INTENDED USE:
Urine Reagent Strips-1B provide a semi-quantitative determination for the presence and concentration of occult blood in urine. The presence of occult blood in urine is important because it is indicative of bleeding which can be caused by a variety of abnormal conditions such as hematuria, hemoglobinuria, myoglobinuria and cancer.

SUMMARY AND EXPLANATION:
URS-1B for urinalysis are firm plastic strips, each strip having a reagent area for detection of occult blood affixed. The reagent area of URS-1B is ready to use upon removal from the bottle and the entire reagent strip is disposable. When the strip is dipped in urine, the test area changes color according to the amount of hemoglobin and its derivatives that are present in the urine. The colors of the test area is compared to the color blocks of the Color Chart directly on the bottle. No additional instrumentation is required.

PRINCIPLE:
BLOOD: This test is based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of cumene hydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange through green; very high levels of blood may cause the color development to continue to blue.

REAGENTS:
(Based on dry weight at time of impregnation)
BLOOD: 5.0% w/w cumene hydroperoxide; 4.0% w/w 3,3',5,5'-tetramethylbenzidine; 48.0% w/w buffer; 43.0% w/w nonreactive ingredients.

WARNINGS AND PRECAUTIONS:
1. URS-1B is for in vitro diagnostic use only
2. URS-1B is not for home use.
3. Do not use if you are color blind.

STORAGE:
1. Store open and unopened bottle at temperature 15°-30°C (59°-86°F) and out of direct sunlight.
2. Do not use after expiration date.

RECOMMENDED PROCEDURES FOR HANDLING URS-1B:
1. All unused strips must remain in original bottle. Transfer to any other container may cause reagent strips to deteriorate and become nonreactive.
2. Do not remove desiccant(s) from the bottle. Replace cap immediately and tightly after removing reagent strip to test.
3. Do not combine urine strips with different lot numbers together.
4. Do not touch test areas of the reagent strip. Work areas and specimen containers should be free of detergents and other contaminating substances.
5. When testing, dip test area in urine completely, but briefly, to avoid dissolving out the reagents. Read test results carefully at the time specified, in a good light and with the test area held near, but not touching the Color Chart on the bottle label.

SPECIMEN COLLECTION AND PREPARATION:
Collect random urine according to NCCLS GP16-T guideline in a clean container and test as soon as possible. If testing cannot be done within an hour after voiding, it is recommended that the urine sample be refrigerated immediately at 2 - 4°C and let it return to room temperature before testing.1 Prolonged exposure of unpreserved urine to room temperature may result in microbial proliferation.2 Bacterial growth from contaminating organisms may cause false positive blood reactions from the peroxidase produced.3 Store urine in clean, dry container and refrigerated at 2 - 4°C.

MATERIALS PROVIDED:
1. 1 bottle containing 100 strips of URS-1B.
2. A visual comparison Color Chart for reading test results is printed on the bottle.

MATERIALS REQUIRED BUT NOT PROVIDED:
1. Clean, dry container for urine sample.
2. Commercial urine controls
3. Timer or watch capable of measuring accurately in seconds.

PROCEDURE: MUST BE FOLLOWED EXACTLY TO ACHIEVE RELIABLE TEST RESULTS.

NOTE: In accordance with CDC guidelines on proper handling of bodily fluids, it is recommended that gloves be worn when performing this test.

1. Collect random urine specimen in a clean, dry container. Mix well immediately before testing. If urine specimens are not tested within 1 hour after voiding store at 2-4°C and bring to room temperature before testing.
2. Remove one strip from bottle and close the cap immediately. Hold the plastic end of the strip. Completely immerse reagent areas of the strip in urine sample and remove immediately to avoid dissolving out reagents.
3. Remove the urine strip slowly avoiding splashing effect. Run the edge of the strip against the rim of the urine container to remove excess urine.

Note: In the case that urine sample splashes onto gloves or body, rinse well with water. Use new gloves when testing a different urine sample. Make sure urine that may have contaminated gloves from previous sample does not contaminate the test sample.

4. Compare reagent area to the color chart on the bottle label and read as specified. HOLD STRIP CLOSE TO COLOR BLOCK AND MATCH CAREFULLY. DO NOT TOUCH THE COLOR BLOCK WITH THE TEST AREA.

