



<b>BXC0662A/BXC0662B</b>	<b>10x10 ml</b>
<b>Lot No.: 662-01-017-2 662-02-020-2</b>	<b>Expiry: 2028/12</b>
<b>STORE AT 2 – 8°C</b>	
<b>FOR IN-VITRO DIAGNOSTIC USE ONLY</b>	

## URINE PRECISION CONTROL LEVEL I & 2

### Intended Use

This product is intended for *in vitro* diagnostic use in the quality control of urine on clinical chemistry systems. The Precision Urine Control is intended for use to monitor the precision of laboratory testing procedures for the analytes listed in this package insert

### Device Description

The Urine Controls are supplied at 2 levels, level 1 and 2. These are lyophilised control materials and guidance values are provided for the parameters listed in this insert.

### Safety Precautions And Warnings

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

### Storage And Stability

OPENED: Store refrigerated (2 to 8°C). Reconstituted urine is stable for 8 hours at +25°C and 5 days at +4°C if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

#### PREPARATION AND STABILITY OF SAMPLES FOR

#### 5-Hydroxyindole Acetic Acid (5-HIAA), Metanepherines, Vanillylmandelic Acid (VMA):

##### 5-Hydroxyindole Acetic Acid (5-HIAA):

This analyte is also unstable in reconstituted urine samples. Acidify using 100 ul of glacial acetic acid per 10ml of reconstituted control. The stability will be extended to 30 days at 2-8°C, when stored tightly capped.

##### Metanepherines, Vanillylmandelic Acid (VMA):

For extending the stability of Metanephrines and VMA acidify with 80 ul of 6M HCl per 10ml of reconstituted control. Alternatively reconstitute the lyophilised control with 10ml of 0.05M HCl.

UNOPENED: Store refrigerated (2 to 8°C). Stable to expiration date printed on individual vials.

### Preparation For Use:

The Precision Urine Control is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised urine with exactly 10 ml of distilled water at +20°C to 25°C. Close the bottle and allow to stand for 15 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
2. Refer to the control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

### Materials Provided:

Precision Urine Control      Level 1&2      10 ml

### Materials Required But Not Provided:

Volumetric Pipette

### Guideline Values:

Values assigned are for guidance only. Individual laboratories have to assign their own means and ranges.

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QUALITY MANAGEMENT SYSTEM  
ISO 13485 CERTIFIED COMPANY

## Guideline Values

		BXC662A	BXC662B
		Level 1	Level 2
METHODS / INSTRUMENTS	Units	Target	Target
<b>17-HYDROXYCORTICOSTEROIDS</b>			
Biochemical Diagnostics 17-OH Corticosteroid Skreen	mg/L	3.30	17.7
<b>17-KETOGENIC STEROIDS</b>			
Biochemical Diagnostics 17-Ketogenic Steroid Skreen	mg/L	2.70	8.70
<b>17-KETOSTEROIDS</b>			
Biochemical Diagnostics 17-Ketosteroid Skreen	mg/L	6.10	18.8
Bio-Rad Column Test (184-3002)	mg/L	6.10	15.2
<b>3-METHOXYTYRAMINE</b>			
Bio-Rad HPLC (195-6019/195-6068/195-6069)	ng/mL	54.0	497
<b>5-HYDROXY-INDOLEACETIC ACID (5-HIAA)</b>			
Bio-Rad HPLC (195-5216)	mg/L	3.50	27.8
<b>ALDOSTERONE</b>			
DiaSorin LIAISON (310450)	µg/L	33.7	97.2
DiaSorin LIAISON XL (310450)	µg/L	29.3	81.2
Immunotech Beckman Coulter RIA (DSL8600)	µg/L	41.5	>48.0
<b>CALCIUM</b>			
Abbott ARCHITECT cSystem/AEROSET (Arsenazo III) (3L79)	mg/dL	4.99	10.3
Abbott ARCHITECT cSystem/AEROSET (Arsenazo III) (7D61)	mg/dL	5.05	10.4
Arsenazo III	mg/dL	5.03	10.5
Atomic Absorption	mg/dL	5.19	10.8
Beckman Coulter AU Systems (Arsenazo III)	mg/dL	4.94	10.6
Beckman Coulter Synchron / UniCel DxC Series (ISE Indirect) (CALC)	mg/dL	4.99	10.5
ISE Indirect	mg/dL	4.99	10.5
O-Cresolphthalein Complexone	g/dL	5.28	11.0
Ortho Vitros / Vitros 5,1 FS (Arsenazo III)	mg/dL	5.28	11.4
Roche Cobas Integra (o-cresolphthalein complexone)	g/dL	5.19	10.9
Roche Hitachi / Modular (BAPTA) (CA2)	g/dL	5.25	11.1
Roche / Hitachi Cobas c Systems (BAPTA)	mg/dL	5.11	10.7
Roche / Hitachi Cobas c Systems (o-cresolphthalein complexone)	mg/dL	5.15	10.8
Siemens ADVIA Chemistry Systems (CA, CA_c) (CPC)	mg/dL	5.12	11.0
Siemens ADVIA Chemistry Systems (CA_2, CA_2c) (Arsenazo III)	mg/dL	5.25	10.9
Siemens Dimension Series (o-cresolphthalein complexone)	mg/dL	5.61	11.3
Siemens Dimension Vista Systems (o-cresolphthalein complexone)	mg/dL	5.44	11.2
<b>CHLORIDE</b>			
Abbott ARCHITECT cSystem (ISE Indirect)	mEq/L	59.4	252
Beckman Coulter AU Systems (ISE Indirect)	mEq/L	61.2	260
Beckman Coulter Synchron / UniCel DxC Series (ISE Indirect) (CL)	mEq/L	57.3	253
ISE Indirect	mEq/L	58.7	257
Roche Cobas Integra (ISE Indirect)	mEq/L	59.5	252
Roche Hitachi / Modular (ISE Indirect)	mEq/L	50.5	268
Roche / Hitachi Cobas c Systems (ISE Indirect)	mEq/L	52.1	>250
Siemens ADVIA Chemistry Systems (CL) (ISE)	mEq/L	62.0	255
Siemens Dimension Series (ISE Indirect)	Eq/L	71.5	262
Siemens Dimension Vista Systems (ISE Indirect)	mEq/L	61.0	265
<b>CORTISOL</b>			
Beckman Coulter Access / 2 / 2i (Chemiluminescence)	µg/dL	6.21	>62.3
Beckman Coulter UniCel DxI (Chemiluminescence)	µg/dL	6.86	>60.0
DiaSorin LIAISON XL	µg/dL	2.32	>80.0

