IFU

Instructions for Use

HARDY DIAGNOSTICS
A Culture of Service™

UriStain™

Cat. no. Z74	UriStain™, Urine Sediment Stain	15ml

INTENDED USE

Hardy Diagnostics UriStain™ is intended for use in sediment staining of urine specimens.

SUMMARY

The stain contains various dyes that aid in differentiating the abnormal and normal cellular elements found in urine. UriStain™ is a one solution modification of the Sternheimer and Malvin procedure.

REAGENT FORMULA

	CAS No.
Ammonium Oxalate	113-38-8
Safranin	477-73-6
Crystal Violet	548-62-9
Ethanol	64-17-5
Deionized Water	

This stain is made from certified dyes.

STORAGE AND SHELF LIFE

Upon receipt store at 2-30ºC. Product should not be used if there are any signs of deterioration or if the expiration date has past.

The expiration dating on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended

quality control incubation times.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." The "Guidelines for Isolation Precautions" is available from the Centers for Disease Control and Prevention at www.cdc.gov/ncidod/dhqp/gl_isolation.html.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

Refer to the document SDS Search instructions on the Hardy Diagnostics' website for more information.

Warning! This product is poisonous and may be fatal or cause blindness if ingested.

Warning! This solution is an irritant. Vapor of ethanol is harmful.

Warning! This product is flammable; keep away from heat, sparks, or flames.

PROCEDURE

Specimen Collection: A fresh, clean-voided urine specimen should be used. When microscopic findings are not normal or a culture is required, the patient must be cleansed before voiding.

Method of Use:

1. Mix the specimen well, as casts tend to settle out.

2. Pour 10-12ml of the sample into a conical tube or test tube and centrifuge at 2000rpm for five minutes.

3. Remove supernatant, leaving a small amount of urine in the tube (1ml).

4. Suspend the sediment. One or two drops of the unstained sediment should be examined with the stained sediment. Place one to two drops of UriStain™ in the remaining sediment and mix.

5. On a clean slide, place one drop of stained sediment and one drop of unstained sediment. Cover each drop with a coverslip, avoiding bubbles.

6. Examine with low power and subdued light, and scan the entire area. Casts will be found along the edges of the coverslip. They are counted under low power (100X) and differentiated under high-dry power (400X). Red blood cells, leukocytes, and epithelial cells are counted in ten fields. Large numbers of squamous epithelial cells, if present, are noted. Bacteria and yeasts are also reported. If crystals are present in large amounts, they are reported.

INTERPRETATION OF RESULTS

Cell Type	Reaction
Erythrocytes	Faint pink color
Yeast cells	Purple
Epithelial cells	Nuclei stain deep purple
Cytoplasm	Stains a red/purple color
Leukocytes	Granulocyte(s) of nuclei stain dark purple
Hyaline casts	Stain pink to red
Granular elements	Stain red to violet
Fat droplets	Brilliant, refractive honeycomb structure
Bacteria	Dead: stain dark purple; Alive: colorless to red
Fungi mycelial and spores	Appear light purple
Trichomonas	Either colorless or light blue

LIMITATIONS

The presence of bacteria may be due to non-sterile conditions of the patient and collection container.

Air bubbles under the coverslip may be confused with fat droplets or red blood cells.

Slide and coverslip must be clean and free of lint and oils. If precipitate is found on the slide, filter the stain and perform the staining procedure again before reporting.

If the sample cannot be tested immediately, it should be refrigerated or a preservative added.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as slides, coverslips, centrifuge, centrifuge tubes, microscopes and specimen cups, etc., are not provided.

USER QUALITY CONTROL

It is recommended that each new lot and each shipment of reagent be tested with known positive and negative controls and retested each week of use thereafter.[1]

It is recommended that positive controls be run in parallel with patient specimens and that results from any staining procedure be reported only if positive control smears are acceptable.

The microscope should be calibrated (within the last 12 months). The objectives and oculars used for the calibration procedure should be in place on the microscope when objects are measured.[4]

PHYSICAL APPEARANCE

UriStain™ should appear opaque and bright blue-violet to purple in color.

REFERENCES

1. Anderson, N.L., et al. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory,* Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.

2. Levinson, S.A. and R.P. MacFate. *Clinical Laboratory Diagnosis*.

3. Todd, J.C., and A.H. Stanford. *Clinical Diagnosis by Laboratory Methods*.

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California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

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