COLLEGE of AMERICAN PATHOLOGISTS

Surveys and Anatomic Pathology Education Programs

Clinical Microscopy
CM-B 2018

Participant Summary

1.0 Credit of Continuing Education Available

This document is available on e-LAB Solutions.

TABLE OF CONTENTS

2018 CM-B
PARTICIPANT SUMMARY

Educational Opportunity

Don't Miss Out on this Educational Opportunity!

With your participation in CAP's Surveys programs, *every member of your team* can take part in education activities: earn Continuing Education (CE) credits or receive Self-Reported Training* at no additional charge.

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**CAP Self-Reported Training activities do not offer CE credit, but can be used towards fulfilling requirements for certification of maintenance by agencies such as the American Society of Clinical Pathology (ASCP). Please verify with your certifying agency to determine your education requirements.*

Evaluation Criteria

QUALITATIVE

For qualitative procedures in urinalysis, evaluation is based on participant consensus by method and instrument. For each analyte, a minimum of two, but not more than four, responses will be given a passing score. Analyte results graded “Good” performance must have 80% participant consensus. Eighty percent participant consensus can be determined by grouping the **mode** with the next one or two most frequent responses. This group will be given “Good” performance. “Acceptable” performance will be given to additional responses until a minimum of 90% of participant results are given a passing score. In the case of a negative specimen, negative responses must constitute 90% participant consensus. Specimens with results for one of more methods distributed over both negative and positive responses (non-consensus) will not be evaluated. Specimens for which there is greater than 90% of participant responses distributed over more than four responses will be graded as “Non-consensus.”

Analyte	Evaluation Criteria
Bilirubin, Confirmatory	80% overall participant consensus/intended response
Gastric Occult Blood	80% overall participant consensus/intended response
Gastric pH	80% overall participant consensus/intended response
Nitrite	80% overall participant consensus/intended response
Occult Blood	80% overall participant consensus/intended response
Protein, Confirmatory	80% overall participant consensus/intended response
Urine hCG	80% overall participant consensus/intended response

QUANTITATIVE

Analyte	Target Value	Evaluation Criteria
Gastric pH	Peer Group Mean	± 3 SD
Osmolality	Peer Group Mean	± 3 SD
Specific Gravity	Peer Group Mean	± 2 SD or 0.010, whichever is greater

The quantitative data tables provided in the Participant Summary include the mean, SD, median, %CV and/or the lowest and highest values reported for each peer group. The low and high values are not the limits of acceptability. The acceptable limits are located on your participant evaluation report.

Data are not included for methods used by fewer than 10 laboratories.

PHOTOGRAPHS

Photographs are evaluated for CAP purposes according to 80% or greater consensus of either referees or participant laboratories. "Good" performance is given for the intended response. Additionally, the Hematology and Clinical Microscopy Resource Committee may, at its discretion, grant either "good" or "acceptable" performance for other equivalent responses.

To provide a timely evaluation of your results, statistics presented in this Participant Summary reflect participant data received by the due date. In the event a result is not graded, a numeric code will appear next to your result. A definition of the code will appear on the first page of the evaluation. Please see “Actions Laboratories Should Take when a PT Result is Not Graded” on page 108.

Osmolality - mOsm/kg (mmol/kg)

		No. Labs	Mean	S.D.	C.V.
CM-10	Advanced Instruments	750	869.5	5.1	0.6
	ARKRAY	58	866.5	4.7	0.5
	Fiske	41	876.1	4.8	0.5
	Precision Systems	19	865.9	14.2	1.6
CM-11	Advanced Instruments	739	904.3	5.3	0.6
	ARKRAY	58	902.3	5.5	0.6
	Fiske	41	911.0	5.9	0.6
	Precision Systems	19	902.3	12.5	1.4
CM-12	Advanced Instruments	749	810.2	3.9	0.5
	ARKRAY	57	808.9	4.3	0.5
	Fiske	41	811.3	3.9	0.5
	Precision Systems	19	807.7	7.9	1.0

Urine hCG

The hCG level was intended to be positive.

CM-10

99.9% consensus

Manufacturer	Negative	Positive
ACON One Step (urine only)	-	27
Alere hCG Cassette (20) (Acceava)	-	37
Alere hCG Cassette (25) (Clearview)	1	34
Alere hCG Combo Cassette (20/10)	1	102
Alere hCG Combo Cassette (25) (Clearview)	-	55
Alere hCG Dipstick	-	17
Beckman Coulter ICON 20	1	213
Beckman Coulter ICON 25	1	299
Cardinal Health Cassette (waived)	-	154
Cardinal Health Combo	1	825
Cen-Med Elite Plus One Step hCG	-	17
Clearview hCG Combo II	-	11
Consult Diagnostics Cassette	2	77
Consult Diagnostics Combo	-	32
Consult Diagnostics Dipstick (waived)	-	13
Eiken	-	10
Ekla Novaplus hCG Combo	-	19
Formosa One Sure Pregnancy Kit	-	11
Henry Schein OneStep+ Urine Cassette	-	20
Innovatek BioStrip	-	12
LifeSign Status (serum/urine)	1	9
Medline hCG Urine Cassette	-	18
Meridian ImmunoCard STAT (waived)	-	28
Polymedco Poly stat (waived)	-	16
Quidel QuickVue One-Step Combo	-	275
Quidel QuickVue One-Step Urine	-	309
Quidel QuickVue+ One-Step Combo	2	565
Quidel Sofia	-	22
SA Scientific (Serum/Urine)	-	12
Sekisui OSOM (waived)	-	55
Sekisui OSOM Combo	-	171
Siemens Clinitek Status	-	325
Stanbio QuPID	1	46
Stanbio QuPID PLUS	-	58
Stanbio True 20 Plus	-	23
Sure-Vue	-	80
Sure-Vue (Serum/Urine)	1	303
Sure-Vue STAT (Serum/Urine)	1	341
Other and Methods with <10 responses	-	649

Note: The manufacturer's stated sensitivity level (mIU/mL) will no longer be displayed. Refer to the manufacturer package insert.

Urine hCG

The hCG level was intended to be positive.

CM-11

99.8% consensus

Manufacturer	Negative	Positive
ACON One Step (urine only)	-	27
Alere hCG Cassette (20) (Acceava)	-	37
Alere hCG Cassette (25) (Clearview)	-	35
Alere hCG Combo Cassette (20/10)	-	103
Alere hCG Combo Cassette (25) (Clearview)	-	55
Alere hCG Dipstick	-	17
Beckman Coulter ICON 20	-	214
Beckman Coulter ICON 25	3	297
Cardinal Health Cassette (waived)	-	154
Cardinal Health Combo	-	826
Cen-Med Elite Plus One Step hCG	-	17
Clearview hCG Combo II	-	11
Consult Diagnostics Cassette	-	79
Consult Diagnostics Combo	-	32
Consult Diagnostics Dipstick (waived)	-	13
Eiken	1	9
Ekla Novaplus hCG Combo	-	19
Formosa One Sure Pregnancy Kit	-	11
Henry Schein OneStep+ Urine Cassette	-	20
Innovatek BioStrip	-	12
LifeSign Status (serum/urine)	-	10
Medline hCG Urine Cassette	-	18
Meridian ImmunoCard STAT (waived)	-	28
Polymedco Poly stat (waived)	-	16
Quidel QuickVue One-Step Combo	-	275
Quidel QuickVue One-Step Urine	1	308
Quidel QuickVue+ One-Step Combo	2	565
Quidel Sofia	-	22
SA Scientific (Serum/Urine)	-	12
Sekisui OSOM (waived)	-	55
Sekisui OSOM Combo	-	171
Siemens Clinitek Status	-	325
Stanbio QuPID	-	47
Stanbio QuPID PLUS	-	58
Stanbio True 20 Plus	-	23
Sure-Vue	-	80
Sure-Vue (Serum/Urine)	1	303
Sure-Vue STAT (Serum/Urine)	1	341
Other and Methods with <10 responses	-	650

Note: The manufacturer's stated sensitivity level (mIU/mL) will no longer be displayed. Refer to the manufacturer package insert.