Roche Elecsys / E170 / Cobas e Systems	µg/dL	2.93	>63.4
Siemens ADVIA Centaur CP (COR) (CAL lot CE 39 and below)	µg/dL	5.70	>75.0
Siemens ADVIA Centaur CP (COR) (CAL lot CE 40 and above)	µg/dL	5.13	>75.0
Siemens ADVIA Centaur Systems (COR) (CAL lot CE 39 and below)	µg/dL	7.00	>75.0
Siemens ADVIA Centaur Systems (COR) (CAL lot CE 40 and above)	µg/dL	6.29	>75.0
<b>CREATININE</b>			
Abbott ARCHITECT cSystem (Alkaline picrate kinetic IDMS-traceable) (3L81)	mg/dL	77.7	220
Alkaline picrate-kinetic (Jaffe Reaction) (5)	mg/dL	80.5	227
Beckman Coulter AU Systems (Alkaline picrate-kinetic)	mg/dL	82.8	228
Beckman Coulter Synchron / UniCel DxC Series (Alkaline Picrate-kinetic)	mg/dL	84.8	241
Enzymatic (5)	mg/dL	78.3	225
Ortho Vitros / Vitros 5,1 FS (Enzymatic)	mg/dL	77.2	224
Roche Cobas Integra (Alkaline picrate-kinetic)	mg/dL	76.6	216
Roche Cobas Integra (Enzymatic)	mg/dL	74.3	217
Roche/Hitachi Cobas c Systems (Alkaline picrate-kinetic)	mg/dL	78.3	223
Roche/Hitachi Cobas c Systems (Enzymatic)	mg/dL	82.4	232
Siemens ADVIA Chemistry Systems (CREA) (Jaffe)	mg/dL	77.9	221
Siemens ADVIA Chemistry Systems (ECRE_2, enzymatic) (Creatininase)	mg/dL	79.9	229
Siemens Dimension Series (Alkaline picrate-kinetic)	mg/dL	83.9	244
Siemens Dimension Vista Systems (Alkaline picrate-kinetic rate blanked, IFCC-IDMS Standardized) (CRE2)	mg/dL	82.6	241
Siemens Dimension Vista Systems (Alkaline picrate-kinetic)	mg/dL	79.0	216
Siemens Dimension Vista Systems (Enzymatic)	mg/dL	80.0	236
<b>DOPAMINE</b>			
Bio-Rad HPLC Test (195-6071 / 195-6072)	ng/mL	86.0	559
Bio-Rad Reverse Phase HPLC (195-5370 / 195-5380 / 195-5700 / 195-5841)	ng/mL	86.5	521
IBL ELISA	ng/mL	58.0	348
<b>EPINEPHRINE</b>			
Bio-Rad HPLC (195-6071 / 195-6072)	ng/mL	13.9	87.0
Bio-Rad Reverse Phase HPLC (195-5370 / 195-5380 / 195-5700 / 195-5841)	ng/mL	13.6	84.6
IBL ELISA	ng/mL	10.5	64.0
<b>GLUCOSE</b>			
Beckman Coulter AU Systems (Hexokinase)	mg/dL	20.3	305
Beckman Coulter Synchron / UniCel DxC Series (Glucose Oxidase)	mg/dL	20.7	304
Glucose Oxidase	mg/dL	18.9	295
Hexokinase	mg/dL	20.4	303
Ortho Vitros / Vitros 5,1 FS (Glucose oxidase, hydrogen peroxide (Trinder))	mg/dL	22.1	309
Roche Cobas Integra (Hexokinase)	mg/dL	20.3	301
Roche Hitachi / Modular (Hexokinase)	mg/dL	20.2	308
Roche / Hitachi Cobas c Systems (Hexokinase)	mg/dL	20.3	297
Siemens ADVIA Chemistry Systems (GLUH) (Hexokinase)	mg/dL	19.3	299
Siemens ADVIA Chemistry Systems (GLUO) (Gluc Oxidase Trinder)	mg/dL	16.3	282
Siemens Dimension Series (Hexokinase)	mg/dL	22.7	313
Siemens Dimension Vista Systems (Hexokinase)	mg/dL	21.3	302
<b>HOMOVANILLIC ACID (HVA)</b>			
Bio-Rad HPLC (195-5210)	mg/L	1.90	18.1
PANTEX Immunoplate HVA	mg/L	1.22	13.6
<b>LEAD</b>			
Atomic Absorption	µg/L	47.2	96.5
<b>MAGNESIUM</b>			
Abbott ARCHITECT cSystem (Arsenazo I)	mg/dL	3.25	8.19
Atomic Absorption	mg/dL	5.08	11.1