QUALITY CONTROL:
For best results, performance of reagent strips should be confirmed by testing known negative and positive controls whenever a new bottle is first opened. Negative and positive controls may also be randomly hidden in each batch of specimens tested. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

RESULTS:
Results with URINE REAGENT STRIPS are obtained in clinically meaningful units directly from the Color Chart comparison. The color blocks represent nominal values; actual values will vary around the nominal values.

LIMITATIONS OF PROCEDURE:
As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method. All positive results should be confirmed by a quantitative method where accuracy and sensitivity are greater.

High blood concentration in sample may mask color development or cause atypical color formation. Turbid urine may be used; however reaction must be observed carefully.

Substances that cause abnormal urine color, such as Serenium®, drugs containing Azo dyes (e.g., Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Macrodantin®, Furadantin®), and riboflavin, may affect the readability of reagent areas on urinalysis reagent strips. The color development on the reagent pad may be masked or a color reaction may be produced on the pad that could be interpreted as a false positive.

BLOOD: The significance of the Trace reaction may vary among patients, and clinical judgment is required for assessment in an individual case. Development of green spots (intact erythrocytes) or green color (free hemoglobin/myoglobin) on the reagent area within 60 seconds indicated the need for further investigation. Blood is often, but not always found in the urine of menstruating females.

URS-1B is for professional use only and not for home use. Do not use if individual performing the test is color blind, or has any vision impairment. Do not combine urine strips with different lot numbers together at any time. Contamination of both urine sample and reagent strips must be avoided. This test is inappropriate for neonatal urine specimens and cannot be used.

EXPECTED VALUES:
BLOOD: This test is negative for normal urine. Any green spots or green-blue color developing of the reagent area is significant and the urine should be examined further.
PERFORMANCE CHARACTERISTICS:
The performance characteristics of URS-1B urine reagent strips have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy and precision. Generally, this test has been developed to be specific for the constituent to be measured with the exception of interferences listed previously. (see LIMITATIONS OF PROCEDURE).

For visually read strips, accuracy is a function of the manner in which the color block on the bottle label are determined and the discrimination of the human eye in reading the test. Precision is difficult to assess in a test of this type because of the variability of the human eye. It is for this reason that users are encouraged to developed their own standards of performance.

**Sensitivity:**

**BLOOD:** At the time of reagent manufacture, the test has a sensitivity to free hemoglobin of 0.015 mg/dl or 5 intact red blood cells/μL of urine. The sensitivity of this test may be reduced in urine with high specific gravity. The test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.

**BIBLIOGRAPHY:**

URINE REAGENT STRIPS
(1 PARAMETER)
Tests for Glucose
Catalog No. URS-1

INTENDED USE:
Urine Reagent Strips-1 parameter provide a semi-quantitative determination for the presence and concentration of glucose in random urine.

SUMMARY AND EXPLANATION:
URS-1 for Urinalysis are firm plastic strips to which glucose reagent areas are affixed. The reagent area of URS-1 is ready to use upon removal from the bottle and the entire reagent strip is disposable. When the strip is dip in random urine, the test area changes color according to the amount of glucose present in the urine. The developing color of the test area is compare to the color blocks of the Color Chart after a specific time. Each color block corresponds to a nominal unit, which gives an indication of the amount of glucose present in the urine sample.

CLINICAL UTILITY:
URS-1 provides a rapid, inexpensive and visual screening procedure for the presence and concentration of glucose by examining random urine. Results from URS-1 may also provide a guide to monitor treatment of diabetic patients.

PRINCIPLE:
This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to brown.

REAGENTS:
(Based on dry weight at time of impregnation)

1. Glucose oxidase (Aspergillus niger) ≥16.3% w/w
2. Peroxidase (Horseradish) ≥0.6% w/w
3. Potassium iodide 7.0% w/w
4. Buffer and nonreactive ingredients 60.7% w/w

WARNINGS AND PRECAUTIONS:
1. Urine reagent strips are for in vitro diagnostic use only.
2. Urine reagent strips are not for in home use.
3. Do not use if you are color blind.
4. To obtain optimal results, it is necessary to use freshly voided, well mixed and uncentrifuged urine.
5. The directions must be followed exactly.
6. Accurate timing is essential to provide optimal results.
7. Avoid contamination with hydrogen peroxide or any strong oxidizing agent, such as hypochlorite.¹
8. Exposure of URS-1 to light, moisture or heat will cause deterioration and decrease reactivity.