Urine hCG

The hCG level was intended to be negative.

CM-12

99.6% consensus

Manufacturer	Negative	Positive
ACON One Step (urine only)	27	-
Alere hCG Cassette (20) (Acceava)	37	-
Alere hCG Cassette (25) (Clearview)	35	-
Alere hCG Combo Cassette (20/10)	103	-
Alere hCG Combo Cassette (25) (Clearview)	55	-
Alere hCG Dipstick	17	-
Beckman Coulter ICON 20	214	-
Beckman Coulter ICON 25	297	3
Cardinal Health Cassette (waived)	152	2
Cardinal Health Combo	825	1
Cen-Med Elite Plus One Step hCG	17	-
Clearview hCG Combo II	11	-
Consult Diagnostics Cassette	77	2
Consult Diagnostics Combo	32	-
Consult Diagnostics Dipstick (waived)	13	-
Eiken	9	1
Ekla Novaplus hCG Combo	19	-
Formosa One Sure Pregnancy Kit	11	-
Henry Schein OneStep+ Urine Cassette	20	-
Innovatek BioStrip	12	-
LifeSign Status (serum/urine)	10	-
Medline hCG Urine Cassette	18	-
Meridian ImmunoCard STAT (waived)	28	-
Polymedco Poly stat (waived)	15	1
Quidel QuickVue One-Step Combo	274	1
Quidel QuickVue One-Step Urine	309	-
Quidel QuickVue+ One-Step Combo	561	5
Quidel Sofia	22	-
SA Scientific (Serum/Urine)	12	-
Sekisui OSOM (waived)	54	1
Sekisui OSOM Combo	171	-
Siemens Clinitek Status	325	-
Stanbio QuPID	47	-
Stanbio QuPID PLUS	58	-
Stanbio True 20 Plus	23	-
Sure-Vue	80	-
Sure-Vue (Serum/Urine)	303	-
Sure-Vue STAT (Serum/Urine)	340	2
Other and Methods with <10 responses	649	-

Note: The manufacturer's stated sensitivity level (mIU/mL) will no longer be displayed. Refer to the manufacturer package insert.

Specific Gravity

CM-10

Method/Instrument	No. Labs	Mean	S.D.	C.V.
77 Elektronika Reagent Strips				
77 Elektronika urine chemistry analyzers	22	1.0253	0.0020	0.2
ARKRAY Aution Sticks				
ARKRAY Aution Hybrid	87	1.0240	0.0014	0.1
ARKRAY Aution MAX	153	1.0216	0.0020	0.2
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips				
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	21	1.0197	0.0029	0.3
DIRUI H-800 series reagent strips				
DIRUI FUS systems	11	1.0230	0.0024	0.2
Eiken Uropaper				
Eiken US-3100R/3100Rplus/3500	17	1.0276	0.0012	0.1
Refractometer				
ARKRAY Aution Hybrid	16	1.0244	0.0017	0.2
ARKRAY Aution MAX	46	1.0220	0.0023	0.2
Eiken US-3100R/3100Rplus/3500	17	1.0275	0.0007	0.1
Visual	166	1.0252	0.0009	0.1
Roche Chemstrip/Combur				
Roche Chemstrip Criterion/II	34	1.0113	0.0031	0.3
Roche cobas u411, Urisys 1800	273	1.0108	0.0028	0.3
Roche Urisys 1100	191	1.0107	0.0027	0.3
Visual	177	1.0105	0.0028	0.3
Roche cobas u Pack Cassette				
Roche cobas u601	57	1.0259	0.0011	0.1
Roche Urisys Cassette				
Roche Urisys 2400	59	1.0248	0.0008	0.1
Siemens Clinitek Atlas Reagent				
Siemens Clinitek Atlas	345	1.0250	0.0011	0.1
Siemens Clinitek Novus/Pro Cassette				
Siemens Clinitek Novus	235	1.0257	0.0009	0.1
Siemens Reagent Strips				
Siemens Clinitek 10 or 100	11	1.0259	0.0030	0.3
Siemens Clinitek 50	32	1.0250	0.0018	0.2
Siemens Clinitek 500, Advantus	1339	1.0250	0.0001	0.0
Siemens Clinitek Atlas	13	1.0252	0.0013	0.1
Siemens Clinitek Status	1264	1.0250	0.0001	0.0
Visual	303	1.0211	0.0040	0.4
Sysmex Reagent Strips				
Sysmex UC-3500	16	1.0269	0.0010	0.1

Method/Instrument	No. Labs	Median	Low	High
Greater-Than Values				
Siemens Reagent Strips				
Siemens Clinitek 10 or 100	10	1.030	1.030	1.030
Siemens Clinitek 50	5	1.030	1.030	1.030
Siemens Clinitek 500, Advantus	36	1.030	1.030	1.030
Siemens Clinitek Status	471	1.030	1.029	1.030

Specific Gravity

CM-11

Method/Instrument	No. Labs	Mean	S.D.	C.V.
77 Elektronika Reagent Strips				
77 Elektronika urine chemistry analyzers	22	1.0293	0.0010	0.1
ARKRAY Aution Sticks				
ARKRAY Aution Hybrid	85	1.0271	0.0013	0.1
ARKRAY Aution MAX	151	1.0244	0.0026	0.2
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips				
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	19	1.0242	0.0044	0.4
DIRUI H-800 series reagent strips				
DIRUI FUS systems	10	1.0273	0.0022	0.2
Eiken Uropaper				
Eiken US-3100R/3100Rplus/3500	16	1.0312	0.0010	0.1
Refractometer				
ARKRAY Aution Hybrid	16	1.0276	0.0010	0.1
ARKRAY Aution MAX	46	1.0244	0.0025	0.2
Eiken US-3100R/3100Rplus/3500	17	1.0314	0.0007	0.1
Visual	168	1.0281	0.0014	0.1
Roche Chemstrip/Combur				
Roche Chemstrip Criterion/II	34	1.0115	0.0023	0.2
Roche cobas u411, Urisys 1800	274	1.0130	0.0026	0.3
Roche Urisys 1100	191	1.0115	0.0023	0.2
Visual	177	1.0147	0.0026	0.3
Roche cobas u Pack Cassette				
Roche cobas u601	56	1.0288	0.0012	0.1
Roche Urisys Cassette				
Roche Urisys 2400	59	1.0275	0.0010	0.1
Siemens Clinitek Atlas Reagent				
Siemens Clinitek Atlas	313	1.0282	0.0014	0.1
Siemens Clinitek Novus/Pro Cassette				
Siemens Clinitek Novus	200	1.0292	0.0011	0.1
Siemens Reagent Strips				
Siemens Clinitek 10 or 100	11	1.0264	0.0023	0.2
Siemens Clinitek 50	24	1.0256	0.0022	0.2
Siemens Clinitek 500, Advantus	1205	1.0250	0.0001	0.0
Siemens Clinitek Atlas	11	1.0288	0.0012	0.1
Siemens Clinitek Status	939	1.0265	0.0023	0.2
Visual	302	1.0248	0.0040	0.4
Sysmex Reagent Strips				
Sysmex UC-3500	16	1.0307	0.0009	0.1

Specific Gravity

CM-11

Method/Instrument	No. Labs	Median	Low	High
Less-Than Values				
Siemens Reagent Strips				
Siemens Clinitek Status	5	1.030	1.025	1.303
Greater-Than Values				
Siemens Clinitek Atlas Reagent				
Siemens Clinitek Atlas	36	1.030	1.030	1.030
Siemens Clinitek Novus/Pro Cassette				
Siemens Clinitek Novus	37	1.030	1.030	1.035
Siemens Reagent Strips				
Siemens Clinitek 10 or 100	10	1.030	1.030	1.030
Siemens Clinitek 50	13	1.030	1.030	1.030
Siemens Clinitek 500, Advantus	254	1.030	1.030	1.030
Siemens Clinitek Status	937	1.030	1.025	1.060
Visual	5	1.030	1.020	1.030

