**INTENDED USES**

The McKesson CONSULT® 121-10SG Urine Reagent Strips are for the qualitative and semi-quantitative detection of certain constituents in human urine. The test is based on the use of a strip containing sensitive reagents that react with specific components of the urine sample to produce a visible change in color. The reagents are intended for use in screening for pathologies or specific disease states in the urine of hospitalized or ambulatory patients. The strips are intended for use in screening for nitrite and other substances in the urine of hospitalized or ambulatory patients. The strips are not intended for use in the diagnosis of any specific pathologies.

**SUMMARY**

Nitrite is produced in the body by anaerobic bacteria and is normally absent from urine. Elevated nitrite levels in urine can be found from various causes, such as, a part of proper health screening. The McKesson CONSULT® 121-10SG Urine Reagent Strips can be used as a rapid test for the detection of nitrite in urine. Nitrite levels are elevated in urine from patients with various conditions, including urinary tract infections, metabolic disorders, and certain diseases.

**REAGENTS AND PERFORMANCE CHARACTERISTICS**

Nitrite: This test is based on a modified Ehrlich reaction between p-diethylaminobenzaldehyde and nitrites to produce a pink to purple color. The sensitivities of this test are reduced for urine specimens with highly buffered urine. The presence of azo-compounds or low urine pH may inhibit color formation. Microbial activity may cause false positive results. Urine specimens containing high concentrations of ascorbic acid may inhibit color formation. The sensitivity of this test is reduced for urine specimens with highly buffered urine.

**INTERPRETATION OF RESULTS**

Positive—blood: +2 blocks (≥ 50 mg/dL) or +3 blocks (≥ 100 mg/dL). Negative—blood: -2 blocks (≤ 20 mg/dL).

**QUALITY CONTROL**

The performance of this test is subject to the following limitations:

- The presence of certain substances in the urine may cause interference with the test results.
- The presence of certain substances in the urine may cause false-positive results.
- The presence of certain substances in the urine may cause false-negative results.
- The presence of certain substances in the urine may cause variations in the test results.
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