

CENSLIDE 2000 URINALYSIS SYSTEM VS. KOVA SYSTEM

APPLICATION REPORT: CENSLIDE 2000 Centrifuge
(The original studies performed on CenSlide 1500, Software Version 5.5. which was re-introduced in May 1997 by StatSpin as CenSlide 2000.)

DATE: 10/11/96

SUMMARY

Testing demonstrated there is no difference between the abilities of the KOVA System for standardized urinalysis and the CENSLIDE 2000 Urinalysis System, to detect abnormal at the 5% level of significance with agreement ranging from 96% to 100% for eight analytes measured.

MATERIALS

CENSLIDE 2000 Centrifuge	Serial # 46641564
CENSLIDE Tubes	Part# 50128A Lot# 2014
KOVA System Super Pac 1000	Part# 87153 Lot#68009
IEC Centrifuge	Model# HN-SII Serial# 23555511
KOVA Glasstic Slide 10	Part# 87146 Lot# 65160

TESTING

A total of 205 urine samples had microscopic analyses performed in duplicate testing using both the CENSLIDE 2000 Urinalysis System and the KOVA System.

1. Each urine sample was aliquoted according to manufacturer's recommendation as to volume and centrifuged according to accepted protocol.
2. Each sample was then viewed under both low power (100x) and high power (400x) to enumerate formed elements present in the urine.
3. Each sample was scanned over the entire viewing area to determine if an even dispersion of sediment was achieved.
4. A random sampling of five fields for both low and high power were counted and recorded to validate dispersion and determine correlation between the two systems.

In the case of arbitration, a "manual" microscopic analysis was performed to validate the results obtained and was noted in the data. This consisted of a wet mount of the sediment examined by conventional slide microscopy.

Doc. # 64-004067-001 Rev. A

STATISTICAL METHODS AND DEFINITIONS

While it is recognized that a definition of normal is controversial, for purposes of this study, normal ranges were based on the ranges presented in the KOVA System package insert except for hyaline casts and bacteria whose ranges were established in-house.

ANALYTE	NORMAL
WBC	0-5/hpf
RBC	0-3/hpf
Crystals	0-3/hpf (non-pathogenic)
Yeasts	0
Casts	0/lpf (other than hyaline) 0-2/lpf (hyaline)
Bacteria	0-5/hpf (trace)

hpf= high power field 400x lpf=low power field 100x

FALSE POSITIVE (FP) in the context of this document, is a positive result on the CENSLIDE System where the reference method (KOVA System) is negative on the same sample. (TP= total positive)

$$\text{FALSE POSITIVE RATIO} = \frac{FP}{FP+TP} \times 100$$

FALSE NEGATIVE (FN) in the context of this document is a negative result by the CENSLIDE System on a sample where the reference method (KOVA System) result is positive.

$$\text{FALSE NEGATIVE RATIO} = \frac{FN}{FN+TP} \times 100$$

To evaluate the detection of abnormal analytes or analyte concentrations for the test and reference methods, a 2 x 2 cross tabulation table was employed and the % AGREEMENT and the MCNEMAR's statistic were calculated. (TN=total negative)

$$\% \text{ AGREEMENT} = \frac{TP+TN}{TP+FN+FP+TN} \times 100 = \%$$

$$\text{MCNEMAR'S STATISTIC} = \frac{(B-C)^2}{B+C}$$

where B = False Negatives and C = False Positives. *For McNemar's statistic, if the value does not exceed 3.84, there is no difference between the abilities of the test and reference methods to detect abnormal at the 5% level of significance.*

RESULTS AND DISCUSSION:

COLOR--There appears to be no difference in color detection between the KOVA and the CENSLIDE tubes. Most colors were easily recognizable in both systems.

CLARITY--Tubes recorded as cloudy in KOVA tubes were for the most part, also noted as cloudy in the CENSLIDE tubes except for a few that were called hazy. Some slight differences were noted with hazy and slightly hazy tubes, but overall the clarity was fairly consistent between the two systems.

CASTS--Five specimens were found to have hyaline casts (<1 per lpf) detected with the CENSLIDE System that were not detected by the KOVA System, and three specimens had hyaline casts (<1 per lpf) detected by the KOVA System that were not detected with the CENSLIDE System. Note that detection at this level is clinically insignificant since less than one hyaline cast per lpf is considered normal.

However, there were three samples in which abnormal casts were detected with the CENSLIDE System that were not seen with the KOVA System, and one in which abnormal casts were found with the KOVA System that were not detected in the CENSLIDE System. In each of these, the number or casts present were <1 per lpf.