Specific Gravity

CM-12

Method/Instrument	No. Labs	Mean	S.D.	C.V.
77 Elektronika Reagent Strips				
77 Elektronika urine chemistry analyzers	20	1.0143	0.0008	0.1
ARKRAY Aution Sticks				
ARKRAY Aution Hybrid	86	1.0138	0.0018	0.2
ARKRAY Aution MAX	150	1.0134	0.0016	0.2
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips				
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	21	1.0154	0.0022	0.2
DIRUI H-800 series reagent strips				
DIRUI FUS systems	11	1.0145	0.0025	0.3
Eiken Uropaper				
Eiken US-3100R/3100Rplus/3500	17	1.0147	0.0013	0.1
Refractometer				
ARKRAY Aution Hybrid	16	1.0141	0.0018	0.2
ARKRAY Aution MAX	46	1.0133	0.0011	0.1
Eiken US-3100R/3100Rplus/3500	17	1.0146	0.0006	0.1
Visual	168	1.0145	0.0019	0.2
Roche Chemstrip/Combur				
Roche Chemstrip Criterion/II	34	1.0121	0.0039	0.4
Roche cobas u411, Urisys 1800	279	1.0118	0.0040	0.4
Roche Urisys 1100	193	1.0114	0.0031	0.3
Visual	177	1.0055	0.0037	0.4
Roche cobas u Pack Cassette				
Roche cobas u601	56	1.0145	0.0007	0.1
Roche Urisys Cassette				
Roche Urisys 2400	58	1.0140	0.0008	0.1
Siemens Clinitek Atlas Reagent				
Siemens Clinitek Atlas	338	1.0143	0.0010	0.1
Siemens Clinitek Novus/Pro Cassette				
Siemens Clinitek Novus	237	1.0146	0.0006	0.1
Siemens Reagent Strips				
Siemens Clinitek 10 or 100	20	1.0220	0.0034	0.3
Siemens Clinitek 50	37	1.0186	0.0042	0.4
Siemens Clinitek 500, Advantus	1507	1.0185	0.0034	0.3
Siemens Clinitek Atlas	11	1.0141	0.0009	0.1
Siemens Clinitek Status	1860	1.0215	0.0025	0.2
Visual	304	1.0133	0.0042	0.4
Sysmex Reagent Strips				
Sysmex UC-3500	16	1.0146	0.0009	0.1

Method/Instrument	No. Labs	Median	Low	High
<u>Greater-Than Values</u>				
Siemens Reagent Strips				
Siemens Clinitek Status	12	1.030	1.020	1.030

pH, Urine

CM-10

Method/Instrument	≤3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	≥9.0
77 Elektronika Reagent Strips												
77 Elektronika urine chemistry analyzers	-	-	-	-	-	-	-	22	1	-	-	-
ARKRAY Aution Sticks												
ARKRAY Aution Hybrid	-	-	-	-	-	-	-	-	39	65	-	-
ARKRAY Aution MAX	-	-	-	-	-	1	-	5	199	6	-	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips												
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	-	-	-	-	2	19	4	-	-	-
DIRUI H-800 series reagent strips												
DIRUI FUS systems	-	-	-	-	-	-	-	5	6	-	-	-
Eiken Uropaper												
Eiken US-3100R/3100Rplus/3500	-	-	-	-	-	-	-	-	37	-	-	-
Roche Chemstrip/Combur*												
Roche Chemstrip Criterion/II	-	-	-	-	-	-	-	13	-	22	-	-
Roche cobas u411, Urisys 1800	-	-	-	-	-	-	1	192	1	105	-	-
Roche Urisys 1100	-	-	-	-	-	-	-	67	-	137	-	-
Visual**	-	-	-	-	-	-	1	125	5	69	-	-
Roche cobas u Pack Cassette*												
Roche cobas u601	-	-	-	-	-	-	-	32	-	29	-	-
Roche Urisys Cassette*												
Roche Urisys 2400	-	-	-	-	-	-	-	48	1	12	-	-
Siemens Clinitek Atlas Reagent												
Siemens Clinitek Atlas	-	-	-	-	-	2	-	235	122	1	-	-
Siemens Clinitek Novus/Pro Cassette												
Siemens Clinitek Novus	-	-	-	-	-	-	1	47	199	2	-	-
Siemens Reagent Strips												
Siemens Clinitek 10 or 100	-	-	-	-	-	-	-	5	18	-	-	-
Siemens Clinitek 50	-	-	-	-	-	-	-	10	28	-	-	-
Siemens Clinitek 500, Advantus	-	-	-	1	-	2	2	119	1467	5	-	-
Siemens Clinitek Atlas	-	-	-	-	-	-	-	11	3	-	-	-
Siemens Clinitek Status	-	-	-	2	-	2	-	959	966	3	1	-
Visual	-	-	-	-	-	-	2	15	302	17	5	-
Sysmex Reagent Strips												
Sysmex UC-3500	-	-	-	-	-	-	-	-	16	-	-	-

* Roche Cassette and all other Roche pH users: Results should be reported in whole numbers from 5.0 to 9.0, with the exception of 6.5.

** Roche pH Visual Users: Results should be reported in whole numbers; 0.5 increments are not allowed.

pH, Urine

CM-11

Method/Instrument	≤3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	≥9.0
77 Elektronika Reagent Strips												
77 Elektronika urine chemistry analyzers	-	-	-	-	-	-	23	-	-	-	-	-
ARKRAY Aution Sticks												
ARKRAY Aution Hybrid	-	-	-	-	-	-	-	104	-	-	-	-
ARKRAY Aution MAX	-	-	-	-	1	5	1	203	-	1	-	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips												
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	-	-	-	6	19	-	-	-	-	-
DIRUI H-800 series reagent strips												
DIRUI FUS systems	-	-	-	-	-	-	7	4	-	-	-	-
Eiken Uropaper												
Eiken US-3100R/3100Rplus/3500	-	-	-	-	-	-	3	34	-	-	-	-
Roche Chemstrip/Combur*												
Roche Chemstrip Criterion/II	-	-	-	-	-	-	1	33	-	1	-	-
Roche cobas u411, Urisys 1800	-	-	-	-	-	2	14	283	-	-	-	-
Roche Urisys 1100	-	-	-	-	-	1	19	183	-	-	-	1
Visual**	1	-	-	-	-	53	8	135	-	2	-	-
Roche cobas u Pack Cassette*												
Roche cobas u601	-	-	-	-	-	-	-	61	-	-	-	-
Roche Urisys Cassette*												
Roche Urisys 2400	-	-	-	-	-	-	1	60	-	-	-	-
Siemens Clinitek Atlas Reagent												
Siemens Clinitek Atlas	-	-	-	-	-	1	332	26	1	-	-	-
Siemens Clinitek Novus/Pro Cassette												
Siemens Clinitek Novus	-	-	-	-	-	1	227	19	1	-	1	-
Siemens Reagent Strips												
Siemens Clinitek 10 or 100	-	-	-	-	-	-	-	23	-	-	-	-
Siemens Clinitek 50	-	-	-	-	-	-	11	27	-	-	-	-
Siemens Clinitek 500, Advantus	-	-	-	-	-	1	80	1509	3	4	-	-
Siemens Clinitek Atlas	-	-	-	-	-	-	12	2	-	-	-	-
Siemens Clinitek Status	-	-	-	-	-	5	86	1838	1	2	1	-
Visual	-	-	-	-	-	6	63	255	7	9	1	-
Sysmex Reagent Strips												
Sysmex UC-3500	-	-	-	-	-	-	3	13	-	-	-	-

* Roche Cassette and all other Roche pH users: Results should be reported in whole numbers from 5.0 to 9.0, with the exception of 6.5.

