



C.H.U. *de Charleroi*

# Analyse automatisée des particules urinaires par cytométrie: Évaluation de la chaîne Sysmex U-Next ( UC-3500 + UF-5000 + UD-10)

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Évaluation réalisée au laboratoire de biologie clinique de l'Hôpital Civil Marie Curie  
(CHU de Charleroi)

Corata Belgique

5<sup>ème</sup> congrès de Biologie Clinique

Le Touquet, 28 septembre 2017

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# Plan

- " Analyse des particules urinaires par cytométrie en flux
  - " UF-5000
    - . 1<sup>ère</sup> partie: évaluation technique
      - " Répétabilité
      - " Reproductibilité
      - " Linéarité
      - " Carry-Over
    - . 2<sup>ème</sup> partie : comparaison de méthodes et diagnostic
      - " Comparaison avec l'iQ200
      - " Comparaison avec la culture bactérienne
  - " UC-3500
  - " UD-10
-



UD-10

UF-5000

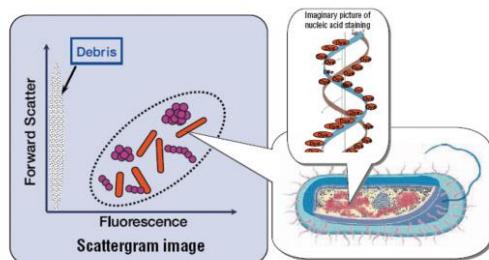
UC-3500

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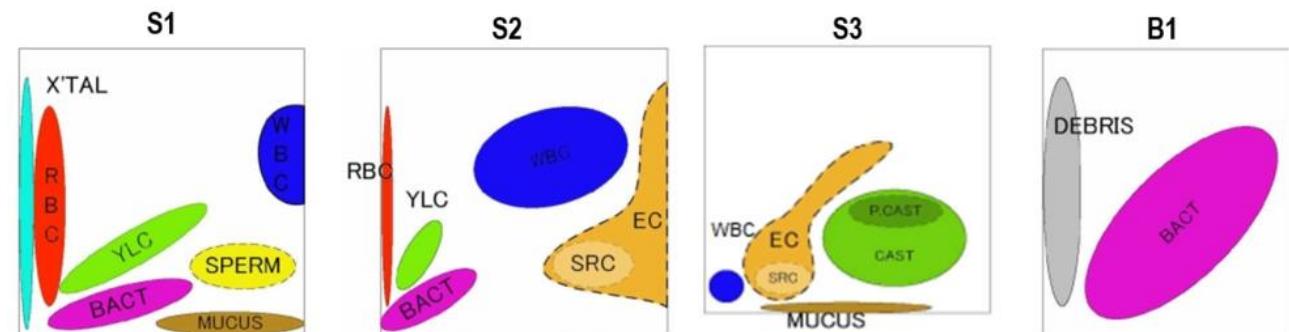
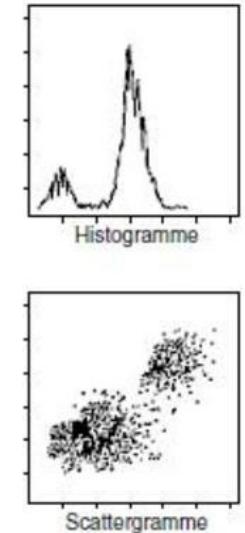
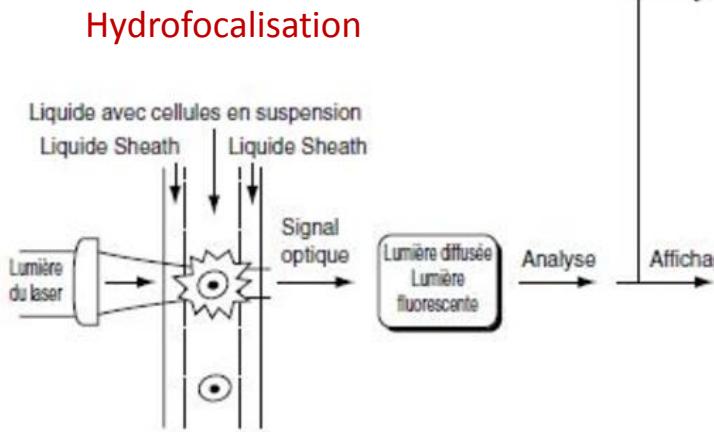


# Principe Sysmex UF series

## Traitement des particules urinaires

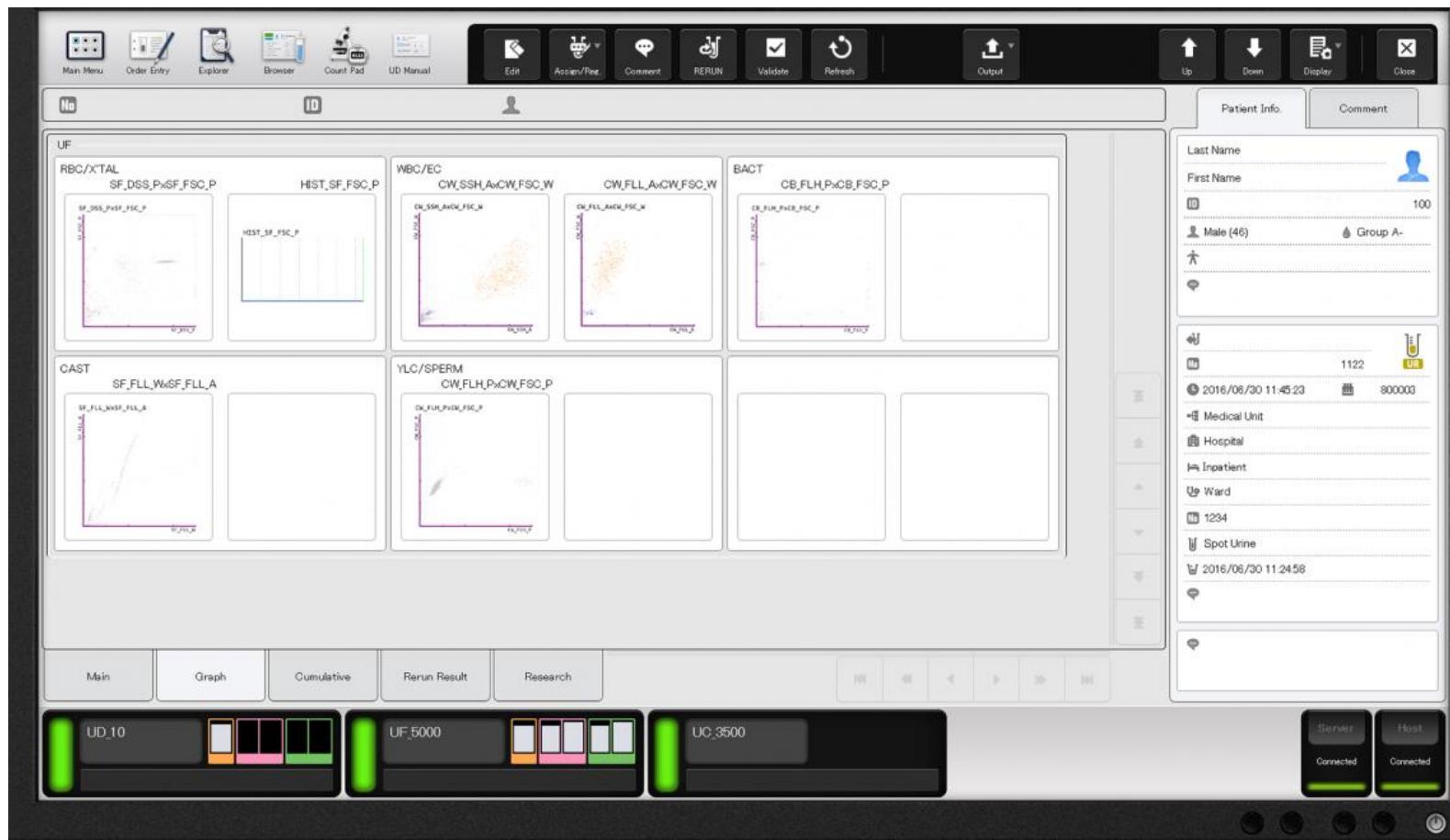


Laser Bleu  
(488 nm)





# Principe Sysmex UF series





# Sysmex UF-5000

## 17 paramètres rapportés:

- |             |                        |               |                   |
|-------------|------------------------|---------------|-------------------|
| . RBC:      | Red Blood Cells        | . CAST:       | Casts             |
| . NL RBC:   | Non Lysed RBC          | . Hy. CAST:   | Hyaline Casts     |
| . WBC:      | White Blood Cells      | . Path. CAST: | Pathological CAST |
| . WBCc:     | WBC Clumps             | . BACT:       | Bacteria          |
| . EC:       | Total Epithelial Cells | . XTAL:       | Cristals          |
| . sEC:      | Squamous EC            | . YLC:        | Yeast-like Cells  |
| . Tran. EC: | Transitional EC        | . SPERM:      | Spermatozoa       |
| . RTEC:     | Renal Tubular EC       | . MUCUS:      | Mucus             |





# Vérification technique

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# Répétabilité

“ Pools d'urines, 15 passages successifs

	CHU Charleroi			Sysmex		Previtali et al	
RBC	$\mu$ (/ $\mu$ L)	SD	CV (%)	$\mu$ (/ $\mu$ L)	CV (%)	$\mu$ (/ $\mu$ L)	CV (%)
	18,6	2,3	<b>12,4</b>	10	<b>15</b>	8,6	<b>13,81</b>
	28,4	2,2	<b>7,8</b>				
	90,7	3,2	<b>3,6</b>				
	902,5	37,2	<b>4,1</b>			2042,1	<b>1,36</b>
	6555,2	160,1	<b>2,4</b>	5000	<b>10</b>		
	49595,3	2031,7	<b>4,1</b>				



