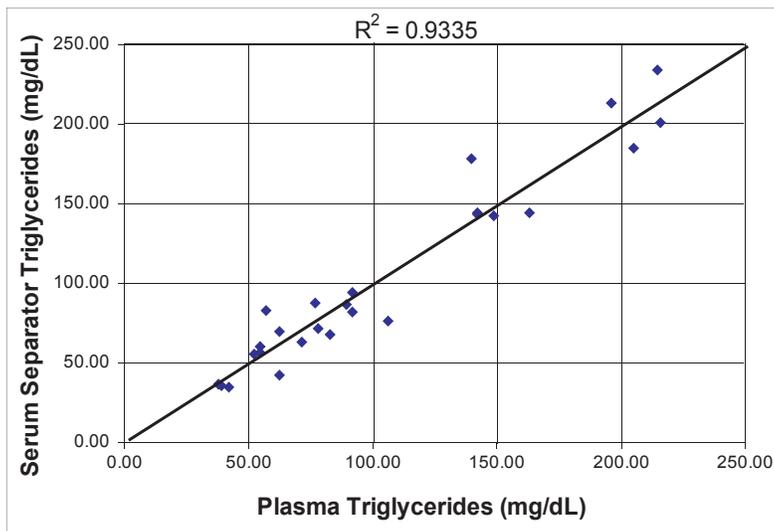
Specimen Stability

Lipid samples were accelerated to 40° C inside the special AdvanceDx 100 collection foil pouch. Subsequent testing showed no change indicating that lipid samples are stable with no change when transported or kept at room temperature or below for at least 28 days.

Triglyceride Performance Characteristics Using the AdvanceDx 100 Serum Collection Card

Whole Blood collected on the AdvanceDx 100 Serum collection card paired with serum collected by venipuncture were assayed on the Beckman Coulter Synchron CX9 Pro clinical Systemc chemistry analyzer. The amount of the triglycerides in mg/dL was plotted and the paired concentrations were compared using linear regression analysis.

Correlation Coefficient (R) 0.9662
Slope 1.2881
Intercept 0.52



The AdvanceDx 100 collection card is intended for screening purposes for various clinically significant abnormal analytes. This Technical Bulletin pertains to whole blood using the AdvanceDx 100 collection card followed by laboratory testing of the triglyceride levels.

The Triglyceride blood test is used to check the levels of one type of fat that comes from certain foods. Triglycerides can also be made and stored in the body and used as an energy source. High levels of triglycerides in the blood may mean that there is excess carbohydrate or fat in the diet. Hypertriglyceridemia (high levels of triglycerides) has been associated with coronary heart disease especially when elevated triglycerides are concomitantly observed with unhealthy low levels of HDL (hyper-density lipoproteins) otherwise known as "good cholesterol".

Reportable Range

When used correctly, the AdvanceDx 100 collection card for triglycerides allows for detection of low concentrations down to 20 mg/dL or as high as 5000 mg/dL.

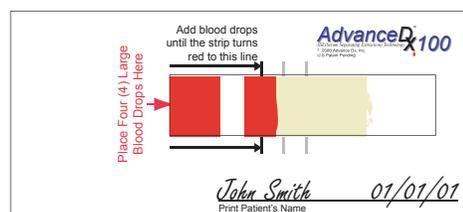
Reference Range

Less than 150 mg/dL

No significant interference by bilirubin, hemolysis or lipemia. In very rare cases gammopathy, in particular, IgM Waldenstrom's Macroglobulinemia may cause unreliable results.

Specimen Requirements

The AdvanceDx 100 collection card requires approximately four (4) drops of capillary blood placed in the clearly marked application point on the collection card. Blood is placed until the red blood cells reach an easy to read mark identified on the card. The card is air dried and then placed in an envelope containing an oxygen scrubber and mailed back to the laboratory. An illustrated instruction guide is included with each AdvanceDx 100 collection card.



Card Stability

The unused AdvanceDx 100 collection card is stable when kept from extremes in humidity and temperature for greater than 2 years.

