

AUTION Sticks 9EB For Urine Chemistry

INTENDED USE

For the determination of Glucose, Protein, Bilirubin, Urobilinogen, pH, Blood, Ketones, Nitrite, and Leukocytes in urine.

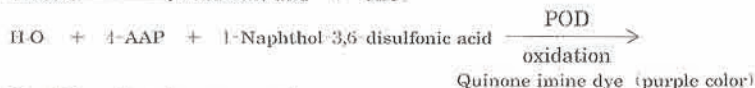
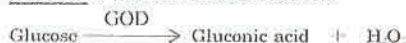
AUTION Sticks 9EB are manufactured for use only in the AUTION MAX AX-4280 Urine Analyzer.

AUTION Sticks 9EB are multi-parameter test strips intended for use with the AUTION MAX AX-4280 Urine Analyzer to measure certain constituents in urine. The AUTION Sticks 9EB consist of a plastic strip containing 9 pads impregnated with chemicals specific for the determination of a particular constituent. The pads permit the determination of Glucose, Protein, Bilirubin, Urobilinogen, pH, Blood, Ketones, Nitrite, and Leukocytes. An additional correction pad is included, to compensate for the natural color of urine and its effect on the color reactions of the reactive pads.

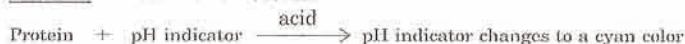
The AUTION MAX AX-4280 Urine Analyzer utilizes reflectance spectroscopy, in combination with AUTION Sticks reagent chemistry, to provide qualitative or semi-quantitative results. At defined wavelengths, the AUTION MAX AX-4280 Urine Analyzer analyzes the color and the intensity of reflected light from the reacted pads to calculate clinically meaningful results. The AUTION MAX AX-4280 Urine Analyzer also utilizes refractometry to determine the specific gravity of urine samples.

PRINCIPLE

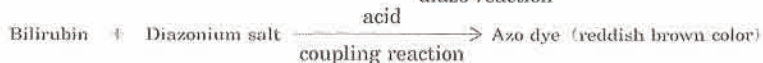
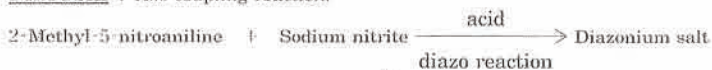
Glucose : Glucose oxidase reaction.



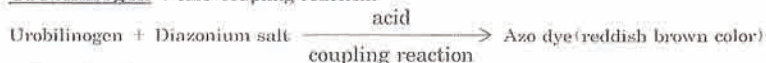
Protein : Protein-error reaction.



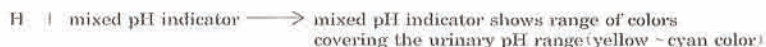
Bilirubin : Azo-coupling reaction.



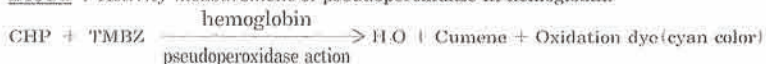
Urobilinogen : Azo coupling reaction.



pH : pH indicator.



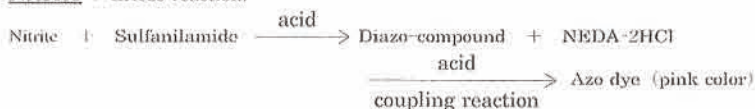
Blood : Activity measurement of pseudoperoxidase in hemoglobin.



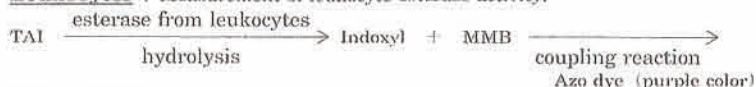
Ketones : Legal reaction.



Nitrite : Griess reaction.



Leukocytes : Measurement of leukocyte esterase activity.



REAGENTS

Composition of 100 AUTION Sticks is as follows :