# Répétabilité

“ Pools d'urines, 15 passages successifs

	CHU Charleroi			Sysmex		Previtali et al	
WBC	$\mu$ (/ $\mu$ L)	SD	CV (%)	$\mu$ (/ $\mu$ L)	CV (%)	$\mu$ (/ $\mu$ L)	CV (%)
	8,6	1,2	<b>13,9</b>	10	<b>15</b>	12,8	<b>10,2</b>
	62,7	2,4	<b>3,9</b>				
	114,7	5,8	<b>5,1</b>				
	510,6	31,3	<b>6,1</b>				
	2411,1	64,0	<b>2,7</b>	5000	<b>10</b>		
	8975,1	272,1	<b>3,0</b>			14653,9	<b>1,4</b>
	22421,0	248,1	<b>1,1</b>				



# Répétabilité

“ Pools d'urines, 15 passages successifs

	CHU Charleroi			Sysmex		Previtali et al	
	$\mu$ (/ $\mu$ L)	SD	CV (%)	$\mu$ (/ $\mu$ L)	CV (%)	$\mu$ (/ $\mu$ L)	CV (%)
EC	9,6	1,5	<b>15,2</b>	7	30	6,42	<b>17,9</b>
	17,0	1,9	<b>11,3</b>				
	27,8	1,7	<b>6,0</b>				
	43,5	2,6	<b>6,0</b>				
	72,1	6,6	<b>9,1</b>				
	101,5	4,7	<b>4,7</b>	200	30	204,4	<b>6,3</b>



# Répétabilité

” Pools d'urines, 15 passages successifs

	CHU Charleroi				Sysmex	
BCT	$\mu$ (/ $\mu$ L)	SD	CV (%)		$\mu$ (/ $\mu$ L)	CV (%)
	19,5	6,7	<b>34,6</b>			
	220,2	49,5	<b>22,5</b>		100	<b>20</b>
	1419,3	75,5	<b>5,3</b>			
	39434,1	3020,8	<b>7,7</b>		10000	<b>20</b>
	95838,7	2022,2	<b>2,1</b>			

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# Reproductibilité

“ Solutions de contrôle, 2 niveaux, 1x/jour durant 20 jours

		CHU de Charleroi			Annonces Sysmex		Previtali et al.	
	Level	$\mu$ (per $\mu\text{L}$ )	SD (per $\mu\text{L}$ )	CV (%)	$\mu$ (per $\mu\text{L}$ )	CV (%)	$\mu$ (per $\mu\text{L}$ )	CV (%)
RBC	Low	40.7	2.8	<b>6.9</b>	40	<b>40</b>	42,90	<b>6,2</b>
	High	202.0	5.4	<b>2.6</b>	200	<b>30</b>	212,4	<b>1,6</b>
WBC	Low	40.1	2.0	<b>5.0</b>	40	<b>15</b>	40,8	<b>4,1</b>
	High	798.4	23.6	<b>2.9</b>	800	<b>10</b>	806,0	<b>1,9</b>
BCT	Low	209.0	15.1	<b>7.2</b>	200	<b>20</b>		
	High	826.1	40.2	<b>4.8</b>	800	<b>20</b>		
EC	Low	12.4	2.1	<b>16.6</b>	10	<b>30</b>	11,2	<b>7,6</b>
	High	86.0	6.8	<b>7.8</b>	80	<b>30</b>	78,9	<b>7,3</b>



# Linéarité

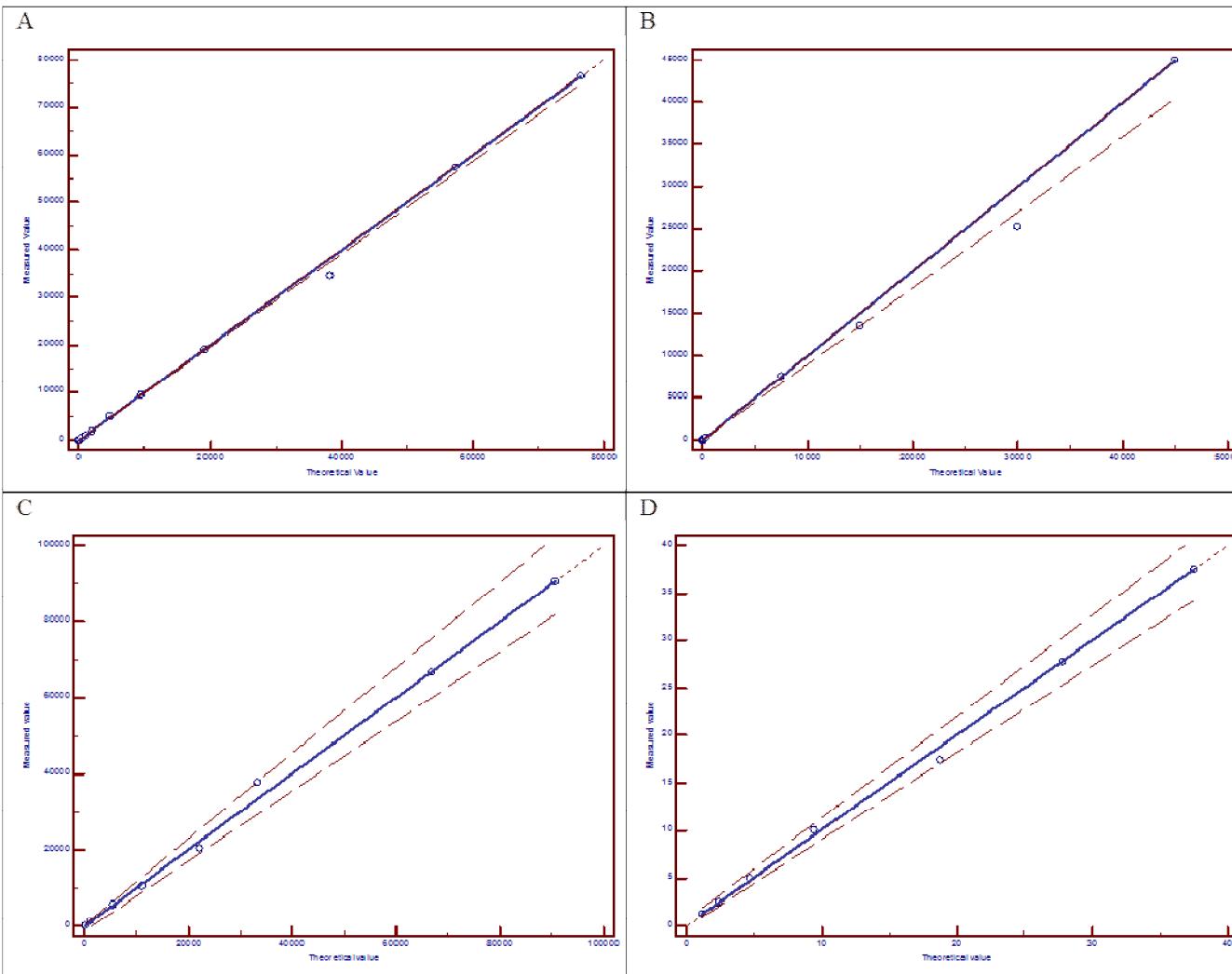
- " RBC: 9,7 → 76 547,5 / $\mu$ L (n = 11)
- " WBC: 2,2 → 44 964,9 / $\mu$ L (n = 12)
- " BCT : 111,3 → 90 675,5 / $\mu$ L (n = 8)
- " EC: 1,2 → 37,5 / $\mu$ L (n = 7)
- " 3 passages par niveau de concentration

Parameter	Slope (CI 95)	Intercept (CI 95)	rho	p <sub>Cusum test</sub>	CCC (CI 95)
RBC	0.999 (0.979 - 1.003)	30.487 (-6.667 - 40.573)	1.000 (1.000 - 1.000)	0.77	0.999 (0.997 - 1.000)
WBC	0.999 (0.898 - 1.001)	0.003 (-1.731 - 3.925)	1.000 (1.000 - 1.000)	0.86	0.995 (0.984 - 0.998)
BCT	0.999 (0.915 - 1.123)	86.619 (-1190.832 - 540.311)	1.000 (1.000 - 1.000)	1.00	0.999 (0.993 - 1.000)
EC	0.994 (0.912 - 1.065)	0.226 <b>(0.004 - 0.721)</b>	1.000 (1.000 - 1.000)	0.43	0.999 (0.994 - 1.000)