RBC--There appears to be a slight bias in red blood cell detection at the higher levels, with the KOVA System recovering higher counts than the CENSLIDE System. At decision levels however, (<3 per hpf) there appears good correlation (0.957) and agreement (99.5%) with no false negatives noted and only one false positive seen.

WBC—The overall correlation (0.984) and agreement (97.1%) on white blood cell detection between the KOVA System and the CENSLIDE System appears to be good.

EPITHELIAL CELLS--Counts on epithelial cells were noted for dispersion information only. Only one specimen was noted to contain renal epithelial cells, and they were observed with both systems.

YEAST—The overall agreement (97%) on the detection of yeast between the KOVA System and the CENSLIDE appears to be good. Any discrepancies noted were equally distributed between the two systems and were within one range of each other (see data).

CRYSTALS—The ability to detect the presence of crystals was evaluated by crystal type.

1. **CaOx Crystals** - Good overall agreement (98%) was found between the CENSLIDE and KOVA Systems. Any discrepancies were equally distributed and were within one range of each other (see data).
2. **Uric Acid Crystals** - Good overall agreement (99%) was found between the CENSLIDE and KOVA Systems. There appears to be a slightly higher recovery of Uric Acid crystals, at least one range higher, seen with the CENSLIDE System than with the KOVA System.
3. **Triple Phosphate Crystals** - When present, were observed in both systems.
4. **Cystine Crystals** - When present, were observed in both systems. *Note: One advantage seen with the CENSLIDE Closed System was on reexamination of the sample two days later, crystals were still present and easily identifiable.*

BACTERIA--There appears to be good agreement (96%) between the KOVA System and the CENSLIDE System for bacteria. Any discrepancies noted were equally distributed between the two systems with the majority of results within one range of each other (see data).

AMORPHOUS—There appears to be good agreement (97%) between the KOVA System and the CENSLIDE System for amorphous elements. The CENSLIDE System either matched or recovered slightly less than the KOVA System for amorphous elements on the majority of the samples tested.

ADVANTAGES OF THE CENSLIDE SYSTEM

The CENSLIDE System is an easy to use, closed system (once the urine sample is poured into the CENSLIDE tube, no further contact with the specimen is necessary). This eliminates the need to decant the supernatant, resuspend the sediment and pipet it onto a slide and cover it with a coverslip; or in the case of the KOVA System, decanting, mixing, and pipetting onto the Glasstic slide.

DISADVANTAGES OF THE KOVA SYSTEM

When pipetting onto the Glasstic slide of the KOVA System, the sample has to be placed so that the urine will flow by capillary action into the viewing area. Sometimes this placement proved to be a problem and the sample did not flow into the viewing area but along the edge of it.

Sometimes difficult to determine, especially if the sample was not particularly viscous or full of particles, whether the sample had entered the viewing chamber or not.

If too large a drop of specimen was placed on the slide, the remaining sample could be picked up by the microscope optic and the lens would have to be cleaned before examining the remaining slides.

CORRELATION:

RED BLOOD CELLS		CENSLIDE	
		Pos.	Neg.
		51	154
KOVA	POS.	TP	FN
	50	50	0
	NEG.	FP	TN
155	1	154	

AGREEMENT
99.5%

BACTERIA		CENSLIDE	
		Pos.	Neg.
		49	156
KOVA	POS.	TP	FN
	49	45	4
	NEG.	FP	TN
156	4	152	

AGREEMENT
96.1%

WHITE BLOOD CELLS		CENSLIDE	
		Pos.	NEG.
		45	160
KOVA	POS.	TP	FN
	41	40	1
	NEG.	FP	TN
164	5	159	

AGREEMENT
97.1%

YEAST		CENSLIDE	
		Pos.	NEG.
		28	177
KOVA	POS.	TP	FN
	27	24	3
	NEG.	FP	TN
178	4	174	

AGREEMENT
96.6%

RENAL CELLS EPITHELIAL		CENSLIDE	
		Pos.	NEG.
		1	204
KOVA	POS.	TP	FN
	1	1	0
	NEG.	FP	TN
204	0	204	

AGREEMENT
100%

AMORPHOUS		CENSLIDE	
		Pos.	NEG.
		31	174
KOVA	POS.	TP	FN
	35	30	5
	NEG.	FP	TN
170	1	169	

AGREEMENT
97.1%

	RBC'S	WBC'S	R EPI'S	BACT.	YEAST	AMOR.
N	50	40	1	45	24	30
SAME RANGE	41	28	1	31	22	16
± 1 RANGE	9	12	0	13	2	12
> 1 RANGE	0	0	0	1	0	2
% SAME RANGE	82%	70%	100%	69%	92%	53%
% ± 1 RANGE	18%	30%	0%	29%	8%	40%
% > 1 RANGE	0%	0%	0%	2%	0%	7%
FALSE POS.	0.7%	3.1%	0%	2.6%	2.3%	0.6%
FALSE NEG.	0%	2.4%	0%	8.2%	11.1%	14.3%
MCNEMAR'S	1.0	2.7	0	0	0.14	2.7