Glucose :	
Glucose oxidase (GOD)	700 I.U.
Peroxidase (POD)	175 P.U.
4-Aminoantipyrine (4-AAP)	14.0 mg
1-Naphthol-3,6-disulfonic acid, disodium salt	14.0 mg
Protein :	
Tetrabromophenol blue (TBPB)	0.35 mg
Bilirubin :	
2-Methyl-5-nitroaniline	1.9 mg
Sodium nitrite	1.0 mg
Urobilinogen :	
3,3'-Dimethoxy-4,4'-biphenylbis (diazonium tetrafluoroborate)	0.16 mg
pH :	
Bromocresol green	0.07 mg
Bromoxylene blue	0.72 mg
Blood :	
Cumene hydroperoxide (CHP)	30.0 mg
3,3', 5,5'-Tetramethylbenzidine (TMBZ)	15.0 mg
Ketones :	
Sodium nitroprusside	12.0 mg
Nitrite :	
Sulfanilamide	3.9 mg
N-1-Naphthylethylenediamine dihydrochloride (NEDA-2HCl)	0.3 mg
Leukocytes :	
3-(N-Toluenesulfonyl-L-alanyloxy)indole (TAI)	0.49 mg
2-Methoxy-4-(N-morpholino)benzenediazonium (MMB)	0.17 mg

PRECAUTIONS and WARNINGS

For In Vitro Diagnostic Use. Utilize standard precautions required for the handling of all laboratory reagents

Warnings: Toxic. AUTION Sticks contain one or more of the following chemicals: Diazonium salt and phenol.

Gloves. Avoid contact with skin and mucous membranes. Wearing of gloves, when handling blood and body fluids, is included in the Center for Disease Control's recommended universal precautions.

STORAGE and HANDLING

Store AUTION Sticks between 34° to 86° F (1° to 30°C). DO NOT FREEZE. PROTECT AGAINST HEAT, LIGHT AND MOISTURE (Ambient Humidity). Each vial contains a desiccant to prevent exposure to moisture in the air (humidity). Immediately re-cap vials after removal of desired number of strips.

Any discoloration of the pad(s) may indicate deterioration. If discoloration is observed or if control/patient results are questionable or in conflict with expected results, check the following : A) Confirm the AUTION Sticks are still within the expiration date indicated on the vial ; B) controls are within the expected range ; C) results are equivalent when fresh product is tested. If a problem still exists, contact IRIS Customer Technical Support at (800) PRO-IRIS.

AUTION Sticks are stable for two years after the date of manufacture, when stored in their original, unopened container, and maintained at 34° to 86° F (1° to 30°C).

SPECIMEN COLLECTION and PREPARATION

Use freshly voided urine specimen, collected in a clean container. If analysis cannot be performed within one hour after collection, immediately refrigerate (2° to 8°C) the specimen. Bring the specimen to room temperature prior to analysis. Mix the specimen well prior to analysis. Do not add preservatives or centrifuge the specimen prior to analysis.

NOTE: Bilirubin and Urobilinogen are unstable in urine at room temperature, when exposed to light. Specimens collected between 2 - 4 PM may demonstrate higher levels of Urobilinogen. It is recommended that first morning urine specimen be analyzed for Nitrite since such specimens allow for the most favorable analytic results.

TESTING PROCEDURE

Follow the correct testing set-up, testing and control procedures, as outlined in the AUTION MAX AX-4280 Urine Analyzer Operating Manual.

Remove only the number of AUTION Sticks required for testing and immediately replace the vial cap.

QUALITY CONTROL

Performance of the AUTION Sticks should be confirmed regularly utilizing both known negative and known positive urine specimens or control materials.

RESULTS

Results, using AUTION Sticks, in combination with the AUTION MAX AX-4280 Urine Analyzer, are reported in clinically useful and common units of measure. Results can be printed directly from the urine analyzer and/or transferred to the Laboratory Information System (LIS).

Interpretation :

Analyte	Semi-quantitative symbol	Interpretation	Interpretation															
			±	+1	+2	+3	+4	OVER	OVER	OVER	OVER	OVER						
Glucose	Concentration (mg/dL)	NORMAL	30	50	70	100	150	200	300	500	1000	OVER						
	Concentration (mg/dL)	NORMAL	±		+1		+2		+3		+4							
Protein	Concentration (mg/dL)	NEGATIVE	10	20	30	50	70	100	200	300	600	OVER						
	Concentration (mg/dL)	NEGATIVE	±		+1		+2		+3		+4							
Bilirubin	Concentration (mg/dL)	NEGATIVE	0.5	1.0	2.0	3.0	4.0	6.0	8.0	10.0	OVER							
	Concentration (mg/dL)	NEGATIVE	+1		+2		+3		+4		OVER							
Urobilinogen	Concentration (mg/dL)	NORMAL	2.0	3.0	4.0	6.0	8.0	12.0	OVER									
	Concentration (mg/dL)	NORMAL	+1		+2		+3		+4		OVER							
pH	Measurement Result		5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0							
Blood	Concentration (mg/dL)	NEGATIVE	±	+1		+2		+3		+4								
	Concentration (mg/dL)	NEGATIVE	0.03	0.06	0.10	0.20	0.50	1.0	OVER									
Ketones	Concentration (mg/dL)	NEGATIVE	±	+1		+2		+3		+4								
	Concentration (mg/dL)	NEGATIVE	±	+1		+2		+3		+4								
Nitrite	Semi-quantitative symbol	NEGATIVE	+1	+2														
Leukocytes	Value (Leu/fL)	NEGATIVE	25	75	250	500												

