

IRISpec™ CA/CB

REF: 800-0074

Intended use: IRISpec™ CA/CB is an assayed QC material for monitoring of urine chemistry analytes and devices as listed on the package insert. For *in vitro* diagnostic (IVD) use only.

Storage: 2°C to 8°C. Protect from light. Refrigerate at 2°C to 8°C immediately upon receipt.

Unopened stability: Stable until expiration date printed on bottles.

Open stability: 15 days at 2° to 8°C.

Limitations: Minimize oxygen exposure of product. Do not shake bottles. Improper storage and handling will reduce analyte concentration (specifically Bilirubin) and may prematurely result in a negative reading. A color change from orange to green for the CA control may indicate such a process has occurred. The CB control may become turbid with time; this does not impact the performance. Each laboratory should establish its own precision parameters.

Precautions: All biological materials used in this control set are of non-human origin. This product does not contain azide. Handle using universal precautions.

Do not pipette.

Directions:

FIRST AID: Eye contact—Flush with plenty of water. Seek medical advice.
Skin contact—Flush with plenty of water.
Ingestion—Seek medical advice.

Contents: Glucose, 11 g/L
Bilirubin, 80 mg/L
Sodium nitrite, 6.7 mg/L
Hemoglobin, 14.3 mg/L
Dimethylindole, 200 mg/L
Albumin, 4.5 g/L

Calcium chloride, 8.0 g/L
Acetone, 16 mL/L
Microbial esterase, 120 mg/L
Stabilizing agents, buffers, preservatives and deionized water.

1. Remove double control set from the refrigerator; pour an aliquot from each bottle into a separate tube. Insure sufficient volume to wet the strip if testing manually or follow instrument manufacturer's instructions. Return tightly capped control bottles to the refrigerator immediately.
2. Allow aliquots to warm to room temperature (20° to 28°C). Use control aliquots within one hour of pouring.
3. Treat each aliquot as a separate control material. If using visual read strips, do not dip more than one strip into an aliquot.
4. Compare results obtained for each control with the Assay Value – Table of Acceptable Result Ranges (shown below) for the appropriate strip or strip-instrument combination. Ranges given are intended only as guidelines.
5. Discard aliquots after single use. Do not pour back into bottle.

ASSAY VALUES, INSTRUMENT AND VISUAL – TABLE OF ACCEPTABLE RESULT RANGES

iChem®100 Urine Chemistry System with iChem® 10 SG Strips, vChem® Strips

Parameter	IRISpec CA	IRISpec CB
Bilirubin	2 – 4 mg/dL 35 – 70 µmol/L (++) – (+++)	NEG.
Urobilinogen	NORM.	4 – 12 mg/dL 70 – 200 µmol/L (++) – (++++)
Ascorbic Acid	NEG.	NEG.
Protein	100 – ≥ 500 mg/dL 1 – ≥ 5 g/L (++) – (+++)	NEG.
Blood	0.03-0.2mg/dL (5-10)-50 RBCs/µL (+) – (++)	NEG.
pH	8 – 9	5 – 6
Nitrite	NEG.	POS.
Leukocytes	NORM.	75 – 500/µL
SG	1.000 – 1.005	1.030 – 1.035

ANALYTES FOR WHICH VISUAL AND INSTRUMENT READINGS ARE DIFFERENT

Ketone (instrument read)	NEG.	100 – 300 mg/dL 10 – 30 mmol/L (++) – (+++)
Ketone (visual read)	NEG.	25-100 mg/dL 2.5-10 mmol/L (+) – (++)
Glucose (instrument read)	150 – >1000 mg/dL 8 – 56 mmol/L (++) – (++++)	NEG.
Glucose (visual read)	500 – >1000 mg/dL 28 – 56 mmol/L (+++ – (++++)	NEG.

ASSAY VALUES, INSTRUMENT – TABLE OF ACCEPTABLE RESULT RANGES
 IRIS CHEMSTRIP® READER with CHEMSTRIP IRIStrip™ Reporting Mode—CLINITEK® Unit Outputs

Parameter	IRISpec CA	IRISpec CB
SG	<1.005 – 1.020	1.025 – > 1.030
pH	7.0 – 9.0	5.0 – 7.0
Protein	30 – >300 mg/dL	NEG
Glucose	TR – >1000 mg/dL	NEG
Ketone	NEG	15 – >80 mg/dL
Bilirubin	SM – LG	NEG
Blood	SM – LG	NEG
Nitrite	NEG	POS
Urobilinogen	0.2 EU/dL	1 – 8 EU/dL
Leukocytes	NEG	SM – LG

ASSAY VALUES, INSTRUMENT – TABLE OF ACCEPTABLE RESULT RANGES

AUTION MAX™ AX-4280 Urine Chemistry Analyzer with AUTION 9EB Sticks
 AUTION JET™ AJ-4270 Urine Chemistry Analyzer with AUTION 10EA Sticks

Parameter	IRISpec CA	IRISpec CB
Glucose	30 – >1000 mg/dL	NORMAL
Protein	100 – >600 mg/dL	NEG
Bilirubin	0.5 – 6 mg/dL	NEG
Urobilinogen	NORMAL	4 – >12 mg/dL
pH	7.5 – 9.0	5.0 – 6.0
Blood	0.06 – 1.0 mg/dL	NEG
Ketone	NEG	10 – >150 mg/dL
Nitrite	NEG	+1 – +2
Leukocytes	NEG	75 – 500/μL
SG	1.000 – 1.025	1.000 – 1.020



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