

AUTION Sticks 10EA For Urine Chemistry

INTENDED USE

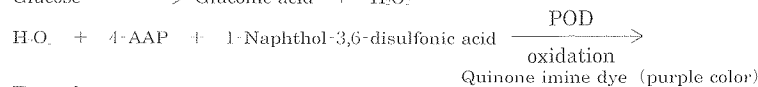
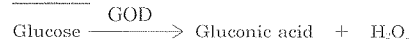
For the determination of Glucose, Protein, Bilirubin, Urobilinogen, pH, Specific Gravity, Blood, Ketones, Nitrite, and Leukocytes in urine. *AUTION Sticks 10EA* are manufactured for use only in the *AUTION JET AJ-4270 Urine Analyzer*.

AUTION Sticks 10EA are multi-parameter test strips intended for use with the *AUTION JET AJ-4270 Urine Analyzer* to measure certain constituents in urine. The *AUTION Sticks 10EA* consist of a plastic strip containing 10 pads impregnated with chemicals specific for the determination of a particular constituent. The pads permit the determination of Glucose, Protein, Bilirubin, Urobilinogen, pH, Specific Gravity, 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 JET AJ-4270 Urine Analyzer* utilizes reflectance spectroscopy, in combination with *AUTION Sticks* reagent chemistry, to provide qualitative or semi-quantitative results. At defined wavelengths, the *AUTION JET AJ-4270 Urine Analyzer* analyzes the color and the intensity of reflected light from the reacted pads to calculate clinically meaningful results.

PRINCIPLE

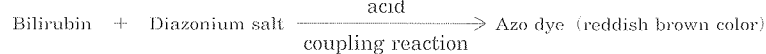
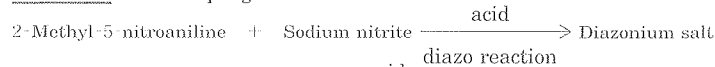
Glucose : Glucose oxidase reaction.



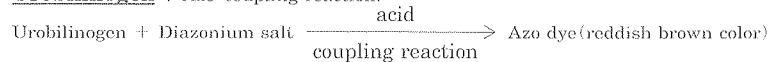
Protein : Protein-error reaction.



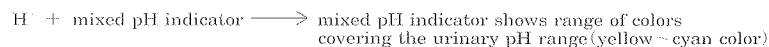
Bilirubin : Azo-coupling reaction.



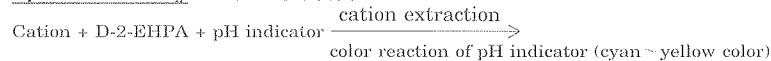
Urobilinogen : Azo-coupling reaction.



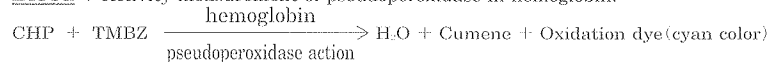
pH : pH indicator.



Specific Gravity : Cation extraction



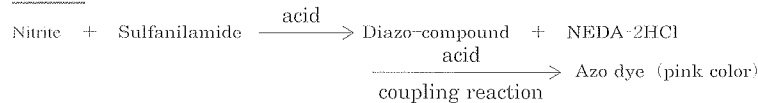
Blood : Activity measurement of pseudoperoxidase in hemoglobin.



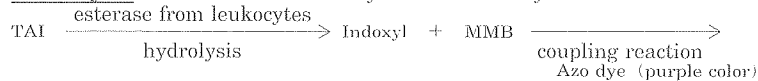
Ketones : Legal reaction.



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
Bromoxyleneol blue	0.72 mg
Specific Gravity :	
Di (2-ethylhexyl) phosphoric acid (D-2-EHPA)	8.0 mg
Bromthymol blue	0.7 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.

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 JET AJ-4270 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.

Users should follow local, state, and federal requirements when establishing their QC program.

RESULTS

Results, using *AUTION Sticks*, in combination with the *AUTION JET AJ-4270 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	Interpretation	Interpretation									
		NORMAL		+1		+2		+3		+4	
Glucose	Semi-quantitative symbol										
	Concentration (mg/dL)	30	50	70	100	150	200	300	500	1000	OVER
Protein	Semi-quantitative symbol	±		+1		+2		+3		+4	
	Concentration (mg/dL)	10	20	30	50	70	100	200	300	600	OVER
Bilirubin	Semi-quantitative symbol	+1		+2		+3		+4			
	Concentration (mg/dL)	0.5	1.0	2.0	3.0	4.0	6.0	8.0	10.0	OVER	
Urobilinogen	Semi-quantitative symbol	+1		+2		+3		+4			
	Concentration (mg/dL)	2.0	3.0	4.0	6.0	8.0	12.0	OVER			
pH	Measurement Result	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	
Specific Gravity	Measurement Result	<1.005		1.010		1.015		1.020		1.025 >1.030	
Blood	Semi-quantitative symbol	±		+1		+2		+3			
	Concentration (mg/dL)	0.03	0.06	0.10	0.20	0.50	1.0	OVER			
Ketones	Semi-quantitative symbol	±		+1		+2		+3		+4	
	Concentration (mg/dL)		10	20	40	60	80	100	150	OVER	
Nitrite	Semi-quantitative symbol	NEGATIVE		+1		+2					
Leukocytes	Value (Leu/µL)	NEGATIVE		25	75	250	500				