# Linéarité

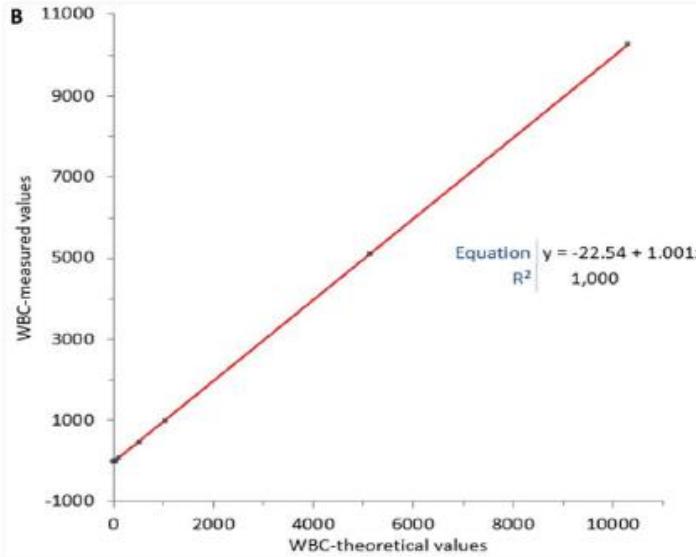
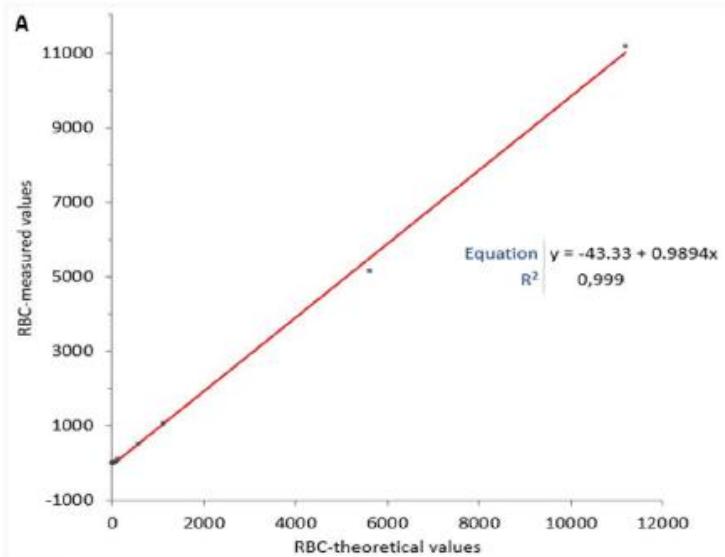
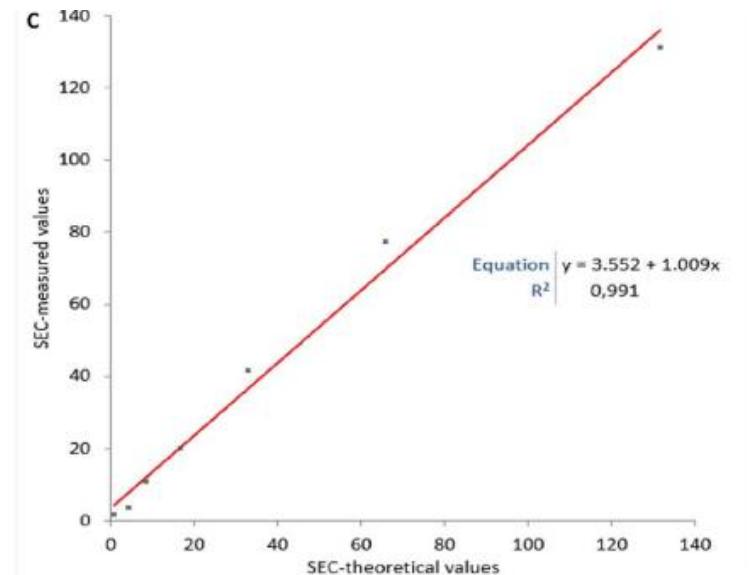
Figure 1: Assessment of linearity for RBC (A), WBC (B), BCT (C) and EC (D).





# Linéarité

Previtali et al.





# Carry Over

- " RBC: 49 595,3/ $\mu\text{L}$
- " WBC: 22 421,0/ $\mu\text{L}$
- " BCT:
  - . Sans auto-wash: 95 838,7/ $\mu\text{L}$
  - . Avec auto-wash : 99 980,3/ $\mu\text{L}$

$$CO = \frac{(mB1 - mB3)}{(mH - mB3)} \times 100$$

Parameter	mH (/ $\mu\text{L}$ )	mB1 (/ $\mu\text{L}$ )	mB3 (/ $\mu\text{L}$ )	CO (%)	Sysmex		Previtali et al.	
					mH	CO	mH	CO
RBC	49 595,3	28,2	4,1	0,05	10 000	< 0,05	14 379,0	0,00
WBC	22 421,0	3,6	0,7	0,01	10 000	< 0,05	16 462,0	0,00
Bct (without Auto-wash)*	95 838,7	82,8	1,9	0,08	10 000	< 0,05	97 805,0	0,00
Bct (with Auto-wash)*	99 980,3	9,9	1,9	0,01				

\* p = 0,04



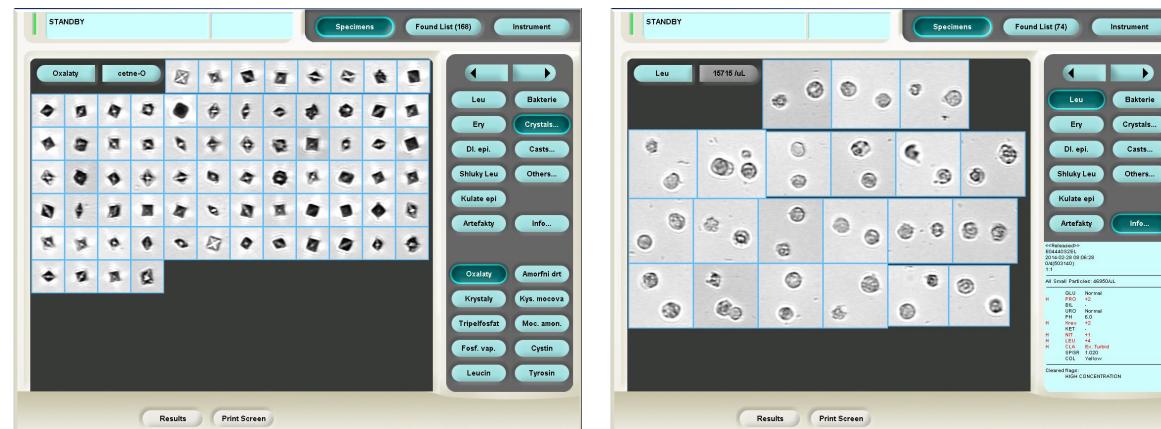
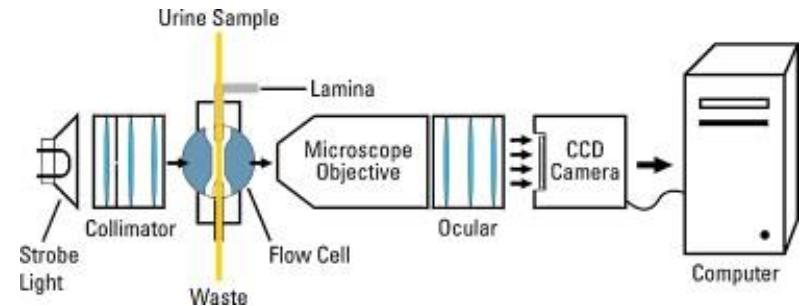
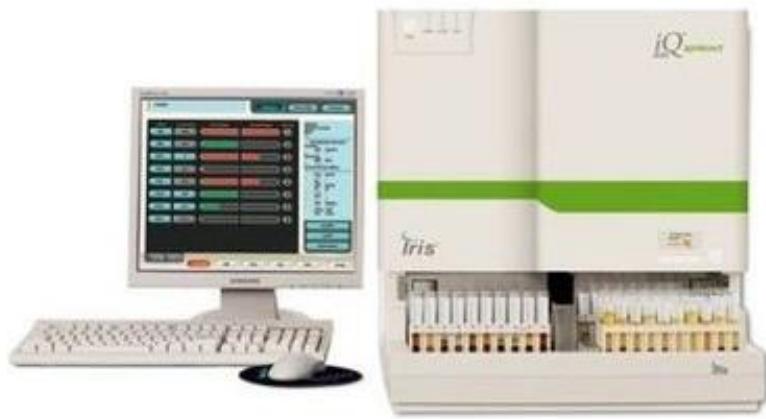
## Comparaison de méthodes

UF-5000

IQ200



# Iris IQ200





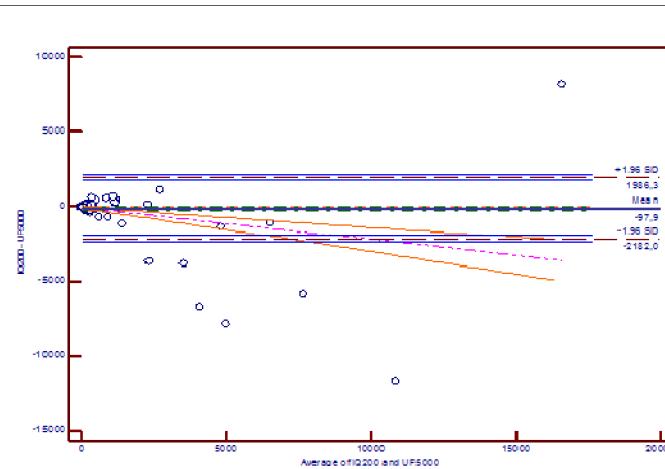
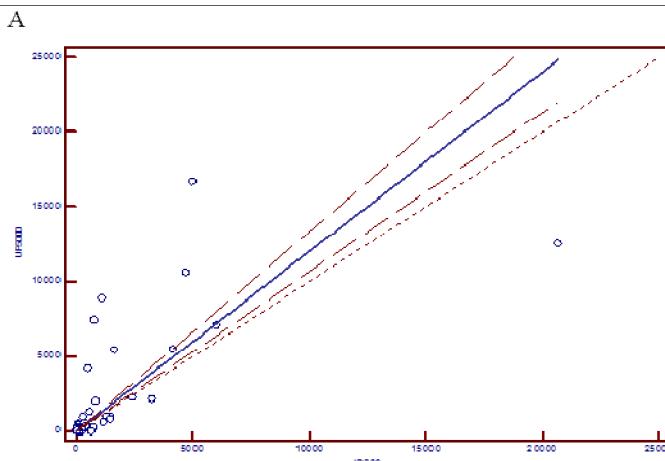
# Comparaison IQ200/UF-5000: Quantitatif