STORAGE:
1. Store opened and unopened bottle at temperature 15°- 30°C (59°- 86° F) and out of direct sunlight.
2. Do not use after expiration date.
3. The reagent strips must be kept in its original bottle with the cap tightly closed to maintain reagent reactivity.

RECOMMENDED PROCEDURES FOR HANDLING URS-1:

NOTE: All warnings, precautions and proper storage procedures must be followed to avoid deterioration and insure reactivity of URS-1.

1. All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become unreactive.

2. Do not remove desiccant(s) from bottle. Replace cap immediately and tightly after removing reagent strip.
3. Do not combine urine strips with different lot numbers together.

4. Do not touch test areas of the reagent strip. Work areas and specimen containers should be free of detergents and other contamination substances.

5. When testing, dip test areas in urine completely, but briefly, to avoid dissolving out the reagents. Read test results carefully at the time specified, in a good light and with the test area held near, but not touching the Color Chart on the bottle label.

IMPORTANT: PROTECTION AGAINST AMBIENT MOISTURE, LIGHT AND HEAT IS ESSENTIAL TO GUARD AGAINST ALTERED REAGENT REACTIVITY.

Discoloration or darkening of reagent areas may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with expected findings, the following steps are recommended: (1) Confirm that the product is within the expiration date shown on the label. (2) Check performance against known positive control materials. (3) Retest with fresh product.

SPECIMEN COLLECTION AND PREPARATION:
Collect random urine according to NCCLS GP16-T guideline in a clean container and test as soon as possible. If testing cannot be done within an hour after voiding, it is recommended that the urine sample be refrigerated immediately at 2 - 4°C and let it return to room temperature before testing. If prolonged exposure of unpreserved urine to room temperature may result in microbial contamination and bacterial consumption of urine glucose. Contamination of urine with hydrogen peroxide or a strong oxidizing agent, such as hypochlorite, produces false positive results. Store urine in clean, dry container refrigerated at 2 - 4°C.

MATERIALS REQUIRED BUT NOT PROVIDED:
1. Clean, dry container for urine sample.
2. Commercial urine controls
3. Timer or watch capable of measuring accurately in seconds.

PROCEDURE: MUST BE FOLLOWED EXACTLY TO ACHIEVE RELIABLE TEST RESULTS.

NOTE: In accordance with CDC guidelines on proper handling of bodily fluids, it is recommended that gloves be worn when performing this test.

1. Collect random urine specimen in a clean, dry container. Mix well immediately before testing. If urine specimens are not tested within 1 hour after voiding store at 2-4°C and bring to room temperature before testing.

2. Remove one strip from bottle and close the cap immediately. Hold the plastic end of the strip. Completely immerse reagent areas of the strip in urine sample and remove immediately to avoid dissolving out reagents.

3. Remove the urine strip slowly avoiding splashing effect. Run the edge of the strip against the rim of the urine container to remove excess urine. Note: In the case that urine sample splashes onto gloves or body, rinse well with water. Use new gloves when testing a different urine sample. Make sure urine that may have contaminated gloves from previous sample do not contaminate the test sample.

4. Compare reagent area to the color chart on the bottle label at exactly 30 seconds. HOLD STRIP CLOSE TO COLOR BLOCK AND MATCH CAREFULLY. DO NOT TOUCH THE COLOR BLOCK WITH THE TEST AREA.

QUALITY CONTROL:
For best results, it is recommended that the performance of reagent strips be confirmed by testing known positive and negative controls whenever a new bottle is first opened, or with every new batch of specimen. In addition, commercially available control materials with varying glucose concentrations may be used for quality control. Failure to obtain the proper low and high values in the assay of control material may indicate either reagent deterioration, instrument malfunction, or procedural errors. It is recommended that each laboratory establish its own goals for adequate standards of performance.