** Roche pH Visual Users: Results should be reported in whole numbers; 0.5 increments are not allowed.

pH, Urine

CM-12

Method/Instrument	≤3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	≥9.0
77 Elektronika Reagent Strips												
77 Elektronika urine chemistry analyzers	-	-	-	-	-	-	-	-	10	13	-	-
ARKRAY Aution Sticks												
ARKRAY Aution Hybrid	-	-	-	-	-	-	-	-	-	104	-	-
ARKRAY Aution MAX	-	-	-	-	-	-	1	1	15	194	-	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips												
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	-	-	-	1	-	6	16	2	-	-
DIRUI H-800 series reagent strips												
DIRUI FUS systems	-	-	-	-	-	-	-	1	8	2	-	-
Eiken Uropaper												
Eiken US-3100R/3100Rplus/3500	-	-	-	-	-	-	-	-	3	34	-	-
Roche Chemstrip/Combur*												
Roche Chemstrip Criterion/II	-	-	-	-	-	-	-	-	-	18	-	17
Roche cobas u411, Urisys 1800	-	-	-	-	-	-	-	4	-	282	-	13
Roche Urisys 1100	-	-	-	-	-	-	-	4	-	133	-	67
Visual**	-	-	-	-	-	-	-	5	-	168	6	21
Roche cobas u Pack Cassette*												
Roche cobas u601	-	-	-	-	-	-	-	-	-	42	-	19
Roche Urisys Cassette*												
Roche Urisys 2400	-	-	-	-	-	-	-	-	-	56	-	5
Siemens Clinitek Atlas Reagent												
Siemens Clinitek Atlas	-	-	-	-	-	-	1	1	14	342	2	-
Siemens Clinitek Novus/Pro Cassette												
Siemens Clinitek Novus	-	-	-	-	-	-	-	1	4	69	170	5
Siemens Reagent Strips												
Siemens Clinitek 10 or 100	-	-	-	-	-	-	-	-	2	13	8	-
Siemens Clinitek 50	-	-	-	-	-	-	-	2	11	14	11	-
Siemens Clinitek 500, Advantus	-	-	-	-	-	3	-	269	230	894	199	2
Siemens Clinitek Atlas	-	-	-	-	-	-	-	-	1	11	2	-
Siemens Clinitek Status	-	-	-	-	-	2	2	75	306	310	1237	3
Visual	-	-	-	3	-	7	12	7	31	226	54	1
Sysmex Reagent Strips												
Sysmex UC-3500	-	-	-	-	-	-	-	-	3	13	-	-

* Roche Cassette and all other Roche pH users: Results should be reported in whole numbers from 5.0 to 9.0, with the exception of 6.5.

** Roche pH Visual Users: Results should be reported in whole numbers; 0.5 increments are not allowed.

Protein – Qualitative, Method 1

CM-10

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	-	-	1	11	5	-
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	-	-	-	39	-
ARKRAY Aution MAX	-	-	-	3	88	1
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	-	2	13	10
DIRUI H-800 series reagent strips						
DIRUI FUS systems	-	-	-	2	9	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	-	-	-	-	34	1
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	-	-	-	-	15	-
Roche cobas u411, Urisys 1800	1	-	-	2	44	67
Roche Urisys 1100	-	-	-	-	15	46
Visual	-	-	1	41	131	5
Roche cobas u Pack Cassette						
Roche cobas u601	-	-	-	-	8	30
Roche Urisys Cassette						
Roche Urisys 2400	-	-	-	1	8	2
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	-	-	-	1	135	3
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	-	-	-	1	75	2
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	1	-	1	11	1
Siemens Clinitek 500, Advantus	-	-	-	17	573	10
Siemens Clinitek Status	1	-	1	2	754	17
Visual	-	-	2	47	163	90
Sysmex Reagent Strips						
Sysmex UC-3500	-	-	-	-	14	-

Protein – Qualitative, Method 1

CM-11

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	-	-	-	11	6	-
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	-	-	-	39	-
ARKRAY Aution MAX	1	-	1	7	82	1
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	-	2	14	9
DIRUI H-800 series reagent strips						
DIRUI FUS systems	-	-	-	2	9	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	-	-	-	-	33	2
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	-	-	-	-	15	-
Roche cobas u411, Urisys 1800	-	-	-	1	45	68
Roche Urisys 1100	-	-	-	-	15	46
Visual	-	1	-	37	136	4
Roche cobas u Pack Cassette						
Roche cobas u601	-	-	1	-	7	30
Roche Urisys Cassette						
Roche Urisys 2400	-	-	-	-	9	2
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	-	-	-	-	105	34
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	1	-	-	-	62	15
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	1	-	-	11	2
Siemens Clinitek 500, Advantus	1	-	-	8	581	11
Siemens Clinitek Status	2	1	-	4	749	19
Visual	1	-	3	35	153	111
Sysmex Reagent Strips						
Sysmex UC-3500	-	-	-	-	12	2

Protein – Qualitative, Method 1

CM-12

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	17	-	-	-	-	-
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	39	-	-	-	-	-
ARKRAY Aution MAX	91	-	-	-	1	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	25	-	-	-	-	-
DIRUI H-800 series reagent strips						
DIRUI FUS systems	11	-	-	-	-	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	35	-	-	-	-	-
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	15	-	-	-	-	-
Roche cobas u411, Urisys 1800	114	-	-	-	-	-
Roche Urisys 1100	62	-	-	-	-	-
Visual	179	-	-	-	-	-
Roche cobas u Pack Cassette						
Roche cobas u601	38	-	-	-	-	-
Roche Urisys Cassette						
Roche Urisys 2400	11	-	-	-	-	-
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	139	-	-	-	-	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	76	-	1	-	1	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	13	1	-	-	-	-
Siemens Clinitek 500, Advantus	600	-	-	1	1	-
Siemens Clinitek Status	772	-	-	2	1	-
Visual	298	2	1	1	-	1
Sysmex Reagent Strips						
Sysmex UC-3500	14	-	-	-	-	-

Protein – Qualitative, Method 2

Protein, Method 2 reporting options in SI units	
Conventional (mg/dL)	**SI (g/L)**
Negative	Negative
10 - 20	0.1 - 0.2
30 - 70	0.3 - 0.7
75 - Roche Users only	0.75
100 - 200	1.0 - 2.0
≥300	≥3.0 or > 6.0 or ≥1000

CM-10

Method/Instrument	Negative	10-20 mg/dL	30-70 mg/dL	75 mg/dL (Roche only)*	100-200 mg/dL	≥300 mg/dL
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	-	-	-	1	65
ARKRAY Aution MAX	-	-	-	-	7	115
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	-	-	-	-	-	20
Roche cobas u411, Urisys 1800	1	-	-	-	4	179
Roche Urisys 1100*	-	-	-	1	1	141
Visual	-	-	-	-	11	25
Roche cobas u Pack Cassette						
Roche cobas u601	-	-	-	-	1	23
Roche Urisys Cassette						
Roche Urisys 2400	-	-	-	-	-	49
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	3	-	-	-	2	215
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	1	-	-	-	1	169
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	-	-	-	-	13
Siemens Clinitek 50	-	-	-	-	-	29
Siemens Clinitek 500, Advantus	1	-	-	-	26	971
Siemens Clinitek Status	2	-	3	-	8	1154
Visual	-	-	1	-	16	115

* Not appropriate for Roche Urisys 1100 users.

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Protein – Qualitative, Method 2

CM-11

Method/Instrument	Negative	10-20 mg/dL	30-70 mg/dL	75 mg/dL (Roche only)*	100-200 mg/dL	≥300 mg/dL
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	-	-	-	-	66
ARKRAY Aution MAX	-	-	-	-	1	121
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	-	-	-	-	-	20
Roche cobas u411, Urisys 1800	1	-	-	-	4	179
Roche Urisys 1100*	-	-	-	1	-	142
Visual	-	-	1	-	8	27
Roche cobas u Pack Cassette						
Roche cobas u601	-	-	-	-	1	23
Roche Urisys Cassette						
Roche Urisys 2400	1	-	-	-	-	48
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	-	-	-	-	-	220
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	1	-	-	-	-	170
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	-	-	-	-	13
Siemens Clinitek 50	-	-	-	-	-	29
Siemens Clinitek 500, Advantus	1	-	-	-	9	988
Siemens Clinitek Status	1	-	4	-	6	1157
Visual	-	-	1	-	7	124

* Not appropriate for Roche Urisys 1100 users.