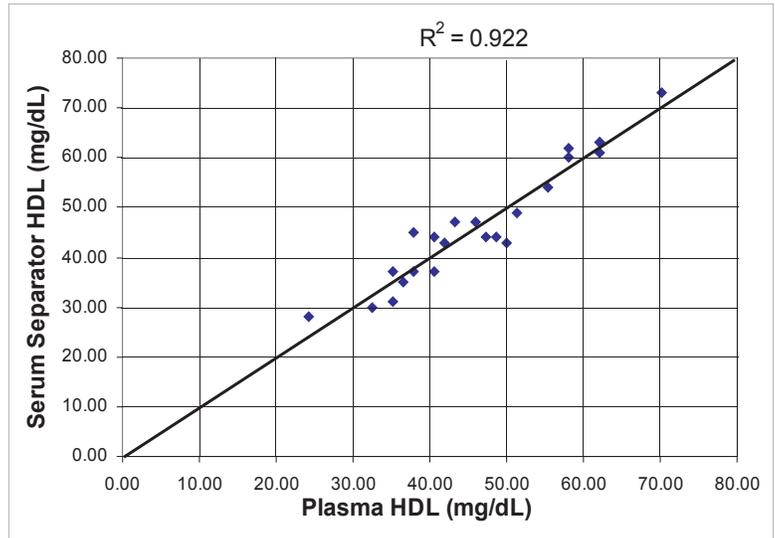
Specimen Stability

Lipid samples were accelerated to 40° C inside the special AdvanceDx 100 collection foil pouch. Subsequent testing showed no change indicating that lipid samples are stable with no change when transported or kept at room temperature or below for at least 28 days.

High Density Lipoprotein (HDL) Performance Characteristics Using the AdvanceDx 100 Serum Collection Card

Whole Blood collected on the AdvanceDx 100 Serum collection card paired with serum collected by venipuncture were assayed on the Beckman Coulter Synchron CX9 Pro clinical Systemc chemistry analyzer. The amount of the high density lipoprotein (HDL) in mg/dL was plotted and the paired concentrations were compared using linear regression analysis.

Correlation Coefficient (R) 0.9602
Slope 1.351
Intercept 4.05



The AdvanceDx 100 collection card is intended for screening purposes for various clinically significant abnormal analytes. This Technical Bulletin pertains to whole blood using the AdvanceDx 100 collection card followed by laboratory testing of the high density lipoprotein (HDL) levels.

The High Density Lipoprotein (HDL) blood Test is used to check the levels of the form of lipoproteins, varying somewhat in their size (8–11 nm in diameter), that carry cholesterol from the body's tissues to the liver. About thirty percent of blood cholesterol is carried by HDL. High levels are associated with a decreased risk of atherosclerosis and coronary heart disease.

Reportable Range

When used correctly, the AdvanceDx 100 collection card for high density lipoprotein (HDL) allows for detection of low concentrations down to 20 mg/dL or as high as 500 mg/dL.

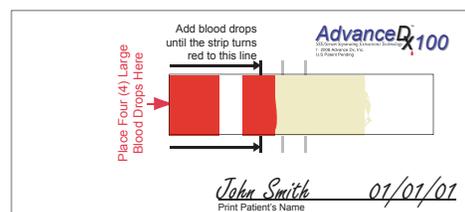
Reference Range

Greater than 40 mg/dL

No significant interference by bilirubin, hemolysis or lipemia. In very rare cases gammopathy, in particular, IgM Waldenstrom's Macroglobulinemia may cause unreliable results.

Specimen Requirements

The AdvanceDx 100 collection card requires approximately four (4) drops of capillary blood placed in the clearly marked application point on the collection card. Blood is placed until the red blood cells reach an easy to read mark identified on the card. The card is air dried and then placed in an envelope containing an oxogen scrubber and mailed back to the laboratory. An illustrated instruction guide is included with each AdvanceDx 100 collection card.



Card Stability

The unused AdvanceDx 100 collection card is stable when kept from extremes in humidity and temperature for greater than 2 years.