LIMITATIONS

Analyte	Substances causing false negative results	Substances causing false positive results	Other
Glucose	Large amount of ascorbic acid	<ul style="list-style-type: none"> Oxidizing substances such as hypochlorite and chlorine Urine with a pH <4.0 	
Protein	Urine with pH <3.0	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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
Specific Gravity	Highly buffered alkaline urine	<ul style="list-style-type: none"> Urine with low pH Protein more than 500 mg/dL 	
Blood	<ul style="list-style-type: none"> Urine with elevated specific gravity Urine with elevated protein Large amount of ascorbic acid 	<ul style="list-style-type: none"> Oxidizing substances such as hypochlorite and chlorine 	
Ketones		<ul style="list-style-type: none"> L-Dopa, BSP, PSP, Phenylketone, Cephalosporin Aldose reductive antienzyme 	
Nitrite	<ul style="list-style-type: none"> Ascorbic acid Urine with elevated specific gravity 		
Leukocytes	<ul style="list-style-type: none"> 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.

Specific Gravity

The normal range for specific gravity of random urine specimens is 1.003 - 1.035 and for a 24-hour specimen is 1.015 - 1.025.

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 JET AJ-4270* 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
Specific Gravity	0.005 unit within specific gravity range of 1.005 to 1.030	1.005 - 1.030
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 10⁷/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.

Specific Gravity

This test permits determination of urine specific gravity between 1.005 to 1.030 by steps of 0.005. Non-electrolytes such as glucose do not affect specific gravity.

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 JET AJ-4270* 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. Of the 227 total samples, 17 (7%) 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 and Specific Gravity, 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, agreement among positives, and agreement among negatives between the *AUTION JET AJ-4270* 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. For Specific Gravity, the statistical measure used was the overall agreement of paired values within 0.01 Specific Gravity unit of each other.

Analyte	Number of Samples	Overall Agreement (%)	Agreement Among Positives (%)	Agreement Among Negatives (%)
Glucose	227	100.0	100.0	100.0
Protein	227	98.7	94.5	100.0
Bilirubin	227	97.8	96.3	98.3
Urobilinogen	227	85.0	100.0	76.4
pH	227	88.5	N/A	N/A
Specific Gravity	227	88.5	N/A	N/A
Blood	227	96.9	91.1	98.4
Ketones	227	96.0	100.0	94.6
Nitrite	227	89.4	71.4	94.4
Leukocytes	227	95.6	92.3	97.8

N/A = Not Applicable

Precision

Reproducibility of the *AUTION JET AJ-4270* was evaluated by performing replicate measurements of two levels of control materials. On each of 21 consecutive test days, three replicates of each of the two levels of controls were analyzed sequentially. 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 and total precision are shown in the table below.

Analyte	Concentration	N	Within-Run Precision			Total Precision		
			Reflectance Value		Coefficient of Variation (%)	Reflectance Value		Coefficient of Variation (%)
			Mean	Standard Deviation		Mean	Standard Deviation	
Glucose	Normal	63	94.11	0.670	0.71	94.11	0.683	0.73
	200 mg/dL	63	35.99	0.795	2.21	35.99	1.089	3.03
Protein	Negative	63	85.46	0.711	0.83	85.46	0.747	0.87
	600 mg/dL	63	29.64	0.878	2.96	29.64	1.110	3.74
Bilirubin	Negative	63	94.15	1.274	1.35	94.15	1.406	1.49
	2 mg/dL	63	64.33	1.491	2.32	64.33	2.128	3.31
Urobilinogen	Normal	63	96.90	1.252	1.29	96.90	1.542	1.59
	8 mg/dL	63	52.77	1.409	2.67	52.77	1.615	3.06
pH	5.0	63	98.81	0.680	0.69	98.81	0.731	0.74
	9.0	63	13.63	0.604	4.43	13.63	0.631	4.63
Specific Gravity	<1.005	63	14.42	0.852	5.91	14.42	1.016	7.05
	1.020	63	35.58	3.332	9.37	35.58	3.847	10.81
Blood	Negative	63	73.05	3.874	5.30	73.05	3.874	5.30
	0.5 mg/dL	63	11.74	0.922	7.85	11.74	1.195	10.17
Ketones	Negative	63	92.45	2.113	2.29	92.45	2.411	2.61
	100 mg/dL	63	33.94	1.801	5.31	33.94	2.068	6.09
Nitrite	Negative	63	101.03	0.537	0.53	101.03	1.163	1.15
	1+	63	86.67	0.649	0.75	86.67	0.713	0.82
Leukocytes	Negative	63	95.03	0.524	0.55	95.03	0.598	0.63
	500 Leu/ μ L	63	34.32	1.291	3.76	34.32	1.651	4.81

PACKAGE CONFIGURATION

100 *AUTION Sticks 10EA* per container.

REFERENCES

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MANUFACTURED BY

ARKRAY FACTORY Inc.
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 520-3306, JAPAN

Issued: JUN. 2003

Rev.: FEB. 2005