- “ RBC, WBC, EC
- “ 334 urines, pas d'exclusion d'outliers

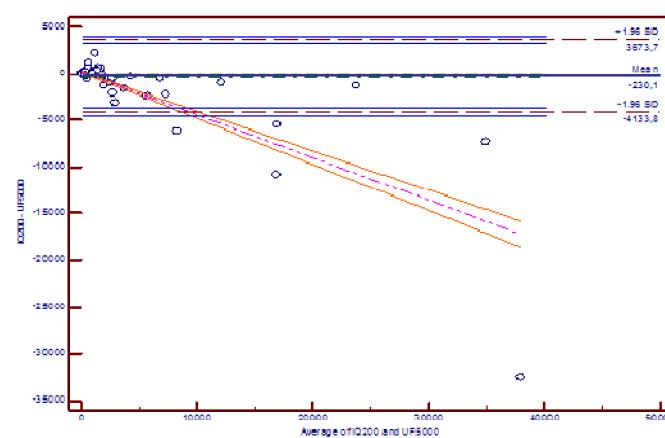
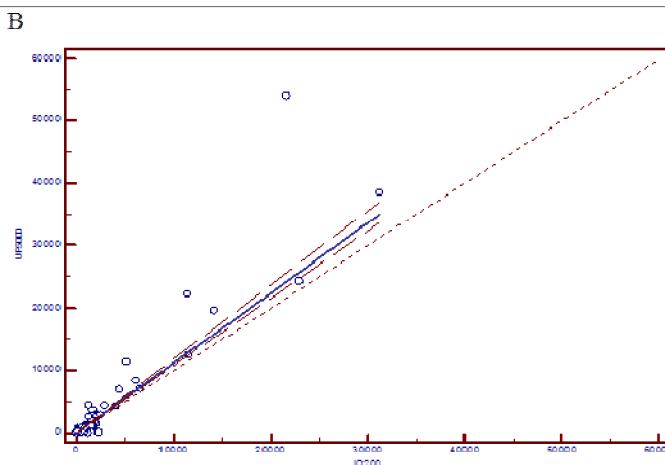
McBride. (2005) :

Strength-of-agreement	Continuous variables	QuantiTray methods
Almost perfect	>0.99	>0.90
Substantial	0.95..0.99	0.8..0.9
Moderate	0.90..0.95	0.65..0.8
Poor	<0.90	<0.65

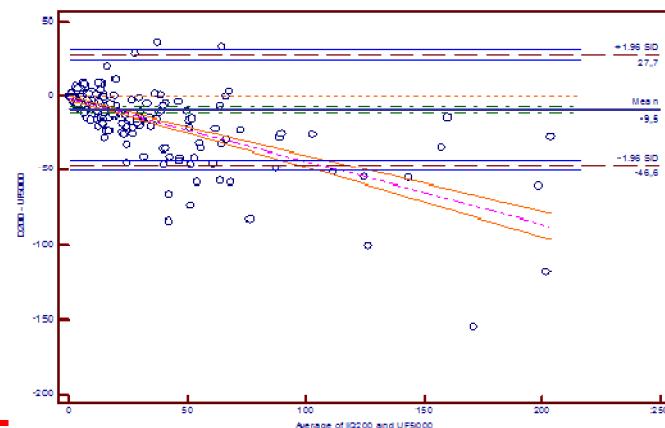
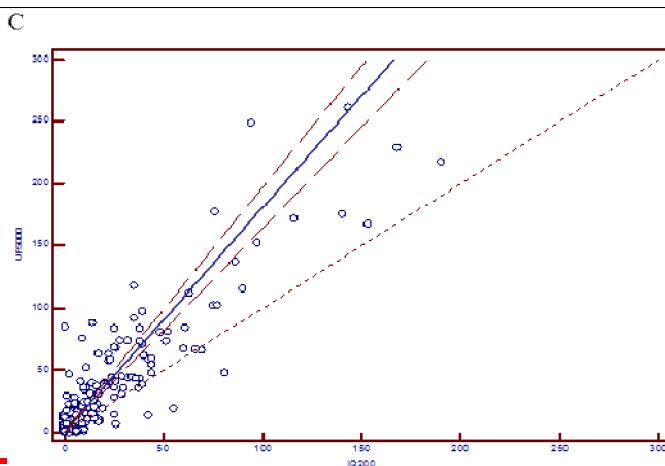
	Slope	Intercept	rho	p <sub>Cusum test</sub>	CCC	Mean Bias (B-A)
RBC	1.200 (1.065 – 1.333)	0.350 (-0.232 – 0.935)	0.780 (0.734 – 0.819)	0.42	0.719 (0.665 - 0.765)	-97.9 (-2182.0 - 1986.3)
WBC	1.118 (1.076 – 1.185)	0.686 (-0.077 – 1.199)	0.916 (0.896 – 0.931)	0.77	0.848 (0.829 – 0.865)	-230.1 (-4133.8 - 3673.7)
EC	1.800 (1.635 - 1.960)	0.600 (0.450 - 1.100)	0.798 (0.755 - 0.834)	0.17	0.802 (0.773 - 0.829)	-9.5 (-46.6 - 27.7)



RBC



WBC



EC



# Comparaison IQ200/UF-5000: Quantitatif

- “ Surestimation de la part de l'UF-5000 pour RBC, WBC et EC
- “ Littérature:

Auteur	Sysmex	Référence	Observations
Ben-Ezra et al.	UF-100	Microscopie (KOVA)	Surestimation de l'UF pour RBC, WBC et EC
Mayo et al.	UF-100	Microscopie, IQ200, Tigettes	Moins bonne corrélation entre UF-100 et microscopie pour RBC
Ottiger et al.	UF-100	Microscopie (KOVA)	Surestimation de l'UF pour RBC, WBC et EC
Chien et al.	UF-100	IQ200, Microscopie (S-Y Slide)	Pas de différence significative entre IQ200 et UF-100 pour RBC et WBC. Meilleure corrélation entre IQ200 et microscopie pour EC

TABLE 3. iQ200 vs. UF-100 Comparison

Parameter	Agreement		
	n	%	Spearman's <i>p</i>
Erythrocytes	477	75	0.506
Leukocytes	491	77	0.751
Epithelial cells	337	52	0.472
Bacteria	607	94	0.791
Crystals	608	95	0.170

TABLE 4. Analyzers vs. Manual Examination of Sediment Comparison

Analyzer	Erythrocytes			Leucocytes			Bacteria/Nitrites		
	n	%	p	n	%	p	n	%	p
iQ200	523	81	0.473	475	73	0.695	564	87	0.538
UF-100	473	74	0.439	498	78	0.761	584	91	0.647
ATLAS	368	88	0.525	447	69	0.684	577	89	0.532
URISYS	556	86	0.539	461	71	0.620	581	90	0.561

Table 1. Deming regression analysis for RBCs, WBCs, and ECs in urine.

	KOVA vs UF-100 <sup>a</sup>	Sediment vs UF-100 <sup>a</sup>
RBCs (n = 212 samples) <sup>b</sup>		
Slope	1.16 (0.02)	0.88 (0.02)
Intercept, $\times 10^6/L$	4.3 (1.26)	-1.25 (1.58)
Correlation coefficient	0.966	0.951
WBCs (n = 241 urine samples) <sup>b</sup>		
Slope	1.50 (0.04)	1.15 (0.04)
Intercept, $\times 10^6/L$	4.4 (1.39)	-1.75 (1.70)
Correlation coefficient	0.935	0.887
ECs (n = 46 urine samples) <sup>b</sup>		
Slope	1.26 (0.09)	
Intercept, $\times 10^6/L$	-1.9 (3.22)	
Correlation coefficient	0.902	

<sup>a</sup>SD of slope and intercept in parentheses.<sup>b</sup>Of a total of 252 samples.Table 2  
Linear regression analysis results among the Iris iQ200, Sysmex UF-100 and manual microscopy

	Slope	Intercept (cells/ $\mu$ L)	Correlation coefficient ( <i>r</i> )	<i>p</i>
WBC	iQ200 vs. UF-100	0.846	11.216	0.948
	iQ200 vs. manual	1.034	6.197	0.935
	UF-100 vs. manual	0.932	10.414	0.954
RBC	iQ200 vs. UF-100	0.789	0.423	0.953
	iQ200 vs. manual	1.177	16.939	0.950
	UF-100 vs. manual	0.985	9.825	0.968
EC <sup>a</sup>	iQ200 vs. UF-100	0.951	4.982	0.888
	iQ200 vs. manual	0.822	-0.089	0.922
	UF-100 vs. manual	0.907	2.832	0.896