CORRELATION: (CONTINUED)

CRYSTAL TRIPLE PHOS.		CENSLIDE		AGREEMENT 99.5%
		POS.	NEG.	
		2	203	
KOVA	POS.	TP	FN	
	2	2	1	
	NEG.	FP	TN	
		202	0	202

CRYSTALS CYSTINE		CENSLIDE		AGREEMENT 100%
		POS.	NEG.	
		1	204	
KOVA	POS.	TP	FN	
	1	1	0	
	NEG.	FP	TN	
		204	0	204

CRYSTALS CAOX		CENSLIDE		AGREEMENT 97.6%
		POS.	NEG.	
		74	131	
KOVA	POS.	TP	FN	
	71	70	1	
	NEG.	FP	TN	
		134	4	130

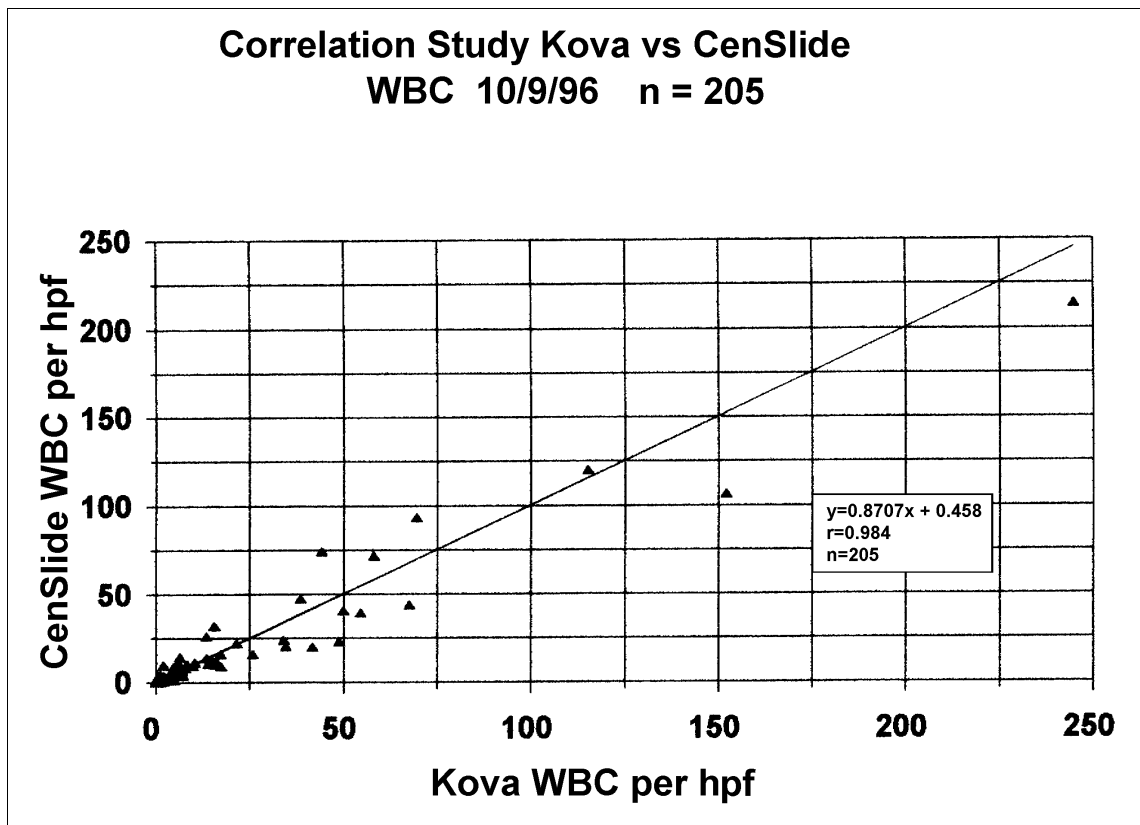
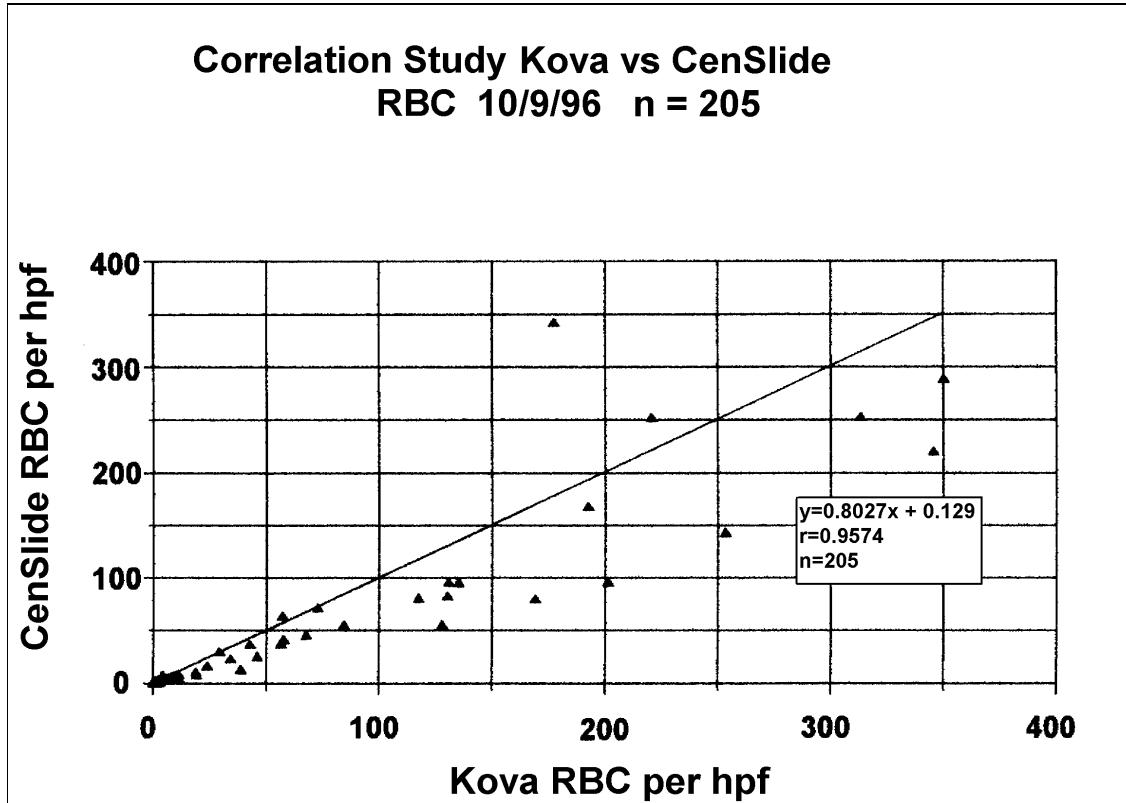
CRYSTALS URIC ACID		CENSLIDE		AGREEMENT 99%
		POS.	NEG.	
		19	186	
KOVA	POS.	TP	FN	
	17	17	0	
	NEG.	FP	TN	
		188	2	186