Beckman Coulter AU Systems (Xylidyl blue)	mg/dL	5.10	11.6
Beckman Coulter Synchron / UniCel DxC Series (Calmagite) (MG)	mg/dL	5.11	11.3
Calmagite	mg/dL	5.11	11.3
Roche Cobas Integra (Chlorophosphonazo III)	mg/dL	4.79	11.5
Roche / Hitachi Cobas c Systems (Chlorophosphonazo III)	mg/dL	5.59	12.4
Roche / Hitachi Cobas c Systems (Xylidyl blue) (MG2)	mg/dL	5.18	11.5
Siemens ADVIA Chemistry Systems (MG, MG_c) (Xylidyl blue)	mg/dL	5.13	11.5
Siemens Dimension Series (Methylthymol blue)	mg/dL	5.22	11.5
Siemens Dimension Vista Systems (Methylthymol blue)	mg/dL	5.19	11.5
Xylidyl blue	mg/dL	5.14	11.5
<b>MERCURY</b>			
Atomic Absorption	µg/L	12.4	148
<b>METANEPHRINE</b>			
Bio-Rad HPLC (195-6019/195-6068/195-6069)	ng/mL	103	511
<b>METANEPHRINE, TOTAL</b>			
Bio-Rad Column Test (189-5501)	mg/L	0.33	1.35
<b>MICROALBUMIN</b>			
Abbott ARCHITECT cSystem (Immunoturbidimetric)	mg/dL	2.43	6.50
Beckman Coulter Synchron/UniCel DxC Series (Immunoturbidimetric)	mg/dL	3.32	9.26
Ortho Vitros / Vitros 5,1 FS (Immunoturbidimetric) (Randox)	mg/dL	1.94	6.13
Roche Cobas Integra 400 (Immunoturbidimetric)	mg/dL	1.31	5.44
Roche Cobas Integra 700 / 800 (Immunoturbidimetric)	mg/dL	0.898	4.92
Roche Hitachi / Modular (US) (Immunoturbidimetric)	mg/dL	1.75	5.73
Roche / Hitachi Cobas c Systems (Immunoturbidimetric) (Tina-quant)	mg/dL	1.56	5.33
Siemens BN Series Nephelometers (Immunonephelometric)	mg/dL	5.72	13.6
Siemens Dimension Series (Immunoturbidimetric)	mg/dL	0.697	4.16
Siemens Dimension Vista Systems (Immunonephelometric)	mg/dL	7.57	11.4
<b>NOREPINEPHRINE</b>			
Bio-Rad HPLC (195-6071 / 195-6072)	ng/mL	45.0	210
Bio-Rad Reverse Phase HPLC (195-5370 / 195-5380 / 195-5700 / 195-5841)	ng/mL	48.9	217
IBL ELISA	ng/mL	33.0	128
<b>NORMETANEPHRINE</b>			
Bio-Rad HPLC (195-6019/195-6068/195-6069)	ng/mL	323	1368
<b>OSMOLALITY</b>			
Freezing Point Depression	mOSM/kg	315	868
<b>pH</b>			
Glass Electrode	-	6.06	6.24
<b>PHOSPHORUS</b>			
Abbott ARCHITECT cSystem (Phosphomolybdate-UV)	mg/dL	38.7	76.5
Beckman Coulter AU Systems (Phosphomolybdate-UV)	mg/dL	37.9	76.2
Beckman Coulter Synchron / UniCel DxC Series (Phosphomolybdate-UV)	mg/dL	38.6	77.3
Ortho Vitros / Vitros 5,1 FS (Phosphomolybdate reduction)	mg/dL	42.1	82.3
Phosphomolybdate-UV (5)	mg/dL	38.5	77.1
Roche Cobas Integra (Phosphomolybdate-UV)	mg/dL	39.2	79.0
Roche Hitachi / Modular (Phosphomolybdate-UV)	mg/dL	37.3	75.0
Roche / Hitachi Cobas c Systems (Phosphomolybdate-UV)	mg/dL	38.9	77.9
Siemens ADVIA Chemistry Systems (IP, IP_c) (Phosphomolybdate-UV)	mg/dL	37.3	74.3
Siemens Dimension Series (DF61)	mg/dL	41.5	83.6
Siemens Dimension Vista Systems (Phosphomolybdate-UV)	mg/dL	37.3	75.6
<b>PORPHYRINS, TOTAL</b>			
Bio-Rad Column Test (187-5001)	µg/L	None detected	950
<b>POTASSIUM</b>			
Abbott ARCHITECT cSystem (ISE Indirect)	mEq/L	23.3	118
Beckman Coulter AU Systems (ISE Indirect)	mEq/L	23.9	117