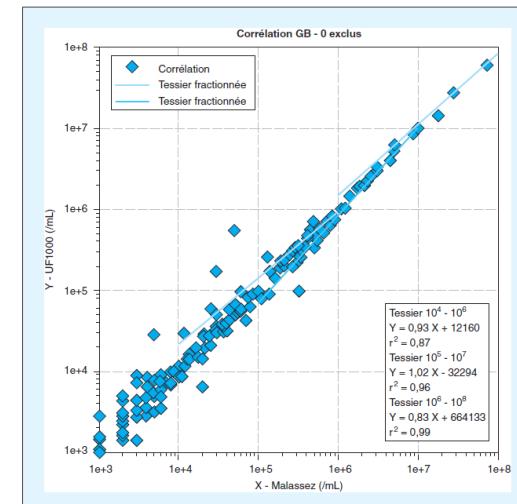
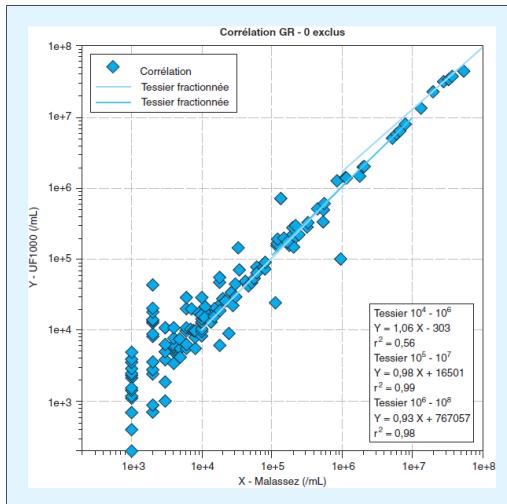
<sup>a</sup> EC, epithelial cell.<sup>b</sup> NS, no significant.Ben-Ezra et al. *Clinical Chemistry* 44:1, 92–95 (1998)Mayo et al. *J. Clin. Lab. Anal.* 22:262–270 (2008)Ottiger et al. *Clinical Chemistry* 49:4, 617–623 (2003)Chien et al. *Clinica Chimica Acta* 384 (2007) 28–34



# Comparaison IQ200/UF-5000: Quantitatif

- “ Surestimation de la part de l'UF-5000 pour RBC, WBC et EC
- “ Littérature:

Auteur	Sysmex	Référence	Observations
Fabbro et al.	UF-1000i	Microscopie (Malassez)	RBC: Corrélation quantitative médiocre pour valeurs basses et satisfaisantes pour les valeurs plus hautes ( $> 100\ 000/\mu\text{L}$ ), Surestimation de l'UF-1000 pour RBC dans 1/3 des cas. WBC: Bonne corrélation.



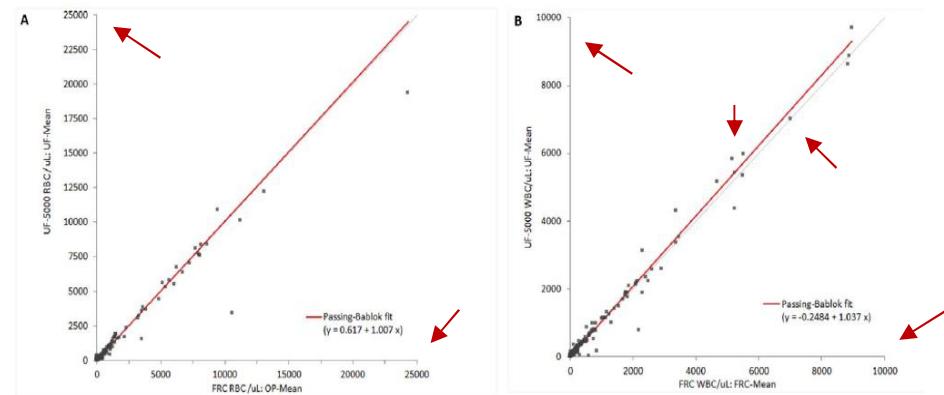


# Comparaison IQ200/UF-5000: Quantitatif

- ~ Surestimation de la part de l'UF-5000 pour RBC, WBC et EC
- ~ Littérature:

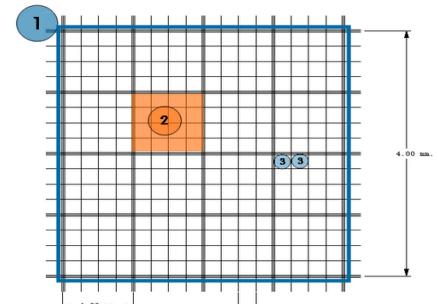
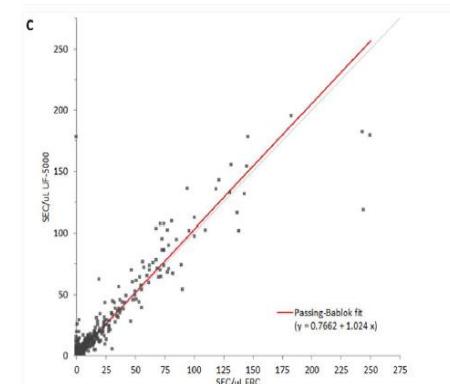


Performance evaluation of the new fully automated urine particle analyser UF-5000 compared to the reference method of the Fuchs-Rosenthal chamber  
 Giulia Previtali\*, Rudi Ravasio, Michela Seghezzi, Sabrina Buoro, Maria Grazia Alessio  
 Clinical Chemistry Laboratory, Department of Laboratory Medicine, Papa Giovanni XXIII Hospital, Piazza OMS 1, Bergamo, Italy



« Excellente corrélation entre UF-5000 et microscopie (Fuchs-Rosenthal) »

???



$$\text{Concentration Cellulaire} = \frac{\text{Cellules totales comptées}}{625}$$

$$\text{Concentration Cellulaire} = \frac{\text{Cellules totales comptées} \times 10.000}{\text{Nombre de carrés}}$$

Fig. 1. Comparison between UF-5000 and Fuchs-Rosenthal chamber (FRC) count using Passing-Bablok statistics.  
 (A) Correlation for Red Blood Cells (RBC);(B) correlation for White Blood Cells (WBC);(C) correlation for Squamous Epithelial Cells (SEC).



# Comparaison IQ200/UF-5000: Qualitatif

## ” Comparaison UF-5000 et iQ200

TABLE XVIII. Maximum allowable false-negative rates in urine microscopy.

Particle type	Particle concentration ( $\times 10^6/L$ )	Maximum allowable false-negative rates (%)
RBC	10	20
	100	5
WBC	20	10
	200	5
Bacteria	10	20
	100	5
Casts	10	10
	50	5



# Comparaison IQ200/UF-5000: Qualitatif

Parameter	Cut Off	Prevalence	Se	Sp	PPV	NPV	FN (%)	k	PABAK	AUC
RBC	10	0.428	0.804 (0.730 – 0.866)	0.812 (0.749 – 0.864)	0.762 (0.686 – 0.827)	0.847 (0.787 – 0.896)	19,6 (13.4 – 27.0)	0.611 (0.526 – 0.697)	0.617 (0.613 – 0.620)	0.909 (0.873 - 0.938)
	100	0.141	0.787 (0.643 – 0.893)	0.976 (0.950 – 0.990)	0.841 (0.699 – 0.934)	0.966 (0.938 – 0.983)	21,3 (10.7 – 35.7)	0.784 (0.684 – 0.884)	0.898 (0.897 – 0.899)	0.957 (0.930 - 0.976)
WBC	10	0.587	0.944 (0.902 – 0.972)	0.819 (0.744 – 0.879)	0.881 (0.829 – 0.922)	0.911 (0.847 – 0.955)	5,6 (2.8 – 9.8)	0.774 (0.705 - 0.844)	0.784 (0.782 – 0.787)	0.962 (0.935 - 0.980)
	20	0.458	0.922 (0.867 – 0.959)	0.867 (0.809 – 0.913)	0.855 (0.791 – 0.905)	0.929 (0.879 – 0.963)	7,8 (4.1 – 13.3)	0.784 (0.718 – 0.851)	0.784 (0.782 – 0.787)	0.970 (0.946 - 0.986)
	200	0.228	0.921 (0.836 – 0.971)	0.985 (0.961 – 0.996)	0.946 (0.867 – 0.985)	0.977 (0.951 – 0.992)	7,9 (2.9 – 16.4)	0.914 (0.862 – 0.967)	0.910 (0.909 – 0.911)	0.987 (0.968 - 0.996)

Table 1 - Interpretation of kappa.

Kappa	Agreement
< 0.00	Less than chance agreement
0.01 - 0.20	Slight agreement
0.21 - 0.40	Fair agreement
0.41 - 0.60	Moderate agreement
0.61 - 0.80	Substantial agreement
0.81 - 0.99	Almost perfect agreement

Landis and Koch, 1977

Byrt T et al. Clin Epidemiol 1993. Vol. 46, No. 5, 423-429



# Comparaison IQ200/UF-5000: Qualitatif

Auteur	Automate Sysmex	Référence	Paramètre	Cut Off	Prévalence	Se	Sp	PPV	NPV
Manoni et al.	UF-1000i	Microscopie (Fuchs-Ros.)	RBC	10	0,51	0,97 (0,92-0,99)	0,94 (0,88-0,98)	0,94 (0,92-0,98)	0,97 (0,91-0,99)
			WBC	10	0,52	1,00 (0,96-1,00)	0,95 (0,88-0,98)	0,96 (0,90-0,99)	1,00 (0,96-1,00)
			EC	7	0,45	0,98 (0,92-1,00)	0,96 (0,91-0,99)	0,96 (0,90-0,99)	0,98 (0,94-1,00)
			Cast	1	0,095	0,95 (0,74-0,99)	0,81 (0,73-0,87)	0,33 (0,21-0,48)	0,99 (0,95-1,00)

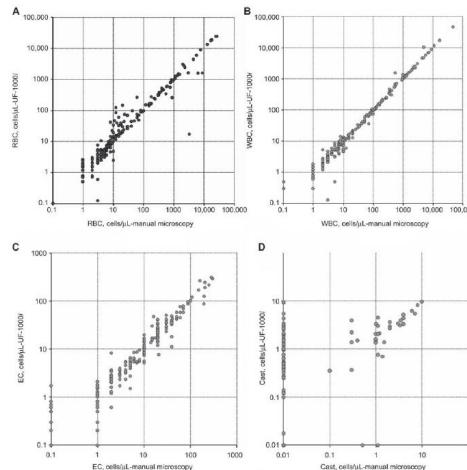


Figure 1 Correlation between UF-1000i and quantitative microscopy evaluated using Pearson's statistic.  
(A) Correlation for RBC; (B) correlation for WBC; (C) correlation for EC; (D) correlation for casts.