LIMITATIONS

Analyte	Substances causing false negative results	Substances causing false positive results	Other
Glucose	Large amount of ascorbic acid	Oxidizing substances such as hypo-chlorite and chlorine Urine with a pH <4.0	
Protein	Urine with pH <3.0	Urine with large amount of hemoglobin Contrast medium Disinfectants, including quaternary ammonium compounds Urine with pH >8.0	
Bilirubin	Ascorbic acid, uric acid and nitrite	Urobilinogen Etodolac	Unstable at room temperature and in light
Urobilinogen		Carbapenem	Urine with high bilirubin causes development of green color
pH			Old urine increases in alkalinity
Blood	Urine with elevated specific gravity Urine with elevated protein Large amount of ascorbic acid	Oxidizing substances such as hypo-chlorite and chlorine	
Ketones		L-Dopa, BSP, PSP, Phenylketone, Cephalosporin Aldose reductive antienzyme	
Nitrite	Ascorbic acid Urine with elevated specific gravity		
Leukocytes	Glucose more than 500 mg/dL Protein more than 300 mg/dL Urine with low pH Urine with elevated specific gravity	Formaldehyde	

EXPECTED VALUES

Glucose

A small amount of glucose may be detected in normal urine. Generally, the amount of glucose is below the sensitivity level of the method; however, on occasion may produce \pm (trace) results. Consistently positive glucose results should be clinically investigated.

Protein

Although very small quantities of protein are normally excreted, the amount is generally below the sensitivity level for detection. Positive results require clinical assessment/additional testing to determine its significance.

Bilirubin

In normal urine, no bilirubin is normally detected. Positive findings should be diagnostically and clinically investigated.

Urobilinogen

Healthy individuals may excrete a small amount of Urobilinogen and may be increased especially after exercise. Concentrations are generally at their peak in the afternoon.

pH

Normal and abnormal urine pH ranges from 5.0 to 8.0 and is influenced by diet. Typical values for first morning specimens, from healthy individuals, are between pH 5.0 - 6.0.

Blood

A blue-green dotted reaction indicates the presence of erythrocytes. Up to 5 erythrocytes/ μ L may be found in normal urine specimens. Urine from menstruating women may contain blood. A large amount of blood should be clinically investigated.

Ketones

Ketones are not normally detected in urine specimens from healthy individuals. However, urine specimens from individuals who are fasting, pregnant, or who undergo regular strenuous exercise, may exhibit significant amounts of ketones. The presence of ketones, in urine specimens from patients with diabetes, may provide a useful marker for metabolic status.

Nitrite

A nitrite concentration of as low as 0.08 mg/dL may be detected and produce a positive test. A negative result may occur during fasting episodes since nitrates are not appearing in the urine.

Leukocytes

Normal urine specimens should not produce a positive reaction. Small amounts of leukocyte esterase, causing a positive reaction should be repeated, using a fresh urine specimen, from the same patient. Positive results require further testing for pyuria.

PERFORMANCE CHARACTERISTICS

The performance characteristics of *AUTION Sticks* have been determined in clinical and analytical studies. In clinical studies, the sensitivity of the tests depends on several inherent factors, including specimen pH, Specific Gravity and interfering factors (see LIMITATIONS). Generally, the *AUTION Sticks* reagent pads have been developed to be specific for the constituent being tested.

Sensitivity and Range

Sensitivity and linearity studies were performed using a series of contrived control materials which covered a wide range of known analyte concentrations. The results of the studies using the *AUTION MAX AX-4280* demonstrated analytical sensitivity and linearity over the measurement ranges as shown in the table below.

Reagent Pad	Analytical Sensitivity	Measurement Range
Glucose	30 mg/dL	30 - 1000 mg/dL
Protein	10 mg/dL	10 - 600 mg/dL
Bilirubin	0.5 mg/dL	0.5 - 10.0 mg/dL
Urobilinogen	2.0 mg/dL	2.0 - 12.0 mg/dL
pH	0.5 unit within pH range of 5.0 - 9.0	pH 5.0 - 9.0
Blood	Hemoglobin 0.03 mg/dL Erythrocyte approximately 10 Ery/ μ L	Hemoglobin 0.03 - 1.0 mg/dL
Ketones	Acetoacetic acid 5 mg/dL	5 - 150 mg/dL
Nitrite	Nitrite 0.08 mg/dL*	Nitrite 0.08 - 0.5 mg/dL
Leukocytes	Approximately 25 Leukocytes/ μ L	25 - 500 Leukocytes/ μ L

* Correlates with bacterial concentration of 10^7 /mL

Glucose

The glucose test pad reacts specifically with β -D-glucose and should not be affected by other reducing sugars such as sucrose, lactose and fructose.