RESULTS:
Results with URS-1 are reported as qualitative values, by comparing the color of the test strip to the Color Chart and match it with the closest color block. Each color block translates into a nominal value; actual values will vary around the nominal values.

LIMITATIONS OF PROCEDURE:
As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method. This test is only for screening; all positive results should be confirmed by a quantitative method where accuracy and sensitivity are greater.
High blood concentration in sample may mask color development or cause atypical color formation. Turbid urine may be used; however reaction must be observed carefully.

Interpretation of results will depend upon several factors: the variability of color perception; the presence or absence of inhibitory factors typically found in urine; and the specific gravity; and the lighting conditions under which the product is used.

Substances that cause abnormal urine color, such as Serenium®, drugs containing Azo dyes (e.g., Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Macrodantin®, Furadantin®), and riboflavin, may affect the readability of reagent areas on urinalysis reagent strips. The color development on the reagent pad may be masked or a color reaction may be produced on the pad that could be interpreted as a false positive.

For urine specimens containing small glucose concentrations of 100 mg/dL, the presence of ascorbic acid in concentrations of 50 mg/dL or greater may cause false negative readings (No color developing on test area). Ketone bodies reduce the sensitivity of the test. Presence of moderately high ketone levels (40 mg/dL) may also cause false negatives for urine specimens containing small glucose concentration (100 mg/dL), however the combination of such ketone levels and low glucose level is metabolically improbable in screening. The reactivity of the glucose test decreases as the SG of the urine increases. Reactivity may also vary with temperature. The glucose test is for professional use only and not for home use. Do not use if individual performing the test is color blind, or have any vision impairment. Do not combine urine strips with different lot numbers together at any time. Contamination of both urine sample and reagent strips must be avoided. This test is inappropriate for neonatal urine specimens and cannot be used to determine glucose concentration.

EXPECTED VALUES:
The amount of glucose excreted normally is negative in this test. However, small amount of glucose below the sensitivity of this test may on occasion produce a color between the negative and the 100 mg/dL color blocks. Results of 100 mg/dL may be significantly abnormal if found consistently.

PERFORMANCE CHARACTERISTICS:
Sensitivity:
The sensitivity of URS-1 is 100 mg/dL or comparable to a trace reading, any concentration below 100 mg/dL will be negative. Sensitivity will vary depending on the limitation factors of each test. (see LIMITATIONS OF PROCEDURE)

Specificity:
The test is specific for glucose; no substance excreted in urine other than glucose is known to give a positive result. The reagent area does not react with lactose, galactose, fructose nor reducing metabolites of drugs (e.g., salicylates and nalidixic acid). This test may be used to determine whether the reducing substance found in urine is glucose. Reactivity may be influenced by urine specific gravity and temperature. In dilute urines with glucose concentrations of 40 mg/dL or less, where specific gravity is lower, the presence of small ascorbic acid at concentrations (5mg/dL or less) may cause false positive readings.

BIBLIOGRAPHY:
INTENDED USE: Urine Reagent Strips (URS-1) for Urinalysis are firm plastic strips to which protein reagent areas are affixed. Urine Reagent Strips provide tests for the semi-quantitative determination of protein in urine.

SUMMARY: Test results may provide information regarding the status of kidney function.1-3

The kidney glomeruli act as ultrafilters for the plasma protein; however as much as 150 mg/dl of protein may normally be excreted into the urine. In glomerular proteinuria, an increase in glomerular permeability occurs, resulting in an increase of urine proteins. High urine protein concentration therefore may indicate proteinuria.4

CHEMICAL PRINCIPLE OF THE PROCEDURE: This test is based on the protein error-of-indicators principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for "Negative" through yellow-green and green to green-blue for "Positive" reactions.

REAGENTS: (Based on dry weight at time of impregnation) 0.3% w/w tetrabromphenol blue; 99.7% w/w buffer and nonreactive ingredients.

WARNINGS AND PRECAUTIONS: Urine reagent strips are for in vitro diagnostic use.

STORAGE: Store opened and unopened bottles at a temperature between 15°-30°C (59°-86°F) and out of direct sunlight. Do not use after expiration date. Deterioration rate will be affected by mishandling of device.