# Comparaison de méthodes

UF-5000

IQ200

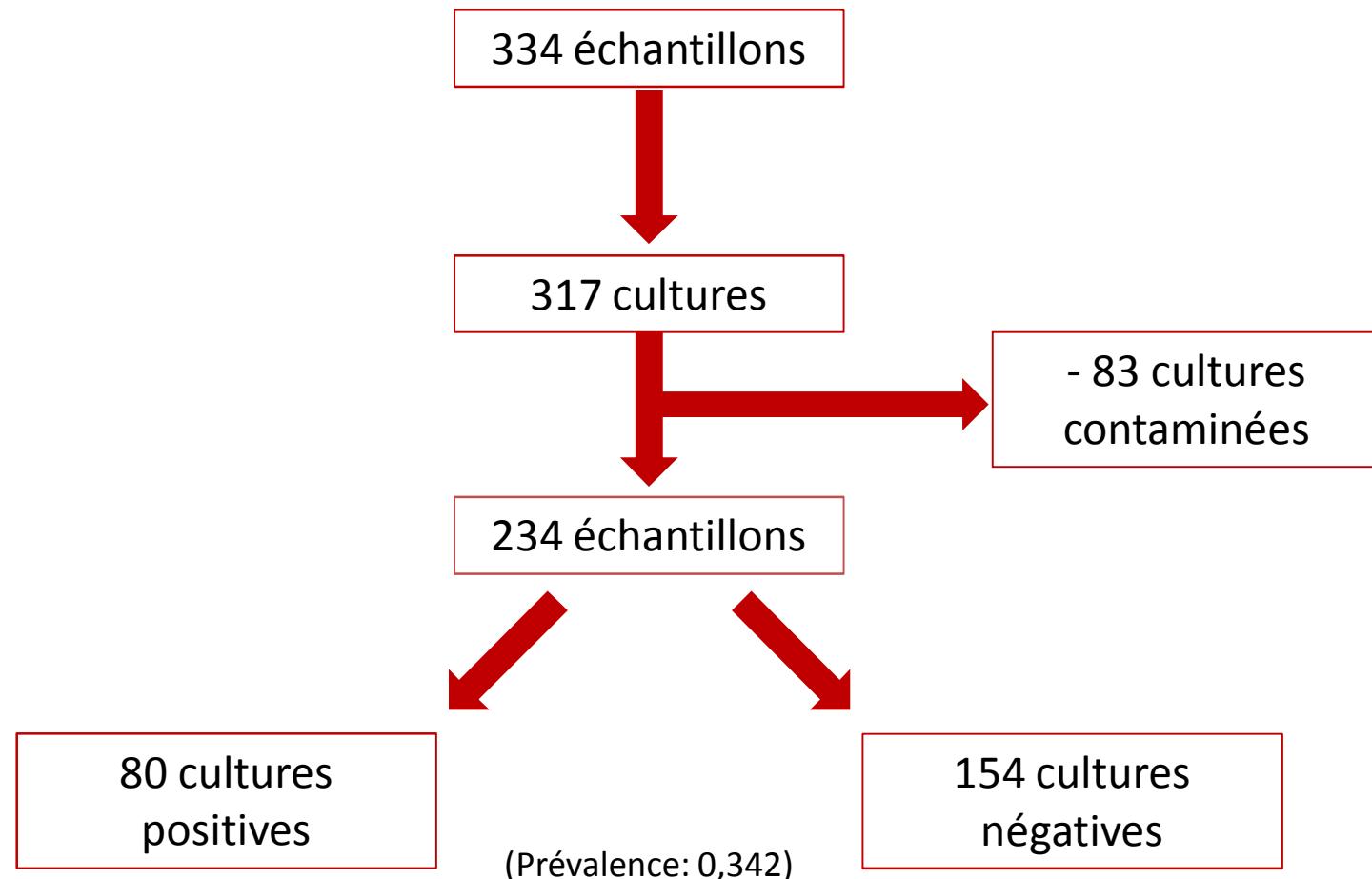
Culture bactérienne





# Comparaison IQ200/UF-5000/Bactériologie

“ Cultures bactériennes





# Comparaison IQ200/UF-5000/Bactériologie

## Classification des cultures

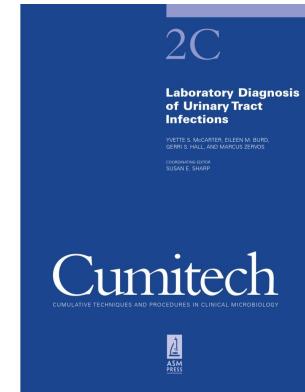
- . Classe 1: < 1x10<sup>3</sup> CFU/mL,
  - . Classe 2: 1x10<sup>3</sup> – 1x10<sup>4</sup> CFU/mL,
  - . Classe 3: 1x10<sup>4</sup> – 5x10<sup>4</sup> CFU/mL,
  - . Classe 4: 5x10<sup>4</sup> – 1x10<sup>5</sup> CFU/mL
  - . Classe 5: > 1x10<sup>5</sup> CFU/mL (8).
- “Significative”: > 1x10<sup>4</sup> CFU/mL.

## Parmi les 80 cultures positives

- . Classe 1: 1
- . Classe 2: 8
- . Classe 3: 7
- . Classe 4: 8
- . Classe 5: 56

## Identification: MALDI-TOF (Bruker Biotyper®)

- |                   |    |
|-------------------|----|
| . E. coli:        | 49 |
| . K. pneumoniae:  | 9  |
| . P. mirabilis:   | 5  |
| . E. faecalis:    | 3  |
| . M. morganii:    | 2  |
| . P aeruginosa:   | 2  |
| . S marcescens:   | 2  |
| . P. stuartii:    | 2  |
| . S. aureus:      | 2  |
| . K. oxytoca:     | 1  |
| . C. koseri:      | 1  |
| . E. cloacae cpx: | 1  |
| . E. enterogenes: | 1  |
| . S. agalactiae:  | 1  |
| . S. bovis:       | 1  |





# Comparaison IQ200/UF-5000/Bactériologie

## ” Prédiction des résultats de la culture bactérienne

- . WBC et Bct séparément sur Iris IQ200 et UF-5000
- . Combinaison WBC + Bct sur chaque automate
- . Alarmes spécifiques sur UF-5000
  - ” « Bacteria: Gram Positive? »
  - ” « Bacteria: Gram negative? »
  - ” « Bacteria: Gram positive/negative? »
  - ” « Bacteria: unclassified »





# Comparaison IQ200/UF-5000/Bactériologie

~ WBC dans la prévision des résultats de la culture:

Parameter	Analyzer	Cut Off	Se	Sp	PPV	NPV	FN%	k	PABAK
WBC	IQ200	10	0.938 (0.860 – 0.979)	0.552 (0.470 – 0.632)	0.520 (0.436 – 0.605)	0.944 (0.875 – 0.982)	6.3 (2.1 – 14.0)	0.411 (0.299 – 0.522)	0.368 (0.360 – 0.375)
		20	0.900 (0.812 – 0.956)	0.701 (0.622 – 0.772)	0.610 (0.516 – 0.699)	0.931 (0.869 – 0.970)	10.0 (4.4 – 18.8)	0.540 (0.432 – 0.647)	0.538 (0.533 – 0.544)
		200	0.625 (0.510 – 0.731)	0.903 (0.844 – 0.945)	0.769 (0.648 – 0.865)	0.823 (0.756 – 0.877)	37.5 (26.9 – 49.0)	0.552 (0.435 – 0.670)	0.615 (0.610 – 0.621)
	UF-5000	10	0.975 (0.913 – 0.997)	0.526 (0.444 – 0.607)	0.517 (0.434 – 0.599)	0.976 (0.916 – 0.997)	2.5 (0.3 – 8.7)	0.413 (0.303 – 0.522)	0.359 (0.352 – 0.366)
		20	0.900 (0.812 – 0.956)	0.669 (0.589 – 0.743)	0.585 (0.493 – 0.674)	0.928 (0.863 – 0.968)	10.0 (4.4 – 18.8)	0.504 (0.394 – 0.613)	0.496 (0.489 – 0.502)
		200	0.600 (0.484 – 0.708)	0.929 (0.876 – 0.964)	0.814 (0.691 – 0.903)	0.817 (0.752 – 0.871)	40.0 (29.2 – 51.6)	0.564 (0.446 – 0.682)	0.632 (0.627 – 0.638)



# Comparaison IQ200/UF-5000/Bactériologie

~ Bct dans la prévision des résultats de la culture:

Parameter	Analyzer	Cut Off	Se	Sp	PPV	NPV	FN%	k	PABAK
BCT	IQ200	1+	0.550 (0.435 – 0.662)	0.818 (0.748 – 0.876)	0.611 (0.489 – 0.724)	0.778 (0.706 – 0.839)	45.0 (33.8 – 56.5)	0.377 (0.247 – 0.507)	0.453 (0.446 – 0.460)
		100	0.950 (0.877 – 0.986)	0.643 (0.562 – 0.718)	0.580 (0.491 – 0.666)	0.961 (0.904 – 0.989)	5.0 (1.4 – 12.3)	0.514 (0.407 – 0.621)	0.496 (0.489 – 0.502)
	UF-5000	1000	0.838 (0.738 – 0.911)	0.890 (0.829 – 0.934)	0.798 (0.696 – 0.878)	0.913 0.856 – 0.953	16.3 (8.9 – 26.2)	0.718 (0.624 – 0.813)	0.744 (0.740 – 0.747)
		10000	0.725 (0.614 – 0.819)	0.961 (0.917 – 0.986)	0.906 (0.807 – 0.965)	0.871 (0.811 – 0.917)	27.5 (18.1 – 38.6)	0.721 (0.624 – 0.818)	0.761 (0.757 – 0.764)



# Comparaison IQ200/UF-5000/Bactériologie

~ Combinaison WBC + Bct dans la prévision des résultats de la culture:

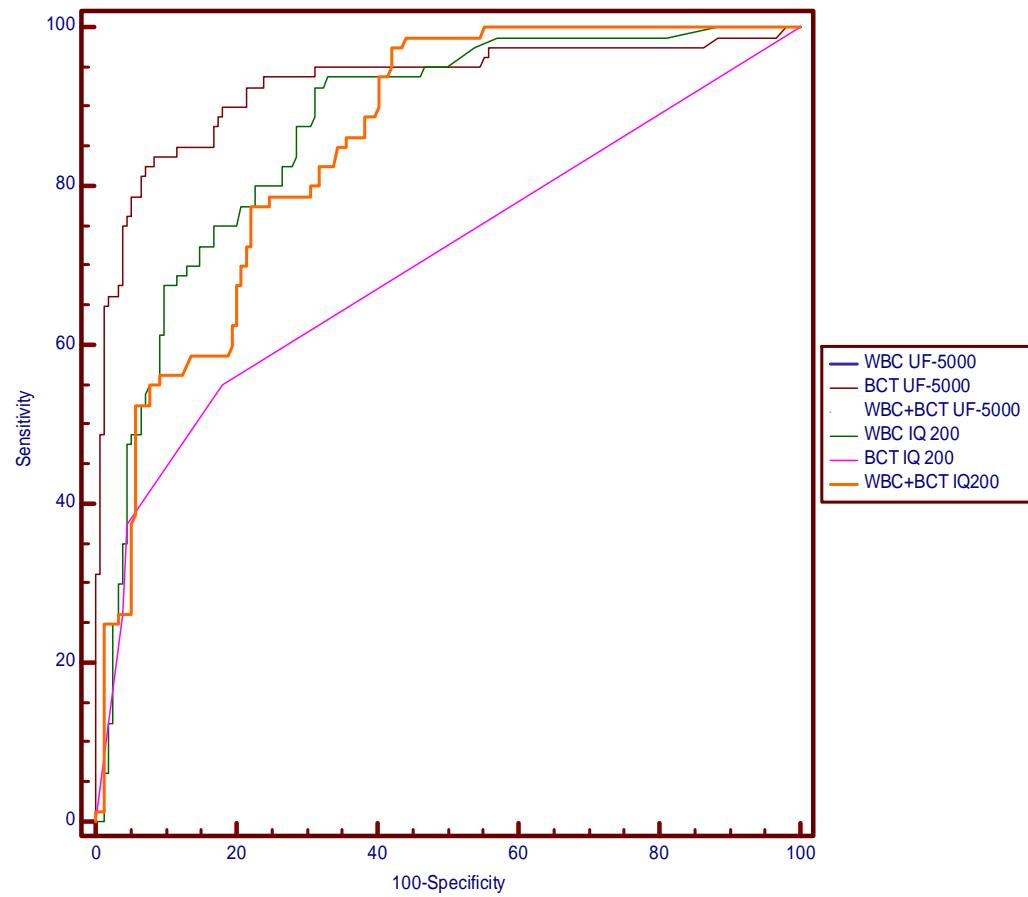
Sp

Parameter	Analyzer	Cut Off	Se	Sp	PPV	NPV	FN%	k	PABAK
WBC + BCT	IQ200	10/1+	0.500 (0.386 – 0.614)	0.896 (0.837 – 0.939)	0.714 (0.578 – 0.827)	0.775 (0.707 – 0.834)	50.0 (38.2 – 61.4)	0.427 (0.296 – 0.558)	0.521 (0.515 – 0.527)
	UF-5000	10/100	0.925 (0.844 – 0.972)	0.753 (0.677 – 0.819)	0.661 (0.565 – 0.748)	0.951 (0.896 – 0.982)	7.5 (3.8 – 15.6)	0.619 (0.517 – 0.720)	0.624 (0.619 – 0.629)
		10/1000	0.825 (0.724 – 0.901)	0.890 (0.829 – 0.934)	0.795 (0.692 – 0.876)	0.907 (0.849 – 0.948)	17.5 (9.9 – 27.6)	0.708 (0.613 – 0.804)	0.735 (0.731 – 0.739)
		20/100	0.899 (0.810 – 0.955)	0.794 (0.721 – 0.854)	0.689 (0.591 – 0.777)	0.939 (0.883 – 0.973)	10.1 (4.5 – 19.0)	0.644 (0.544 – 0.745)	0.658 (0.653 – 0.663)
		20/1000	0.825 (0.724 – 0.901)	0.896 (0.837 – 0.939)	0.805 (0.703 – 0.884)	0.908 (0.850 – 0.949)	17.5 (9.9 – 27.6)	0.717 (0.622 – 0.811)	0.744 (0.740 – 0.747)



# Comparaison IQ200/UF-5000/Bactériologie

## Courbes ROC



	AUC	CI 95
<b>IQ200</b>		
WBC	0,870	0,820 – 0,910
Bct	0,704	0,641 – 0,762
WBC + Bct	0,851	0,799 – 0,894
<b>UF-5000</b>		
WBC	0,881	0,833 – 0,920
Bct	0,928	0,887 – 0,958
WBC + Bct	0,912	0,869 – 0,945

Différences significatives entre:

- “ WBC et BCT sur iQ200 ( $p < 0.01$ )
- “ WBC sur iQ200 et BCT sur UF-5000 ( $p = 0.02$ )
- “ BCT et WBC+BCT sur iQ200 ( $p < 0.01$ )
- “ BCT sur iQ200 et WBC sur UF-5000 ( $p < 0.01$ )
- “ **BCT sur iQ200 et UF-5000 ( $p < 0.01$ )**
- “ BCT sur iQ200 et WBC+BCT on UF-5000 ( $p < 0.01$ )
- “ WBC+BCT sur iQ200 et BCT sur UF-5000 ( $p < 0.01$ )
- “ **WBC et BCT sur UF-5000 ( $p = 0.04$ )**
- “ **WBC+BCT sur iQ200 et UF-5000 ( $p = 0.02$ )**.



# Comparaison IQ200/UF-5000/Bactériologie

## “ Littérature:

Auteur	Automate Sysmex	Critère Positivité culture	Paramètre	Cut Off	Se	Sp	PPV	NPV
Manoni et al.	UF-1000i	> 10x10 <sup>5</sup> CFU/mL	Bct	125	0,97 (0,91-0,99)	0,94 (0,88-0,97)	0,92 (0,83-0,96)	0,98 (0,92-0,98)
			WBC	40	0,87 (0,78-0,94)	0,79 (0,71-0,86)	0,72 (0,61-0,80)	0,92 (0,84-0,96)
			WBC et/ou Bct	125/40	0,99 (0,88-1,00)	0,77 (0,61-0,88)	0,82 (0,67-0,91)	0,98 (0,84-0,99)

## “ Kim et al.:

**Table 2**  
Parameters Including Number of Urine Cultures Made Unnecessary by UF-100 Screening Depending on Cutoff Values for the UF-100 Bacterial Count in 330 Specimens

Parameter	No. of Bacteria (/µL)				
	1,500	2,000	3,000	5,500	8,000
Sensitivity (%)	100	97.2	94.4	81.7	77.5
Specificity (%)	49.8	61	73.4	86.9	90.7
Positive predictive value (%)	35.3	40.6	49.3	63	69.6
Negative predictive value (%)	100	98.8	97.9	94.5	93.6
No. (%) of unnecessary cultures*	127 (38.5)	158 (47.9)	192 (58.2)	236 (71.5)	249 (75.5)
No. (%) of false-negative results†	0 (0.0)	2 (0.6)	4 (1.2)	13 (3.9)	16 (4.8)

\* Predicted number of unnecessary urine cultures using bacterial cutoff values from the UF-100 (TOA Medical Electronics, Kobe, Japan).

† False-negative UF-100 results compared with urine culture results.