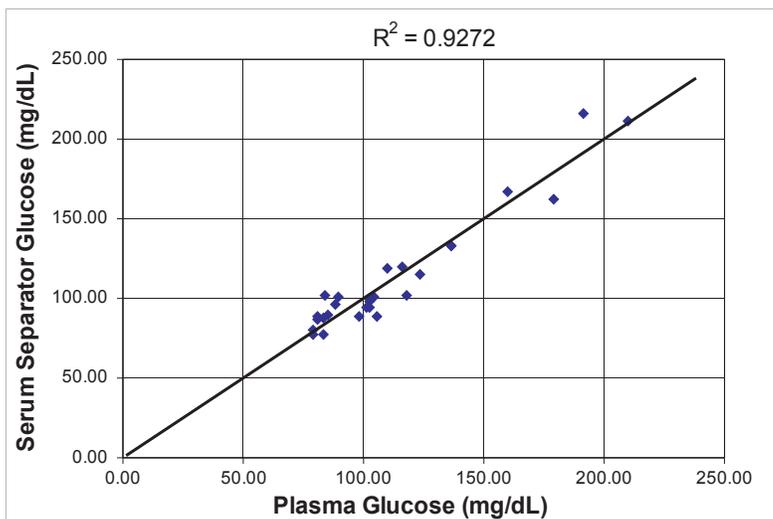
Specimen Stability

Lipid samples were accelerated to 40° C inside the special AdvanceDx 100 collection foil pouch. Subsequent testing showed no change indicating that lipid samples are stable with no change when transported or kept at room temperature or below for at least 28 days.

Glucose Performance Characteristics Using the AdvanceDx 100 Serum Collection Card

Whole Blood collected on the AdvanceDx 100 Serum collection card paired with serum collected by venipuncture were assayed on the Beckman Coulter Synchron CX9 Pro clinical Systemc chemistry analyzer. The amount of glucose in mg/dL was plotted and the paired concentrations were compared using linear regression analysis.

Correlation Coefficient (R)	0.963
Slope	1.064
Intercept	23.52



The AdvanceDx 100 collection card is intended for screening purposes for various clinically significant abnormal analytes. This Technical Bulletin pertains to finger stick collected blood on the AdvanceDx 100 collection card compared to automated clinical chemistry analyzer for glucose levels.

A blood glucose test measures the amount of a type of sugar, called glucose, in your blood. Glucose comes from carbohydrate foods. It is the main source of energy used by the body. Normally, your blood glucose levels increase slightly after you eat. This increase causes your pancreas to release insulin so that your blood glucose levels do not get too high. Disorders in sugar metabolism such as Diabetes cause an increase in blood glucose. Blood glucose levels that remain high over time can damage your eyes, kidneys, nerves, and blood vessels.

Reportable Range

When used correctly, the AdvanceDx 100 collection card for glucose allows for detection of low concentrations down to 30 mg/dL or as high as 1400 mg/dL.

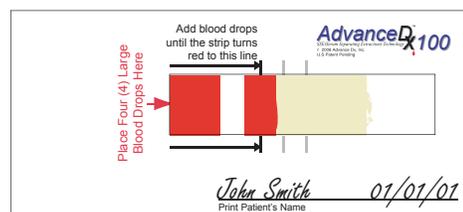
Reference Range

70 to 115 mg/dL

No significant interference by bilirubin, hemolysis or lipemia. In very rare cases gammopathy, in particular, IgM Waldenstrom's Macroglobulinemia may cause unreliable results.

Specimen Requirements

The AdvanceDx 100 collection card requires approximately four (4) drops of capillary blood placed in the clearly marked application point on the collection card. Blood is placed until the red blood cells reach an easy to read mark identified on the card. The card is air dried and then placed in an envelope containing an oxygen scrubber and mailed back to the laboratory. An illustrated instruction guide is included with each AdvanceDx 100 collection card.



Card Stability

The unused AdvanceDx 100 collection card is stable when kept from extremes in humidity and temperature for greater than 2 years.