Protein

The protein test pad is particularly sensitive to albumin and less sensitive to Bence-Jones protein, globulins, hemoglobin and mucoprotein.

Bilirubin

This test is sensitive to Direct-Reacting (conjugated) bilirubin.

Urobilinogen

The Urobilinogen test pad is sensitive to Urobilinogen down to approximately 2 mg/dL. The absolute absence of Urobilinogen in urine cannot be determined by this method.

pH

pH values of 5 - 9 may be read within 0.5 unit.

Blood

The blood test pad is more sensitive to free hemoglobin and myoglobin than to intact (non-hemolyzed) erythrocytes. The pad is sensitive to hemoglobin values as low as 0.03 mg/dL. In the total absence of hemolysis, a negative result may occur and not agree with the results of a urine sediment examination.

Ketones

The ketones pad is more sensitive to acetoacetic acid than to acetone. The pad should not react with β -hydroxybutyric acid. Acetone has about 10% reactivity compared to the reaction with acetoacetic acid.

Nitrite

The nitrite pad is specific for nitrites and will not react with other constituents normally excreted in urine. There is no correlation to the level of color development and the concentration of bacteria in the urine sample. A negative result during fasting can occur since nitrates will not be excreted into the urine.

Leukocytes

The leukocyte pad reacts with esterase derived from granulocytic white blood cells (WBC) in the urine specimen.

Method Comparison

The performance of the *AUTION MAX AX-4280* was evaluated in comparison with a commercially available automated urinalysis system. Urine samples were obtained from a hospital laboratory and included both normal and abnormal levels of urine analytes. Some of the native urine samples were spiked to elevated levels in order to achieve the desired range of abnormal values. Both urinalysis systems provide semi-quantitative results. Therefore, for purposes of data analysis for all analytes except pH, results for the individual urine samples were referred to the respective cut-off values for each system to discriminate between negative (normal) and positive (abnormal) findings. Overall agreement, sensitivity (positive agreement), and specificity (negative agreement) between the *AUTION MAX AX-4280* and the comparative system are shown in the table below. For pH, the statistical measure used was the overall agreement of paired values within 1 pH unit of each other.

Analyte	Number of Samples	Overall Agreement (%)	Sensitivity (%)	Specificity (%)
Glucose	227	97.4	98.5	96.9
Protein	227	94.7	92.1	96.8
Bilirubin	227	99.1	96.3	100.0
Urobilinogen	227	83.3	100.0	73.6
pH	227	91.6	N/A	N/A
Blood	227	97.8	97.8	97.8
Ketones	227	96.5	100.0	95.2
Nitrite	227	91.2	77.6	94.9
Leukocytes	227	95.6	96.7	94.9

N/A = Not Applicable

Precision

Reproducibility of the *AUTION MAX AX-4280* was evaluated by performing replicate measurements of a control material within a single run. Measurement results were reported by the instrument in the reflectance values format instead of concentration values in order to allow for a continuous measurement output. Results for within-run precision are shown in the table below.

Analyte	Number of Replicates	Reflectance Value		Coefficient of Variation (%)
		Mean	Standard Deviation	
Glucose	21	43.28	1.28	2.95
Protein	21	34.49	1.03	2.98
Bilirubin	21	77.59	0.93	1.20
Urobilinogen	21	60.45	0.84	1.39
pH	21	13.45	0.32	2.39
Blood	21	8.78	0.71	8.06
Ketones	21	52.43	3.04	5.79
Nitrite	21	88.97	0.54	0.61
Leukocytes	21	35.95	1.20	3.34

Carryover

Studies were performed to assess the amount of analyte carried over by the *AUTION MAX AX-4280* from one specimen reaction into subsequent specimen reactions. The studies consisted of the measurement of four identical high control samples immediately followed by four identical low control samples. Results of the testing demonstrated zero carryover for all analytes as measured by the *AUTION MAX AX-4280*.

PACKAGE CONFIGURATION

100 *AUTION Sticks 9EB* per container.

REFERENCES

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