**Table 3**  
Change of Sensitivity and Specificity Values According to Cutoff for WBCs in Addition to 3,000/µL for the Bacterial Count

WBCs/µL			
	≥30	60	110
Sensitivity (%)	94.4	94.4	94.4
Specificity (%)	62.3	68.1	70



# Comparaison IQ200/UF-5000/Bactériologie

“ Alarmes bactéries sur UF-5000

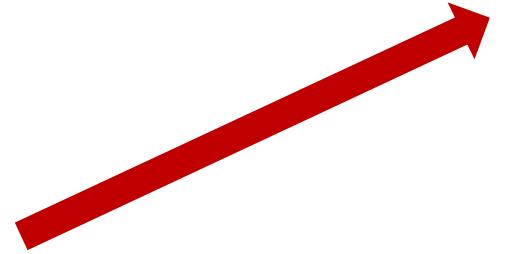
234 échantillons



132 alarmes



“Gram Neg”:	71
“Gram Pos”:	33
“Gram Pos/Neg” :	25
“Unclassified”:	3



57 Faux positifs



“Gram Neg”:	18	(25,4%)
“Gram Pos”:	31	(93,9%)
“Gram Pos/Neg” :	5	(20,0%)
“Unclassified”:	3	(100,0%)

4 Faux négatifs



Classe 1: 1
Classe 2: 3



# Comparaison IQ200/UF-5000/Bactériologie

## “ Alarmes bactéries

	All bacterial cultures (n = 234)		
Flag	All flags	“Gram Pos/Neg” + “Gram Neg”	“Gram Neg”
Culture	All positive	Positive for GN	Positive for GN
Sensitivity	0.950 (0.877 – 0.986)	0.972 (0.903 – 0.997)	0.708 (0.589 – 0.810)
Specificity	0.630 (0.548 – 0.706)	0.840 (0.774 – 0.892)	0.877 (0.816 – 0.923)
PPV	0.571 (0.483 – 0.657)	0.729 (0.629 – 0.815)	0.718 (0.599 – 0.819)
NPV	0.960 (0.902 – 0.989)	0.986 (0.947 – 0.998)	0.871 (0.810 – 0.918)
k (CI 95)	0.500 (0.392 – 0.608)	0.743 (0.654 – 0.832)	0.587 (0.472 – 0.702)
PABAK (CI 95)	0.479 (0.472 – 0.485)	0.761 (0.757 – 0.764)	0.650 (0.645 – 0.654)



# Comparaison IQ200/UF-5000/Bactériologie

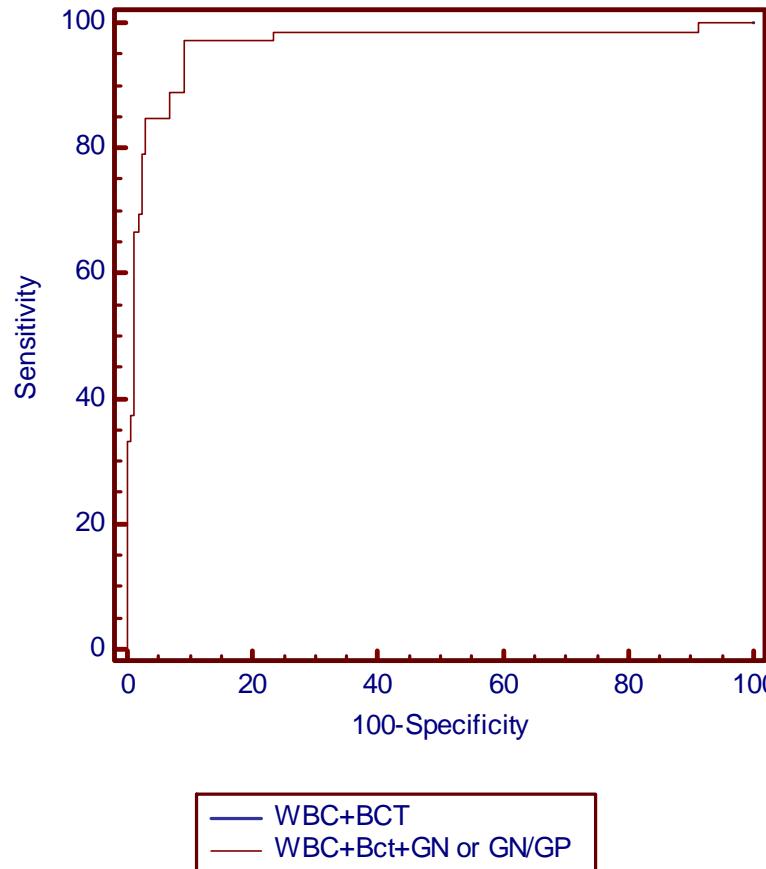
- “ Alarmes bactéries + WBC + Bct: Cultures positives pour GN

	All bacterial cultures (n = 234)	
<b>Flag</b>	All flags	“Gram Pos/Neg” + “Gram Neg”
<b>Culture</b>	All positive	Positive for GN (n = 72)
<b>Sensitivity</b>	0,913 (0,828-0,964)	0,958 (0,883-0,991)
<b>Specificity</b>	0,766 (0,691-0,831)	0,901 (0,845-0,943)
<b>PPV</b>	0,670 (0,573-0,757)	0,812 (0,712-0,888)
<b>NPV</b>	0,944 (0,888-0,977)	0,980 (0,942-0,996)
<b>k (CI 95)</b>	0,624 ((0,523-0,726))	0,819 (0,740-0,897)
<b>PABAK (CI 95)</b>	0,632 (0,627-0,638)	0,838 (0,835-0,840)



# Comparaison IQ200/UF-5000/Bactériologie

„ Comparaison avec culture bactérienne (GN uniquement)



	AUC	CI 95
WBC + Bct	0,944	0,907 – 0,970
WBC + Bct + GN ou GN/GP	0,965	0,933 – 0,985
p	0,125	



# Conclusion UF-5000

- Évaluation technique
  - Bonnes performances: précision et linéarité
  - Contamination négligeable à de hautes concentration, auto-wash à envisager pour les hautes concentrations bactériennes (cf performances diagnostiques à 100 Bct/ $\mu$ L)
- Comparaison avec iQ200
  - Méthodes non interchangeables... voire non comparables (principes  $\neq$ )
- Performances diagnostiques
  - Vs iQ200: acceptable pour les valeurs basses de RBC et WBC
  - Vs culture: bonnes performances, comparables (WBC) voire > iQ200 (BCT)
    - Intérêt de combiner WBC et BCT sur l'UF-5000: meilleur agrément
  - Bonne sensibilité des alarmes >< Gram neg



UC-3500





# UC-3500

Parameter	Cut Off (Aution Max)	Prevalence	Se	Sp	PPV	NPV	k	PABAK
Glc	Traces	0,087	0,966 (0,822-0,999)	0,997 (0,982-1,000)	0,966 (0,822-0,999)	0,997 (0,981-1,000)	0,962 (0,910-1,000)	0,988 (0,986-0,989)
Prot	Traces	0,559	0,667 (0,594-0,734)	1,000 (0,975-1,000)	1,000 (0,971-1,000)	0,703 (0,636-0,764)	0,638 (0,557-0,720)	0,628 (0,624-0,631)
	1+	0,258	0,872 (0,783-0,934)	0,984 (0,959-0,996)	0,949 (0,875-0,986)	0,957 (0,924-0,978)	0,879 (0,819-0,939)	0,910 (0,909-0,911)
Bili	1+	0,003	1,000 (0,025-1,000)	0,994 (0,784-0,999)	0,333 (0,008-0,906)	1,000 (0,989-1,000)	0,498 (0,000-1,000)	0,988 (0,987-0,988)
Uro	1+	0,108	0,639 (0,462-0,792)	0,993 (0,976-0,999)	0,920 (0,740-0,990)	0,958 (0,929-0,977)	0,730 (0,597-0,864)	0,910 (0,909-0,911)
Hb	Traces	0,300	0,940 (0,874-0,978)	0,923 (0,881-0,954)	0,839 (0,758-0,902)	0,973 (0,942-0,990)	0,834 (0,770-0,898)	0,856 (0,854-0,857)
Ket	Traces	0,108	0,472 (0,304-0,645)	1,000 (0,988-1,000)	1,000 (0,805-1,000)	0,940 (0,908-0,963)	0,615 (0,447-0,783)	0,886 (0,885-0,887)
Nit	1+	0,141	0,936 (0,825-0,987)	0,993 (0,975-0,999)	0,957 (0,852-0,995)	0,990 (0,970-0,998)	0,938 (0,883-0,992)	0,970 (0,969-0,971)
Leu Est	25	0,517	0,738 (0,666-0,802)	0,994 (0,966-1,000)	0,992 (0,957-1,000)	0,781 (0,718-0,835)	0,726 (0,652-0,799)	(0,724 (0,721-0,727)



# UC-3500

## “ Tigette Aution Max – IQ200

	Cut Off	Prevalence	Se	Sp	PPV	NPV	k	PABAK
<b>RBC</b> <b>Hb</b>	10 Traces	0,428	0,636 (0,552-0,715)	0,953 (0,912-0,978)	0,910 (0,836-0,958)	0,778 (0,719-0,829)	0,612 (0,524-0,700)	0,635 (0,631-0,638)
<b>WBC</b> <b>Leu Es</b>	10 25	0,587	0,811 (0,749-0,864)	0,906 (0,844-0,949)	0,924 (0,874-0,959)	0,772 (0,699-0,834)	0,699 (0,622-0,776)	0,701 (0,698-0,704)

## “ Tigette UC-3500 – UF-5000

	Cut Off	Prevalence	Se	Sp	PPV	NPV	k	PABAK
<b>RBC</b> <b>Hb</b>	10 Traces	0,451	0,600 (0,517-0,679)	0,885 (0,830-0,928)	0,811 (0,726-0,879)	0,730 (0,666-0,787)	0,497 (0,402-0,592)	0,514 (0,509-0,518)
<b>WBC</b> <b>Leu Es</b>	10 1+	0,628	0,612 (0,543-0,679)	1,000 (0,971-1,000)	1,000 (0,972-1,000)	0,605 (0,534-0,672)	0,541 (0,454-0,628)	0,514 (0,509-0,518)

Red line



UD-10





# UD-10

- “ Taux de revue par défaut ± 10-15%