Beckman Coulter Synchron / UniCel DxC Series (ISE Indirect)	mEq/L	22.9	117
Flame Photometer	mEq/L	25.4	115
ISE Indirect	mEq/L	23.0	117
Ortho Vitros / Vitros 5,1 FS (ISE Direct)	mEq/L	23.3	129
Roche Cobas Integra (ISE Indirect)	mEq/L	24.0	117
Roche Hitachi / Modular (ISE Indirect)	mEq/L	23.7	118
Roche / Hitachi Cobas c Systems (ISE Indirect)	mEq/L	23.6	121
Siemens ADVIA Chemistry Systems (K) (ISE)	mEq/L	23.4	121
Siemens Dimension Series (ISE Indirect)	mEq/L	22.2	111
Siemens Dimension Vista Systems (ISE Indirect)	mEq/L	20.0	108
<b>PREGNANCY</b>			
Beckman Coulter ICON		Negative	Positive
<b>PROTEIN, TOTAL</b>			
Abbott ARCHITECT cSystem (Benzethonium Chloride)	mg/dL	23.5	67.0
Beckman Coulter AU Systems (Pyrogallol Red) (OSR 6170)	mg/dL	23.8	70.4
Beckman Coulter Synchron / UniCel DxC Series (Pyrogallol Red)	mg/dL	19.0	72.1
Benzethonium Chloride	mg/dL	22.3	61.4
Ortho Vitros / Vitros 5,1 FS (Pyrocatechol Violet)	mg/dL	35.5	74.2
Pyrogallol Red	mg/dL	21.7	68.6
Roche Cobas Integra (Pyrogallol Red)	mg/dL	21.8	60.6
Roche Cobas Integra TPUC3 (Benzethonium Chloride)	mg/dL	21.8	60.9
Roche Hitachi / Modular (US) (Benzethonium Chloride)	mg/dL	25.6	62.5
Roche / Hitachi Cobas c Systems (Benzethonium Chloride)	mg/dL	20.3	56.9
Siemens ADVIA Chemistry Systems (UPRO_2)	mg/dL	17.0	62.2
Siemens BN Series Nephelometers (Immunonephelometric, fixed time, kinetic)	mg/dL	35.5	121
Siemens Dimension Series (Pyrogallol Red)	mg/dL	23.9	72.8
Siemens Dimension Vista Systems (Pyrogallol Red)	mg/dL	23.9	73.6
<b>SODIUM</b>			
Abbott ARCHITECT cSystem (ISE Indirect)	mEq/L	59.6	177
Beckman Coulter AU Systems (ISE Indirect)	mEq/L	60.0	178
Beckman Coulter Synchron / UniCel DxC Series (ISE Indirect)	mEq/L	61.8	176
Flame Photometer	mEq/L	60.4	174
ISE Indirect (5)	mEq/L	60.7	176
Ortho Vitros / Vitros 5,1 FS (ISE Direct)	mEq/L	62.3	185
Roche Cobas Integra (ISE Indirect)	mEq/L	61.8	176
Roche Hitachi / Modular (ISE Indirect)	mEq/L	61.0	181
Roche / Hitachi Cobas c Systems (ISE Indirect)	mEq/L	62.4	182
Siemens ADVIA Chemistry Systems (NA) (ISE)	mEq/L	59.1	179
Siemens Dimension Series (ISE Indirect)	mEq/L	60.1	166
Siemens Dimension Vista Systems (ISE Indirect)	mEq/L	59.7	167
<b>SPECIFIC GRAVITY</b>			
Refractometer	-	1.009	1.021
<b>UREA</b>			
Abbott ARCHITECT cSystem (Urease, UV)	mg/dL	805	1628
Beckman Coulter AU Systems (Urease, UV)	mg/dL	829	1634
Beckman Coulter Synchron / UniCel DxC Series (BUN) (Urease, UV)	mg/dL	805	1628
Ortho Vitros / Vitros 5,1 FS (Urease, colorimetric)	mg/dL	883	1730
Roche Hitachi / Modular (Urease, UV)	mg/dL	823	1646
Roche / Hitachi Cobas c Systems (Urease, UV)	mg/dL	817	1628
Siemens ADVIA Chemistry Systems (UN, UN_c) (Urease / GLDH)	mg/dL	829	1652
Siemens Dimension Series (Urease, UV)	mg/dL	931	1874
Siemens Dimension Vista (Urease, UV)	mg/dL	823	1622
Urease, GLDH	mg/dL	829	1652
Urease, UV	mg/dL	838	1672
<b>UREA NITROGEN</b>			
Abbott ARCHITECT cSystem (Urease, UV)	mg/dL	376	760
Beckman Coulter AU Systems (Urease, UV)	mg/dL	386	761

