The Clarity Urinalysis Reagent Strips (Urine) are for the qualitative and semi-quantitative detection of the following analytes in urine: Glucose, Ketone, Protein, Ketone, Blood and Nitrite. This test is based on the enzymatic reaction that occurs between glucose oxidase and hydrogen peroxide in the presence of peroxidase. The extent to which the color is oxidized determines the color which is produced, ranging from green to brown according to the amount of glucose in the specimen. Small amounts of glucose may be detected by the kidney. Glucose concentrations as low as 0.5 mg/dL may be detected by the kidney.

Ketone: This test is based on ketones reacting with ninhydrin and acetic acid to produce a color reaction, which may be negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may be found in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in diabetics, ketone production may be increased as high as 100 mmol/L. In the urine of menstruating females, ketones may be found in the urine. Small amounts of glucose may be detected by the kidney. Glucose concentrations as low as 0.5 mg/dL may be detected by the kidney.

INTENDED USE
The Clarity Urinalysis Reagent Strips (Urine) are for the qualitative and semi-quantitative detection of the following analytes in urine: Glucose, Ketone, Protein, Ketone, Blood and Nitrite. This test is based on the enzymatic reaction that occurs between glucose oxidase and hydrogen peroxide in the presence of peroxidase. The extent to which the color is oxidized determines the color which is produced, ranging from green to brown according to the amount of glucose in the specimen. Small amounts of glucose may be detected by the kidney. Glucose concentrations as low as 0.5 mg/dL may be detected by the kidney.

Ketone: This test is based on ketones reacting with ninhydrin and acetic acid to produce a color reaction, which may be negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may be found in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in diabetics, ketone production may be increased as high as 100 mmol/L. In the urine of menstruating females, ketones may be found in the urine. Small amounts of glucose may be detected by the kidney. Glucose concentrations as low as 0.5 mg/dL may be detected by the kidney.

Ketone: This test is based on ketones reacting with ninhydrin and acetic acid to produce a color reaction, which may be negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may be found in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in diabetics, ketone production may be increased as high as 100 mmol/L. In the urine of menstruating females, ketones may be found in the urine. Small amounts of glucose may be detected by the kidney. Glucose concentrations as low as 0.5 mg/dL may be detected by the kidney.

Ketone: This test is based on ketones reacting with ninhydrin and acetic acid to produce a color reaction, which may be negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may be found in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in diabetics, ketone production may be increased as high as 100 mmol/L. In the urine of menstruating females, ketones may be found in the urine. Small amounts of glucose may be detected by the kidney. Glucose concentrations as low as 0.5 mg/dL may be detected by the kidney.

Ketone: This test is based on ketones reacting with ninhydrin and acetic acid to produce a color reaction, which may be negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may be found in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in diabetics, ketone production may be increased as high as 100 mmol/L. In the urine of menstruating females, ketones may be found in the urine. Small amounts of glucose may be detected by the kidney. Glucose concentrations as low as 0.5 mg/dL may be detected by the kidney.

Ketone: This test is based on ketones reacting with ninhydrin and acetic acid to produce a color reaction, which may be negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may be found in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in diabetics, ketone production may be increased as high as 100 mmol/L. In the urine of menstruating females, ketones may be found in the urine. Small amounts of glucose may be detected by the kidney. Glucose concentrations as low as 0.5 mg/dL may be detected by the kidney.

Ketone: This test is based on ketones reacting with ninhydrin and acetic acid to produce a color reaction, which may be negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may be found in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in diabetics, ketone production may be increased as high as 100 mmol/L. In the urine of menstruating females, ketones may be found in the urine. Small amounts of glucose may be detected by the kidney. Glucose concentrations as low as 0.5 mg/dL may be detected by the kidney.
La prueba se basa en la reacción química que ocurre cuando la glucosa se oxida para producir ácido aldehídico; el ácido aldehídico reacciona con un reagente químico para formar un azul colorante. Con este colorante se puede medir la concentración de glucosa en la orina.

**MATERIALES**
- **Cuencas Céticas**: tamaño 36 x 36 mm, con suficiente espacio para el uréter y la uretra.

**REAGENTES Y PERFORMANCIA**
La prueba es sensible para concentraciones de glucosa de 200 mg/dl. Los resultados se deben leer dentro de 10 minutos después del inicio del reaccionamiento. Los resultados no son afectados por la variación de la concentración del buffer en la orina.

**INTERPRETACIÓN DE LOS RESULTADOS**
Los resultados obtenidos se comparan con una tablas de valores normales y se consideran positivos si la concentración de glucosa es mayor a 100 mg/dl.

**RESUMEN**
La prueba es simple, rápida y precisa para la detección de glucosa en la orina, lo que la convierte en una herramienta esencial en el diagnóstico de enfermedades como la diabetes mellitus.

**CUIDADOS**
- **Nota**: para un resultado preciso, los resultados deben ser interpretados en el rango de pH 4.5-8.5, con un pH óptimo alrededor de 6.0.

**ALMACENAMIENTO Y ESTABILIDAD**
- **Reactivos**: se deben almacenar en un lugar fresco y se deben usar antes de la fecha de expiración.
- **Material de prueba**: se deben almacenar a temperatura ambiente y se deben usar antes de la fecha de expiración.

**NOTAS**
- **Accesorios**: se pueden utilizar en orina fresca, salvia, orina de bebé y orina de recién nacido.
- **Archivos**: se deben mantener registros de todos los casos positivos, así como las muestras de referencia para comparación.

**ACCESORIOS**
- **Material de prueba**: urina fresca, saliva, orina de bebé, orina de recién nacido.
- **Archivos**: registros de casos positivos, muestras de referencia.

**CÓDIGO DE CLASIFICACIÓN**
C.07.14.1

---

**Nota**: todos los procedimientos descritos en este folleto fueron desarrollados por los médicos, farmacéuticos y técnicos de laboratorio de Clarity Diagnostics. No se deben realizar cambios en estos procedimientos sin la aprobación de Clarity Diagnostics.