Protein – Qualitative, Method 2

CM-12

Method/Instrument	Negative	10-20 mg/dL	30-70 mg/dL	75 mg/dL (Roche only)*	100-200 mg/dL	≥300 mg/dL
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	66	-	-	-	-	-
ARKRAY Aution MAX	122	-	-	-	-	-
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	20	-	-	-	-	-
Roche cobas u411, Urisys 1800	184	-	-	-	-	-
Roche Urisys 1100*	142	-	-	-	-	-
Visual	36	-	-	-	-	-
Roche cobas u Pack Cassette						
Roche cobas u601	24	-	-	-	-	-
Roche Urisys Cassette						
Roche Urisys 2400	49	-	-	-	-	-
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	219	-	-	-	-	1
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	171	-	-	-	-	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	13	-	-	-	-	-
Siemens Clinitek 50	29	-	-	-	-	-
Siemens Clinitek 500, Advantus	996	-	-	-	-	2
Siemens Clinitek Status	1168	-	-	-	1	1
Visual	132	-	-	-	-	-

* Not appropriate for Roche Urisys 1100 users.

Glucose, Method 1

CM-10

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	-	-	-	-	2	16
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	-	-	-	36	-
ARKRAY Aution MAX	-	-	-	1	82	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	1	7	14	2	1
DIRUI H-800 series reagent strips						
DIRUI FUS systems	-	-	2	6	3	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	-	-	-	-	-	-
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	-	-	-	-	10	2
Roche cobas u411, Urisys 1800	1	-	-	2	29	76
Roche Urisys 1100	-	-	-	-	9	50
Visual	1	-	-	1	15	67
Roche cobas u Pack Cassette						
Roche cobas u601	-	-	-	-	8	30
Roche Urisys Cassette						
Roche Urisys 2400	-	-	-	-	7	4
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	-	-	17	102	9	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	-	-	2	67	8	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	-	4	5	3	1
Siemens Clinitek 500, Advantus	2	4	186	364	27	-
Siemens Clinitek Status	6	8	463	275	7	3
Visual	-	10	40	52	24	7
Sysmex Reagent Strips						
Sysmex UC-3500	-	-	-	-	14	-

Glucose, Method 1

CM-11

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	-	-	-	-	2	16
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	-	-	-	33	3
ARKRAY Aution MAX	1	-	-	1	63	18
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	3	9	9	4
DIRUI H-800 series reagent strips						
DIRUI FUS systems	-	-	3	7	1	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	-	-	-	-	32	3
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	-	-	-	1	9	2
Roche cobas u411, Urisys 1800	-	-	-	2	25	81
Roche Urisys 1100	-	-	1	1	10	47
Visual	-	-	-	3	12	69
Roche cobas u Pack Cassette						
Roche cobas u601	-	-	-	2	25	11
Roche Urisys Cassette						
Roche Urisys 2400	-	-	-	-	8	3
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	1	-	4	105	18	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	1	-	2	49	23	2
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	-	2	9	-	2
Siemens Clinitek 500, Advantus	3	4	122	408	47	-
Siemens Clinitek Status	4	5	8	733	10	3
Visual	-	2	15	72	37	7
Sysmex Reagent Strips						
Sysmex UC-3500	-	-	-	-	14	-

Glucose, Method 1

CM-12

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	18	-	-	-	-	-
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	36	-	-	-	-	-
ARKRAY Aution MAX	82	-	-	-	1	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	25	-	-	-	-	-
DIRUI H-800 series reagent strips						
DIRUI FUS systems	11	-	-	-	-	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	35	-	-	-	-	-
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	11	-	-	1	-	-
Roche cobas u411, Urisys 1800	108	-	-	-	-	-
Roche Urisys 1100	59	-	-	-	-	-
Visual	84	-	-	1	-	-
Roche cobas u Pack Cassette						
Roche cobas u601	38	-	-	-	-	-
Roche Urisys Cassette						
Roche Urisys 2400	11	-	-	-	-	-
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	128	-	-	-	-	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	76	-	-	1	-	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	13	-	-	-	-	-
Siemens Clinitek 500, Advantus	581	3	-	-	-	-
Siemens Clinitek Status	760	1	-	2	-	-
Visual	133	-	-	-	-	-
Sysmex Reagent Strips						
Sysmex UC-3500	14	-	-	-	-	-

Glucose, Method 2

Glucose, Method 2 reporting options in SI units	
Conventional (mg/dL)	**SI (mmol/L)**
Negative	Negative
30 - 100	1.6 - 6.0
150 - 300	8.3 - 16.6
500	28
>500 or ≥ 1000 or ≥ 2000	> 28 or ≥ 55 or ≥ 111

CM-10

Method/Instrument	Negative	30-100 mg/dL	150-300 mg/dL	500* mg/dL	>500 or ≥1000 or ≥2000 mg/dL
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	-	-	2	64	2
ARKRAY Aution MAX	-	-	28	93	10
Roche Chemstrip/Combur*					
Roche Chemstrip Criterion/II	-	-	2	-	21
Roche cobas u411, Urisys 1800	-	1	34	-	156
Roche Urisys 1100	-	-	5	-	139
Visual*	-	1	3	18	106
Roche cobas u Pack Cassette					
Roche cobas u601	-	-	1	-	23
Roche Urisys Cassette					
Roche Urisys 2400	-	-	2	1	46
Siemens Clinitek Atlas Reagent					
Siemens Clinitek Atlas	2	1	38	184	5
Siemens Clinitek Novus/Pro Cassette					
Siemens Clinitek Novus	1	-	3	156	12
Siemens Reagent Strips					
Siemens Clinitek 10 or 100	-	-	4	7	1
Siemens Clinitek 50	-	1	11	17	2
Siemens Clinitek 500, Advantus	5	7	406	558	39
Siemens Clinitek Status	9	18	714	415	22
Visual	1	7	81	128	70

*Roche Glucose Visual Users: Results may be reported as 500 mg/dL.
All other Roche Glucose Method users should NOT report 500 mg/dL. Analyzers are not able to discern results of 500 vs. 1000 mg/dL.

Glucose, Method 2

CM-11

Method/Instrument	Negative	30-100 mg/dL	150-300 mg/dL	500* mg/dL	>500 or ≥1000 or ≥2000 mg/dL
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	-	-	2	56	10
ARKRAY Aution MAX	-	-	30	72	29
Roche Chemstrip/Combur*					
Roche Chemstrip Criterion/II	-	-	4	-	19
Roche cobas u411, Urisys 1800	-	1	15	-	175
Roche Urisys 1100	-	-	8	-	136
Visual*	-	1	4	6	117
Roche cobas u Pack Cassette					
Roche cobas u601	-	-	15	-	9
Roche Urisys Cassette					
Roche Urisys 2400	-	-	5	1	43
Siemens Clinitek Atlas Reagent					
Siemens Clinitek Atlas	-	1	5	204	20
Siemens Clinitek Novus/Pro Cassette					
Siemens Clinitek Novus	1	-	1	131	39
Siemens Reagent Strips					
Siemens Clinitek 10 or 100	-	-	-	10	2
Siemens Clinitek 50	-	-	-	19	12
Siemens Clinitek 500, Advantus	6	5	214	729	61
Siemens Clinitek Status	9	9	26	1098	36
Visual	2	4	24	147	110

*Roche Glucose Visual Users: Results may be reported as 500 mg/dL.
All other Roche Glucose Method users should NOT report 500 mg/dL. Analyzers are not able to discern results of 500 vs. 1000 mg/dL.

Glucose, Method 2

CM-12

Method/Instrument	Negative	30-100 mg/dL	150-300 mg/dL	500* mg/dL	>500 or ≥1000 or ≥2000 mg/dL
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	68	-	-	-	-
ARKRAY Aution MAX	131	-	-	-	-
Roche Chemstrip/Combur*					
Roche Chemstrip Criterion/II	23	-	-	-	-
Roche cobas u411, Urisys 1800	190	1	-	-	-
Roche Urisys 1100	143	-	-	-	1
Visual*	128	-	-	-	-
Roche cobas u Pack Cassette					
Roche cobas u601	24	-	-	-	-
Roche Urisys Cassette					
Roche Urisys 2400	49	-	-	-	-
Siemens Clinitek Atlas Reagent					
Siemens Clinitek Atlas	229	-	-	1	-
Siemens Clinitek Novus/Pro Cassette					
Siemens Clinitek Novus	172	-	-	-	-
Siemens Reagent Strips					
Siemens Clinitek 10 or 100	12	-	-	-	-
Siemens Clinitek 50	31	-	-	-	-
Siemens Clinitek 500, Advantus	1005	7	1	1	-
Siemens Clinitek Status	1177	2	-	-	1
Visual	287	-	-	-	-

*Roche Glucose Visual Users: Results may be reported as 500 mg/dL.
All other Roche Glucose Method users should NOT report 500 mg/dL. Analyzers are not able to discern results of 500 vs. 1000 mg/dL.