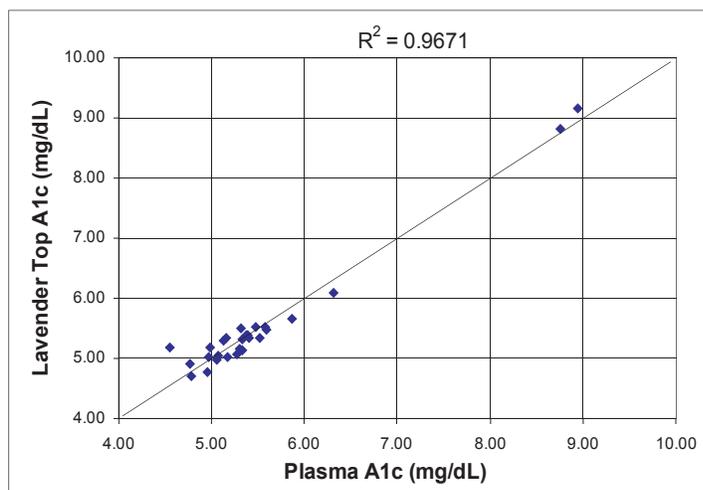
Specimen Stability

Glucose samples were accelerated to 40° C inside the special AdvanceDx 100 collection foil pouch. Subsequent testing showed no change indicating that glucose samples are stable with no change when transported or kept at room temperature or below for at least 28 days.

Hemoglobin A1c (hbA1c) Performance Characteristics Using the AdvanceDx 100 Collection Card

Whole Blood collected on the AdvanceDx 100 collection card paired with whole blood collected by venipuncture were assayed on the Beckman Coulter Synchron CX9 Pro clinical chemistry analyzer. The amount of the hemoglobin A1c (hbA1c) in percent was plotted and the paired concentrations were compared using linear regression analysis.

Correlation Coefficient (R)	0.9834
Slope	1.1199
Intercept	0.9712



The AdvanceDx 100 collection card is intended for screening purposes for various clinically significant abnormal analytes. This Technical Bulletin pertains to finger stick collected whole blood using the AdvanceDx 100 collection card followed by laboratory testing of Hemoglobin A1c (HbA1c).

Hemoglobin (Hb) consists of four protein chains with four heme portions, and is the red-pigmented protein located in the erythrocytes. HbA1c is formed by the nonenzymatic reaction of glucose with the N-terminal amino group of the β -chain of normal adult Hb (HbA). In the erythrocytes, the relative amount of HbA converted to stable HbA1c increases with the average concentration of glucose in the blood. The conversion to stable HbA1c is limited by the erythrocyte's life span of approximately 100 to 120 days. As a result, HbA1c reflects the average blood glucose level during the preceding 2 to 3 months. HbA1c is thus suitable to monitor long-term blood glucose control in individuals with diabetes mellitus. A fasting sample is not required.

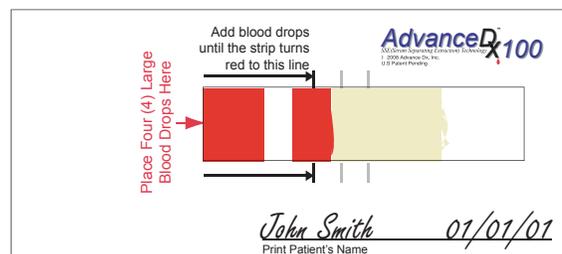
Reportable Range 2% -20%.

Reference Range Less than 6.0% (Diabetics less than 7.0)

Any cause of shortened erythrocyte survival will reduce exposure of erythrocytes to glucose with a consequent decrease in HbA1c (%) values, even though the time-averaged blood glucose level may be elevated. Causes of shortened erythrocyte lifetime might be hemolytic anemia or other hemolytic diseases, homozygous sickle cell trait, pregnancy, recent significant or chronic blood loss. HbA1c values may not accurately reflect mean blood glucose in patients with Hb variants. Glycated HbF (fetal hemoglobin) is not detected as it does not contain the glycated β -chain that characterizes HbA1c. As a consequence, specimens containing high amounts of HbF (>10%) may yield lower than expected HbA1c results. Specimens containing HbS (sickle cell trait) and HbC variants may yield higher than expected HbA1c results.

Specimen Requirements

The AdvanceDx 100 collection card requires approximately four (4) drops of capillary blood placed in the clearly marked application point on the collection card. Blood is placed until the red blood cells reach an easy to read mark identified on the card. The card is air dried and then placed in an envelope containing an oxygen scrubber and mailed back to the laboratory. An illustrated instruction guide is included with each AdvanceDx 100 collection card.



Card Stability

The unused AdvanceDx 100 collection card is stable when kept from extremes in humidity and temperature for greater than 2 years.