Beckman Coulter Synchron / UniCel DxC Series (BUN) (Urease, UV)	mg/dL	375	760
Ortho Vitros / Vitros 5,1 FS (Urease, colorimetric)	mg/dL	411	808
Roche Hitachi / Modular (Urease, UV)	mg/dL	383	768
Roche / Hitachi Cobas c Systems (Urease, UV)	mg/dL	381	760
Siemens ADVIA Chemistry Systems (UN, UN_c) (Urease / GLDH)	mg/dL	385	771
Siemens Dimension Series (Urease, UV)	mg/dL	435	874
Siemens Dimension Vista Systems (Urease, UV)	mg/dL	383	756
Urease, GLDH	mg/dL	385	771
Urease, UV	mg/dL	389	776
<b>URIC ACID</b>			
Abbott ARCHITECT cSystem (Uricase, colorimetric)	mg/dL	10.0	21.9
Beckman Coulter AU Systems (Uricase, colorimetric)	mg/dL	10.7	22.9
Beckman Coulter Synchron / UniCel DxC Series (Uricase, colorimetric)	mg/dL	11.6	23.6
Ortho Vitros / Vitros 5,1 FS (Uricase, colorimetric)	mg/dL	9.95	22.5
Roche Cobas Integra (Uricase, colorimetric)	mg/dL	10.2	22.9
Roche Hitachi / Modular (Uricase, colorimetric)	mg/dL	9.57	21.5
Roche / Hitachi Cobas c Systems (Uricase, colorimetric)	mg/dL	9.85	21.8
Siemens ADVIA Chemistry Systems (UA_c) (Uricase / Peroxidase)	mg/dL	10.3	22.3
Siemens Dimension Series (Uricase, UV)	mg/dL	11.1	24.1
Siemens Dimension Vista Systems (Uricase, UV)	mg/dL	10.6	21.5
Uricase, colorimetric	mg/dL	10.3	22.4
Uricase, UV	mg/dL	10.8	22.6
<b>VANILLYLMADELIC ACID (VMA)</b>			
Bio-Rad HPLC (195-5001/195-5003/195-5004)	mg/L	3.10	14.2
Biochemical Diagnostics VMA-Skreen	mg/L	4.10	16.7
PANTEX Immunoplate VMA	mg/L	2.23	7.95
Bio-Rad Column Test (189-6050)	mg/L	3.60	8.36

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products for life.