Reducing Substance

CM-10

Method	Negative	¼% (Trace)	½%	¾%*	1%	≥2%
Bayer Clinitest, 2 Drop*	-	-	3	2	10	8
Bayer Clinitest, 5 Drop	3	6	19	37	149	47
Germaine Labs AimTab, 5 drop	-	-	1	4	12	9

CM-11

Method	Negative	¼% (Trace)	½%	¾%*	1%	≥2%
Bayer Clinitest, 2 Drop*	1	-	-	-	5	17
Bayer Clinitest, 5 Drop	2	1	4	13	95	146
Germaine Labs AimTab, 5 drop	-	-	1	-	7	18

CM-12

Method	Negative	¼% (Trace)	½%	¾%*	1%	≥2%
Bayer Clinitest, 2 Drop*	23	-	-	-	-	-
Bayer Clinitest, 5 Drop	259	-	-	-	1	1
Germaine Labs AimTab, 5 drop	26	-	-	-	-	-

* Please note ¾% is not an appropriate response for the Bayer Clinitest, 2-drop method.

Ketones, Method 1

CM-10

Method/Instrument	Negative	Trace	Small	Moderate	Large
Roche Chemstrip/Combur					
Roche cobas u411, Urisys 1800	-	-	-	-	21
Visual	-	-	-	3	31
Siemens Clinitek Atlas Reagent					
Siemens Clinitek Atlas	-	-	-	4	6
Siemens Clinitek Novus/Pro Cassette					
Siemens Clinitek Novus	-	-	-	-	14
Siemens Reagent Strips					
Siemens Clinitek 500, Advantus	-	-	-	13	39
Siemens Clinitek Status	-	-	-	5	49
Visual	-	-	-	9	144

CM-11

Method/Instrument	Negative	Trace	Small	Moderate	Large
Roche Chemstrip/Combur					
Roche cobas u411, Urisys 1800	-	-	2	19	-
Visual	-	-	8	25	1
Siemens Clinitek Atlas Reagent					
Siemens Clinitek Atlas	-	1	9	-	-
Siemens Clinitek Novus/Pro Cassette					
Siemens Clinitek Novus	-	-	14	-	-
Siemens Reagent Strips					
Siemens Clinitek 500, Advantus	-	1	50	-	1
Siemens Clinitek Status	-	-	46	8	-
Visual	4	19	52	67	11

CM-12

Method/Instrument	Negative	Trace	Small	Moderate	Large
Roche Chemstrip/Combur					
Roche cobas u411, Urisys 1800	21	-	-	-	-
Visual	35	-	-	-	-
Siemens Clinitek Atlas Reagent					
Siemens Clinitek Atlas	10	-	-	-	-
Siemens Clinitek Novus/Pro Cassette					
Siemens Clinitek Novus	14	-	-	-	-
Siemens Reagent Strips					
Siemens Clinitek 500, Advantus	52	-	-	-	-
Siemens Clinitek Status	55	-	-	-	-
Visual	153	-	-	-	-

Ketones, Method 2

CM-10

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	-	-	1	16	1	-
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	-	-	12	25	-
ARKRAY Aution MAX	-	-	-	3	94	1
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	-	8	16	-
DIRUI H-800 series reagent strips						
DIRUI FUS systems	2	2	2	3	1	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	-	-	-	14	21	-
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	-	-	-	-	15	1
Roche cobas u411, Urisys 1800	1	-	-	3	44	71
Roche Urisys 1100	-	-	-	7	52	1
Visual	-	-	-	24	126	9
Roche cobas u Pack Cassette						
Roche cobas u601	-	-	-	-	6	32
Roche Urisys Cassette						
Roche Urisys 2400	-	-	-	-	13	2
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	-	-	-	5	133	1
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	-	1	1	2	80	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	-	-	-	7	5
Siemens Clinitek 500, Advantus	-	-	11	183	381	5
Siemens Clinitek Status	1	-	-	19	260	451
Visual	-	-	-	8	49	17
Sysmex Reagent Strips						
Sysmex UC-3500	-	-	-	9	5	-

Ketones, Method 2

CM-11

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	-	4	14	-	-	-
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	-	37	-	-	-
ARKRAY Aution MAX	1	-	97	-	-	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	4	17	3	-	-
DIRUI H-800 series reagent strips						
DIRUI FUS systems*	4	2	5	-	-	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	3	-	32	-	-	-
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	-	-	6	9	1	-
Roche cobas u411, Urisys 1800	-	-	10	66	43	-
Roche Urisys 1100	1	-	21	37	1	-
Visual	2	-	63	80	14	-
Roche cobas u Pack Cassette						
Roche cobas u601	-	-	-	11	26	1
Roche Urisys Cassette						
Roche Urisys 2400	-	-	1	12	2	-
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	1	4	134	-	-	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	1	3	79	1	-	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	-	10	2	-	-
Siemens Clinitek 500, Advantus	1	18	557	3	2	-
Siemens Clinitek Status	-	3	616	109	2	1
Visual	-	8	32	28	4	2
Sysmex Reagent Strips						
Sysmex UC-3500*	7	-	7	-	-	-

*code 27 issued: Non-consensus

Ketones, Method 2

CM-12

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	18	-	-	-	-	-
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	37	-	-	-	-	-
ARKRAY Aution MAX	97	-	1	-	-	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	24	-	-	-	-	-
DIRUI H-800 series reagent strips						
DIRUI FUS systems	11	-	-	-	-	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	35	-	-	-	-	-
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	16	-	-	-	-	-
Roche cobas u411, Urisys 1800	119	-	-	-	-	-
Roche Urisys 1100	59	-	-	-	-	-
Visual	158	-	-	1	-	-
Roche cobas u Pack Cassette						
Roche cobas u601	38	-	-	-	-	-
Roche Urisys Cassette						
Roche Urisys 2400	15	-	-	-	-	-
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	139	-	-	-	-	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	83	-	-	-	1	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	12	-	-	-	-	-
Siemens Clinitek 500, Advantus	581	-	-	-	-	-
Siemens Clinitek Status	730	-	1	-	-	-
Visual	74	-	-	-	-	-
Sysmex Reagent Strips						
Sysmex UC-3500	14	-	-	-	-	-

Ketones, Method 3

Ketones, Method 3 reporting options in SI units	
Conventional (mg/dL)	**SI (mmol/L)**
Negative	Negative
5 -10	0.5 - 1.0
15 - 30	1.5 - 2.0
40 - 60	3.9 - 6.0
80 - 100	7.8 - 10.0
≥150	≥15.0

CM-10

Method/Instrument	Negative	5-10 mg/dL	15-30 mg/dL	40 - 60 mg/dL	80 - 100 mg/dL*	≥150 mg/dL
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	-	-	10	51	-
ARKRAY Aution MAX	-	-	2	9	97	3
Roche Chemstrip/Combur*						
Roche Chemstrip Criterion/II	-	-	1	1	-	17
Roche cobas u411, Urisys 1800	-	-	2	4	-	151
Roche Urisys 1100	-	-	4	45	-	95
Roche cobas u Pack Cassette*						
Roche cobas u601	-	-	-	1	-	23
Roche Urisys Cassette*						
Roche Urisys 2400	-	-	-	-	1	44
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	2	-	-	4	201	2
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	-	2	-	4	146	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	-	-	2	8	3
Siemens Clinitek 50	-	-	1	2	20	8
Siemens Clinitek 500, Advantus	1	1	7	248	683	22
Siemens Clinitek Status	1	-	1	21	457	676
Visual	-	1	-	1	52	65

* Roche Urinalysis instruments should not report 80-100 mg/dL. Analyzers are not able to discern ketones between 60 and 150.