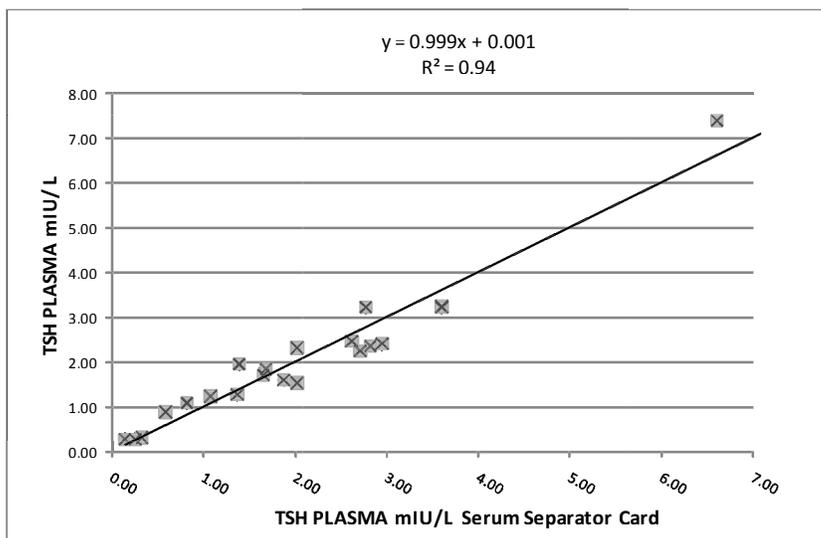
Specimen Stability

HbA1c samples were accelerated to 40° C inside the special AdvanceDx 100 collection foil pouch. Subsequent testing showed no change indicating that hbA1c samples are stable with no change when transported or kept at room temperature or below for at least 28 days.

Thyroid Stimulating Hormone (TSH) Performance Characteristics Using the AdvanceDx 100 Serum Collection Card

Whole Blood collected on the AdvanceDx 100 Serum collection card paired with serum collected by venipuncture were assayed on the ADVIA Centaur Analyzer. The amount of TSH in mIU/L was plotted and the paired concentrations were compared using linear regression analysis.

Correlation Coefficient (R) 0.9695
Slope 0.9999
Intercept 0.001



The AdvanceDx 100 collection card is intended for screening purposes for various clinically significant abnormal analytes. This Technical Bulletin pertains to whole blood using the AdvanceDx 100 collection card followed by laboratory testing of Thyroid Stimulating Hormone (TSH).

A thyroid-stimulating hormone (TSH) blood test is used to check for thyroid gland problems. TSH is produced when the hypothalamus releases a substance called thyrotropin releasing hormone (TRH). TRH then triggers the pituitary gland to release TSH. TSH causes the thyroid gland to make two hormones: triiodothyronine (T3) and thyroxine (T4). T3 and T4 help control your body's metabolism.

Reportable Range

When used correctly, the AdvanceDx 100 collection card for TSH allows for detection of low concentrations down to 0.27 mIU/L or as high as 100 mIU/L.

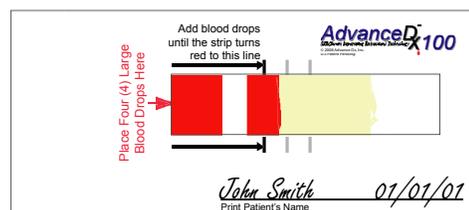
Reference Range

0.27 mIU/mL - 4.2 mIU/mL

The assay is unaffected by icterus (bilirubin <701 μ mol/L or <41 mg/dL), hemolysis (Hb <0.621 mmol/L or <1 g/dL), lipemia (Intralipid <1500 mg/dL), and biotin <102 nmol/L or <25 ng/mL.

Specimen Requirements

The AdvanceDx 100 collection card requires approximately four (4) drops of capillary blood placed in the clearly marked application point on the collection card. Blood is placed until the red blood cells reach an easy to read mark identified on the card. The card is air dried and then placed in an envelope containing a desiccant and mailed back to the laboratory. An illustrated instruction guide is included with each AdvanceDx 100 collection card.



Card Stability

The unused AdvanceDx 100 collection card is stable when kept from extremes in humidity and temperature for greater than 2 years.

Specimen Stability

Whole blood collected on the AdvanceDx 100 collection card is stable for 30 days when stored in the supplied envelope when used for the Thyroid Stimulating Hormone (TSH) analysis.