HYALINE CASTS		CENSLIDE		AGREEMENT 100%
		POS.	NEG.	
		0	205	
KOVA	POS.	TP	FN	
	0	0	0	
	NEG.	FP	TN	
		205	0	205

OTHER CASTS		CENSLIDE		AGREEMENT 98.0%
		POS.	NEG.	
		8	197	
KOVA	POS.	TP	FN	
	6	5	1	
	NEG.	FP	TN	
		199	3	196

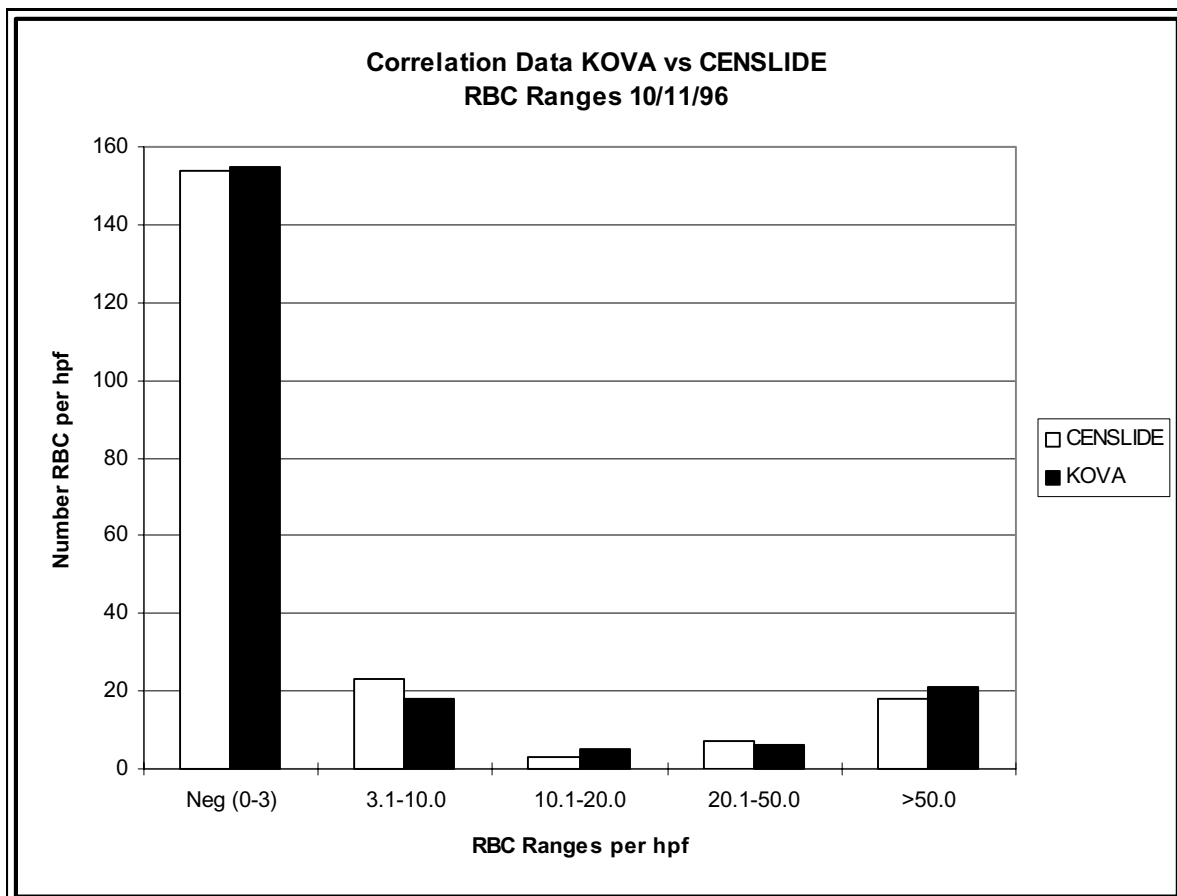
	CRYSTALS				CASTS	
	CAOX	URIC	T. PHOS	CYST.	HYAL.	OTHER
N	70	17	2	1	0	5
SAME RANGE	57	5	0	1	0	5
± 1 RANGE	10	7	1	0	0	0
> 1 RANGE	3	5	1	0	0	0
% SAME RANGE	82%	30%	0%	100%	0%	100%
% ± 1 RANGE	14%	40%	50%	0%	0%	0%
% > 1 RANGE	4%	30%	50%	0%	0%	0%
FALSE POS.	3.0%	1.1%	0%	0%	0%	1.5%
FALSE NEG.	1.4%	0%	33%	0%	0%	16.7%
MCNEMAR'S	1.8	2.0	1.0	0	0.0	1.0

CORRELATION: (CONTINUED)



CORRELATION: (CONTINUED)

RBC	CENSLIDE			KOVA		
	Range	Number	%	Range	Number	%
	Neg (0-3)	154	75.1	Neg (0-3)	155	75.6
	3.1-10.0	23	11.2	3.1-10.0	18	8.8
	10.1-20.0	3	1.5	10.1-20.0	5	2.4
	20.1-50.0	7	3.4	20.1-50.0	6	2.9
	>50.0	18	8.8	>50.0	21	10.2
	Total Pos	51	24.9	Total Pos	50	24.4



CORRELATION: (CONTINUED)

WBC	CenSlide			Kova		
	Range	Number	%	Range	Number	%
	Neg (0-5)	160	78	Neg (0-5)	164	80.0
	5.1-10.0	16	7.8	5.1-10.0	12	5.9
	10.1-20.0	10	4.9	10.1-20.0	10	4.9
	20.1-50.0	10	4.9	20.1-50.0	9	4.4
	>50.0	9	4.4	>50.0	10	4.9
	Total Pos	45	22.0	Total Pos	41	20.0