RECOMMENDED PROCEDURES FOR HANDLING URINE REAGENT STRIPS: All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become unreactive. Do not remove desiccant(s) from bottle. Replace cap immediately and tightly after removing reagent strip. Do not touch test areas of the reagent strip. Work areas and specimen containers should be free of detergents and other contamination substances. Dip test areas in urine completely, but briefly, to avoid dissolving out the reagents. Read test results carefully, in a good light and with the test area held near the appropriate Color Chart on the bottle label.

IMPORTANT: Protection against ambient moisture, light and heat is essential to guard against altered reagent reactivity. Discoloration or darkening of reagent areas may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with expected finding, the following steps are recommended: (1) confirm that the product is within the expiration date shown on the label, (2) check performance against known positive control materials, (3) retest with fresh product.

SPECIMEN COLLECTION AND PREPARATION: Collect urine in a clean container according to NCCLS GP16-T and test as soon as possible. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.

Prolonged exposure of unpreserved urine to room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area.

Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect test results. The user should determine whether the use of such skin cleansers is warranted.

PROCEDURE: MUST BE FOLLOWED EXACTLY TO ACHIEVE RELIABLE TEST RESULTS.

1. Collect FRESH urine specimen in a clean dry container. Mix well immediately before testing.
2. Remove one strip from bottle and close the cap immediately. Completely immerse reagent areas of the strip in FRESH urine and remove immediately to avoid dissolving out reagents.
3. While removing, run the edge of the strip against the rim of the urine container to remove excess urine.
4. Compare reagent areas to corresponding color chart on the bottle label at the time specified. HOLD STRIP CLOSE TO COLOR BLOCKS AND MATCH CAREFULLY.

This test may be read at any time up to one minute after dipping.

QUALITY CONTROL: For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or control daily or whenever a new bottle is first opened. Negative and positive specimens or controls may also be randomly hidden in each batch of specimens tested. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

RESULTS: Results with URS-1 are obtained in clinically meaningful units directly from the Color Chart comparison. The color blocks represent nominal values; actual values will vary around the nominal values.

LIMITATIONS OF PROCEDURE: As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method. This test is only for screening; all positive results should be confirmed by a quantitative method where accuracy and sensitivity are greater.

Substances that cause abnormal urine color, such as Serenium®**, drugs containing azo dyes(e.g.,Pyridium®**, Azo Gantrisin®***, AzoGantanol®***), nitrofurantoin(Macrodantin®†, Furadantin®†), and riboflavin, may affect the readability of reagent areas on urinalysis reagent strips.5 The color development on the reagent pad may be masked or a color reaction may be produced on the pad that could be interpreted as a false positive.

High blood concentration in sample may mask color development or cause atypical color formation. Turbid urine may be used, however reaction must be observed carefully.

Interpretation of results will depend upon several factors: the variability of color perception; the presence or absence of inhibitory factors; the presence or absence of inhibitory factors typically found in urine, the specific gravity or the pH; and the lighting conditions under which the product is used.
False positive results may be obtained with highly concentrated or alkaline urine. Contamination of the urine specimen with quaternary ammonium compounds may also produce false positive results.6

EXPECTED VALUES:
Normal secretion of protein in the urine is less than 15 mg/dl.4 A color matching any block greater than Trace may indicate significant proteinuria. For urine of high specific gravity, the test area may most closely match the trace color block even though only normal concentrations of protein are present. Clinical judgment is needed to evaluate the significance of trace results.

PERFORMANCE CHARACTERISTICS:

Sensitivity:
The following table lists the generally detectable level of protein in contrived urine; however, because of the inherent variability of clinical urines, lesser concentrations may be detected under certain conditions. Sensitivity will vary depending on the limitation factors of the test. (see LIMITATIONS OF PROCEDURE)

<table>
<thead>
<tr>
<th>Reagent Area</th>
<th>Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>15 mg/dL albumin</td>
</tr>
</tbody>
</table>

Specificity
The reagent area is more sensitive to albumin than to globulins, hemoglobin, Bence-Jones Protein and mucoprotein; negative result does not rule out the presence of these other proteins.

BIBLIOGRAPHY: