

JUL 22 1996

K954685/AS

510k Summary

Date of Summary: July 2, 1996

DUPLICATE

Product Name:

Uri-Test - Nitrite in Urine

Product Brand Name:

Health Check - Health Check is a subsidiary of TCPI

Sponsor's Name:

TCPI - Technical Chemical and Products, Inc.

2241 SOUTH W. 15th ST.

POMPANO BEACH, FL 33069

CORRESPONDENT:

MDC ASSOCIATES

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SUBSTANTIALLY EQUIVALENT DEVICES:

Product: MULTISTIX- Reagent Strip for Urinalysis

Manufactured by: Bayer Diagnostics

Product: CHEMSTRIP - Urine Test Strip

Manufactured by: Boehringer Mannheim

PRODUCT DESCRIPTION:

UriTest - Nitrite in Urine is a reagent strip test used to measure the presence of Nitrite in urine. Nitrite is produced by most organisms commonly associated with urinary tract infection. Nitrite is used to detect urinary tract infection.

INTENDED USE:

UriTest- Nitrite in Urine is a nonquantitative test to identify nitrite in urine. Nitrite identification is used for the detection of Urinary Tract Infection.

SUMMARY OF TECHNOLOGY:

Like the predicate device, UriTest Nitrite in Urine test strips are impregnated with the appropriate chemicals (25% w/w Arsanilic Acid, 10% w/w N-1-Naphthylethyldiamine Dihydrochloride, 65% w/w Tartaric Acid). Nitrite if present in patient urine reacts with amine to give an diazonium salt, which couples sulfanilamide to yield a positive pink - red reaction.

PERFORMANCE DATA:

A clinical trial was done to compare the performance of the UriTest to the Bayer Multistix. These data clearly demonstrate that the performance of the Uritest is substantially equivalent to the predicate device; Bayer Multistix.

**Bayer vs. UriTest
(Professional User)**

	Bayer +	Bayer -
TCPI +	16	7
TCPI -	0	78

Sensitivity = 100.00%
Specificity = 91.76%
Accuracy = 93.07%

**Bayer vs. UriTest
(Lay User)**

	Bayer +	Bayer -
TCPI +	16	9
TCPI -	0	76

Sensitivity = 100.00%
Specificity = 89.41%
Accuracy = 91.09%

To assure a sufficient number of positive specimens, a urine sample was spiked with bacteria. Spiked specimens were tested with both the UriTest - Nitrite in Urine and the Bayer Multistix. 100% agreement was observed.

Spiked Samples

	Bayer +	Bayer -
TCPI +	33	0
TCPI -	0	0

Sensitivity = 100.00%
Specificity = Not Valid
Accuracy = 100.00%

STATEMENT OF SAFETY AND EFFICACY:

When compared to a Bayer Multistix and performed by untrained consumers, the product performance was as follows:

Sensitivity - 100%
Specificity - 89%
Accuracy - 90%

These data clearly demonstrate the safety and efficacy of the Uri-Test-Nitrite in Urine.

Technical Chemical and Products, Inc. confirm that any/all data provided in this submission may be released upon request.