Ketones, Method 3

CM-11

Method/Instrument	Negative	5-10 mg/dL	15-30 mg/dL	40 - 60 mg/dL	80 - 100 mg/dL*	≥150 mg/dL
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	12	49	-	-	-
ARKRAY Aution MAX	-	39	69	2	-	1
Roche Chemstrip/Combur*						
Roche Chemstrip Criterion/II	-	1	8	10	-	-
Roche cobas u411, Urisys 1800	-	2	36	113	2	4
Roche Urisys 1100	1	4	85	53	-	1
Roche cobas u Pack Cassette*						
Roche cobas u601	-	-	4	20	-	-
Roche Urisys Cassette*						
Roche Urisys 2400	1	-	2	42	-	-
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	-	-	208	-	1	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	1	1	149	1	-	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	1	11	1	-	-
Siemens Clinitek 50	-	-	30	1	-	-
Siemens Clinitek 500, Advantus	1	24	930	7	1	-
Siemens Clinitek Status	3	16	985	147	2	3
Visual	4	4	52	45	16	-

* Roche Urinalysis instruments should not report 80-100 mg/dL. Analyzers are not able to discern ketones between 60 and 150.

Ketones, Method 3

CM-12

Method/Instrument	Negative	5-10 mg/dL	15-30 mg/dL	40 - 60 mg/dL	80 - 100 mg/dL*	≥150 mg/dL
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	61	-	-	-	-	-
ARKRAY Aution MAX	111	-	-	-	-	-
Roche Chemstrip/Combur*						
Roche Chemstrip Criterion/II	19	-	-	-	-	-
Roche cobas u411, Urisys 1800	157	-	-	-	-	-
Roche Urisys 1100	144	-	-	-	-	-
Roche cobas u Pack Cassette*						
Roche cobas u601	24	-	-	-	-	-
Roche Urisys Cassette*						
Roche Urisys 2400	45	-	-	-	-	-
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	208	-	1	-	-	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	152	-	-	-	-	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	13	-	-	-	-	-
Siemens Clinitek 50	31	-	-	-	-	-
Siemens Clinitek 500, Advantus	962	-	1	-	-	-
Siemens Clinitek Status	1157	-	-	-	-	1
Visual	121	-	-	-	-	-

* Roche Urinalysis instruments should not report 80-100 mg/dL. Analyzers are not able to discern ketones between 60 and 150.

Bilirubin, Method 1

CM-10

Method/Instrument	Negative	Trace/ Small	Positive/ Moderate	Large
ARKRAY Aution Sticks				
ARKRAY Aution Hybrid	-	-	11	33
ARKRAY Aution MAX	5	1	26	49
Roche Chemstrip/Combur				
Roche cobas u411, Urisys 1800	-	-	13	11
Visual	-	-	14	7
Siemens Clinitek Atlas Reagent				
Siemens Clinitek Atlas	2	59	167	-
Siemens Clinitek Novus/Pro Cassette				
Siemens Clinitek Novus	-	-	156	9
Siemens Reagent Strips				
Siemens Clinitek 10 or 100	-	-	7	9
Siemens Clinitek 50	1	-	13	15
Siemens Clinitek 500, Advantus	4	2	931	50
Siemens Clinitek Atlas	-	1	8	1
Siemens Clinitek Status	2	1	919	202
Visual	1	3	21	194

CM-11

Method/Instrument	Negative	Trace/ Small	Positive/ Moderate	Large
ARKRAY Aution Sticks				
ARKRAY Aution Hybrid	-	1	15	28
ARKRAY Aution MAX	5	3	31	42
Roche Chemstrip/Combur				
Roche cobas u411, Urisys 1800	-	-	14	10
Visual	-	-	15	6
Siemens Clinitek Atlas Reagent				
Siemens Clinitek Atlas	2	208	18	-
Siemens Clinitek Novus/Pro Cassette				
Siemens Clinitek Novus	-	7	158	-
Siemens Reagent Strips				
Siemens Clinitek 10 or 100	-	-	8	8
Siemens Clinitek 50	-	2	27	-
Siemens Clinitek 500, Advantus	4	177	803	3
Siemens Clinitek Atlas	-	8	2	-
Siemens Clinitek Status	1	248	869	5
Visual	2	7	42	168

Bilirubin, Method 1

CM-12

Method/Instrument	Negative	Trace/ Small	Positive/ Moderate	Large
ARKRAY Aution Sticks				
ARKRAY Aution Hybrid	44	-	-	-
ARKRAY Aution MAX	81	-	-	-
Roche Chemstrip/Combur				
Roche cobas u411, Urisys 1800	24	-	-	-
Visual	21	-	-	-
Siemens Clinitek Atlas Reagent				
Siemens Clinitek Atlas	227	1	-	-
Siemens Clinitek Novus/Pro Cassette				
Siemens Clinitek Novus	165	-	-	-
Siemens Reagent Strips				
Siemens Clinitek 10 or 100	16	-	-	-
Siemens Clinitek 50	29	-	-	-
Siemens Clinitek 500, Advantus	985	-	2	-
Siemens Clinitek Atlas	10	-	-	-
Siemens Clinitek Status	1125	-	-	-
Visual	220	-	1	-

Bilirubin, Method 2

CM-10

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	-	1	1	10	7	-
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	-	-	-	30	-
ARKRAY Aution MAX	-	-	-	6	89	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	-	3	22	-
DIRUI H-800 series reagent strips						
DIRUI FUS systems	-	-	-	11	-	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	-	-	-	-	34	-
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	-	-	-	1	12	-
Roche cobas u411, Urisys 1800	2	-	-	2	105	-
Roche Urisys 1100	-	-	-	-	55	-
Visual	-	-	-	9	157	4
Roche cobas u Pack Cassette						
Roche cobas u601	-	-	-	1	37	-
Roche Urisys Cassette						
Roche Urisys 2400	-	-	-	-	10	-
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	2	1	36	84	-	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	-	-	-	74	3	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	-	-	3	8	1
Siemens Clinitek 500, Advantus	1	-	-	477	24	-
Siemens Clinitek Status	1	-	2	506	127	-
Visual	1	-	2	19	62	1
Sysmex Reagent Strips						
Sysmex UC-3500	-	-	-	1	13	-

Bilirubin, Method 2

CM-11

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	-	-	5	14	-	-
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	-	-	9	21	-
ARKRAY Aution MAX	1	-	1	24	69	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	3	1	21	-
DIRUI H-800 series reagent strips						
DIRUI FUS systems	-	-	-	11	-	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	-	-	-	-	34	-
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	-	-	-	1	12	-
Roche cobas u411, Urisys 1800	2	-	-	2	105	-
Roche Urisys 1100	-	-	-	-	55	-
Visual	-	-	-	9	157	4
Roche cobas u Pack Cassette						
Roche cobas u601	-	-	-	1	37	-
Roche Urisys Cassette						
Roche Urisys 2400	-	-	-	-	10	-
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	3	1	118	1	-	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	1	-	1	75	-	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	-	-	6	6	-
Siemens Clinitek 500, Advantus	2	-	88	412	1	-
Siemens Clinitek Status	1	-	162	473	-	-
Visual	1	-	6	24	53	1
Sysmex Reagent Strips						
Sysmex UC-3500	-	-	-	-	14	-

Bilirubin, Method 2

CM-12

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	19	-	-	-	-	-
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	30	-	-	-	-	-
ARKRAY Aution MAX	94	-	-	-	1	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	25	-	-	-	-	-
DIRUI H-800 series reagent strips						
DIRUI FUS systems	11	-	-	-	-	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	34	-	-	-	-	-
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	13	-	-	-	-	-
Roche cobas u411, Urisys 1800	109	-	-	-	-	-
Roche Urisys 1100	54	-	-	-	-	-
Visual	168	-	2	-	-	-
Roche cobas u Pack Cassette						
Roche cobas u601	38	-	-	-	-	-
Roche Urisys Cassette						
Roche Urisys 2400	10	-	-	-	-	-
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	123	-	-	-	-	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	76	-	-	1	-	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	12	-	-	-	-	-
Siemens Clinitek 500, Advantus	503	-	-	-	-	-
Siemens Clinitek Status	636	-	1	-	-	-
Visual	84	-	-	1	-	-
Sysmex Reagent Strips						
Sysmex UC-3500	14	-	-	-	-	-

Bilirubin, Method 3

CM-10

Method/Instrument	Negative	0.5 -1.0 mg/dL	2.0 – 4.0 mg/dL	6.0 – 10.0 mg/dL	>10.0 mg/dL
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	1	-	-	23	-
ARKRAY Aution MAX	-	-	2	31	1
Roche Chemstrip/Combur					
Roche Chemstrip Criterion/II	-	-	-	17	-
Roche cobas u411, Urisys 1800	-	1	-	127	-
Roche Urisys 1100	-	-	1	133	2
Roche cobas u Pack Cassette					
Roche cobas u601	-	-	-	23	-
Roche Urisys Cassette					
Roche Urisys 2400	-	-	-	38	1

CM-11

Method/Instrument	Negative	0.5 -1.0 mg/dL	2.0 – 4.0 mg/dL	6.0 – 10.0 mg/dL	>10.0 mg/dL
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	1	-	1	22	-
ARKRAY Aution MAX	1	-	15	18	-
Roche Chemstrip/Combur					
Roche Chemstrip Criterion/II	-	-	-	17	-
Roche cobas u411, Urisys 1800	-	1	-	127	-
Roche Urisys 1100	-	-	1	132	2
Roche cobas u Pack Cassette					
Roche cobas u601	-	-	-	23	-
Roche Urisys Cassette					
Roche Urisys 2400	-	1	-	37	1

CM-12

Method/Instrument	Negative	0.5 -1.0 mg/dL	2.0 – 4.0 mg/dL	6.0 – 10.0 mg/dL	>10.0 mg/dL
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	24	-	-	-	-
ARKRAY Aution MAX	34	-	-	-	-
Roche Chemstrip/Combur					
Roche Chemstrip Criterion/II	17	-	-	-	-
Roche cobas u411, Urisys 1800	129	-	-	-	-
Roche Urisys 1100	135	-	-	-	-
Roche cobas u Pack Cassette					
Roche cobas u601	23	-	-	-	-
Roche Urisys Cassette					
Roche Urisys 2400	39	-	-	-	-

Blood or Hemoglobin, Method 1

CM-10

Method/Instrument	Negative	Trace/ Small	Positive/ Moderate	Marked Pos./Large
ARKRAY Aution Sticks				
ARKRAY Aution Hybrid	-	-	35	8
ARKRAY Aution MAX	-	-	67	8
Roche Chemstrip/Combur				
Roche cobas u411, Urisys 1800	-	-	-	27
Visual	-	-	-	11
Siemens Clinitek Atlas Reagent				
Siemens Clinitek Atlas	2	2	152	57
Siemens Clinitek Novus/Pro Cassette				
Siemens Clinitek Novus	-	-	143	12
Siemens Reagent Strips				
Siemens Clinitek 10 or 100	-	-	6	9
Siemens Clinitek 50	-	2	15	12
Siemens Clinitek 500, Advantus	1	2	197	772
Siemens Clinitek Status	1	1	574	472
Visual	1	3	19	214

CM-11

Method/Instrument	Negative	Trace/ Small	Positive/ Moderate	Marked Pos./Large
ARKRAY Aution Sticks				
ARKRAY Aution Hybrid	-	1	36	6
ARKRAY Aution MAX	-	-	68	7
Roche Chemstrip/Combur				
Roche cobas u411, Urisys 1800	-	-	23	4
Visual	-	-	8	3
Siemens Clinitek Atlas Reagent				
Siemens Clinitek Atlas	-	1	130	82
Siemens Clinitek Novus/Pro Cassette				
Siemens Clinitek Novus	-	-	140	15
Siemens Reagent Strips				
Siemens Clinitek 10 or 100	-	-	10	5
Siemens Clinitek 50	1	-	20	8
Siemens Clinitek 500, Advantus	1	2	332	637
Siemens Clinitek Status	1	6	725	317
Visual	-	8	23	206

Blood or Hemoglobin, Method 1

CM-12

Method/Instrument	Negative	Trace/ Small	Positive/ Moderate	Marked Pos./Large
ARKRAY Aution Sticks				
ARKRAY Aution Hybrid	43	-	-	-
ARKRAY Aution MAX	75	-	-	-
Roche Chemstrip/Combur				
Roche cobas u411, Urisys 1800	27	-	-	-
Visual	12	-	-	-
Siemens Clinitek Atlas Reagent				
Siemens Clinitek Atlas	211	1	1	-
Siemens Clinitek Novus/Pro Cassette				
Siemens Clinitek Novus	155	-	-	-
Siemens Reagent Strips				
Siemens Clinitek 10 or 100	14	1	-	-
Siemens Clinitek 50	29	-	-	-
Siemens Clinitek 500, Advantus	970	1	1	-
Siemens Clinitek Status	1030	17	-	1
Visual	234	1	-	1

Blood or Hemoglobin, Method 2

CM-10

Method/Instrument	Negative	Trace	1+	2+	3+	4+	5+
77 Elektronika Reagent Strips							
77 Elektronika urine chemistry analyzers	-	-	-	17	2	-	-
ARKRAY Aution Sticks							
ARKRAY Aution Hybrid	-	-	-	33	12	-	-
ARKRAY Aution MAX	-	-	1	94	9	-	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips							
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	-	6	19	-	-
DIRUI H-800 series reagent strips							
DIRUI FUS systems	-	-	-	-	11	-	-
Eiken Uropaper							
Eiken US-3100R/3100Rplus/3500	-	-	-	31	4	-	-
Roche Chemstrip/Combur							
Roche Chemstrip Criterion/II	-	-	-	-	1	19	-
Roche cobas u411, Urisys 1800	1	-	-	4	12	49	47
Roche Urisys 1100	-	-	-	21	1	30	1
Visual	1	-	-	20	19	52	1
Roche cobas u Pack Cassette							
Roche cobas u601	-	-	-	-	-	14	23
Roche Urisys Cassette							
Roche Urisys 2400	-	-	-	1	5	5	2
Siemens Clinitek Atlas Reagent							
Siemens Clinitek Atlas	1	-	1	112	30	-	-
Siemens Clinitek Novus/Pro Cassette							
Siemens Clinitek Novus	-	-	-	78	11	-	-
Siemens Reagent Strips							
Siemens Clinitek 10 or 100	-	-	1	5	6	1	-
Siemens Clinitek 500, Advantus	-	-	-	97	477	2	-
Siemens Clinitek Status	3	-	2	394	340	-	-
Visual	-	1	2	8	92	3	2
Sysmex Reagent Strips							
Sysmex UC-3500	-	-	-	7	7	-	-

Blood or Hemoglobin, Method 2

CM-11

Method/Instrument	Negative	Trace	1+	2+	3+	4+	5+
77 Elektronika Reagent Strips							
77 Elektronika urine chemistry analyzers	-	-	-	19	-	-	-
ARKRAY Aution Sticks							
ARKRAY Aution Hybrid	-	-	-	32	13	-	-
ARKRAY Aution MAX	1	-	-	92	11	-	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips							
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	3	6	16	-	-
DIRUI H-800 series reagent strips							
DIRUI FUS systems	-	-	-	-	11	-	-
Eiken Uropaper							
Eiken US-3100R/3100Rplus/3500	-	-	-	35	-	-	-
Roche Chemstrip/Combur							
Roche Chemstrip Criterion/II	-	-	-	7	13	-	-
Roche cobas u411, Urisys 1800	-	-	1	29	41	42	-
Roche Urisys 1100	-	-	1	20	9	22	1
Visual	1	-	11	27	37	17	-
Roche cobas u Pack Cassette							
Roche cobas u601	-	-	-	2	13	22	-
Roche Urisys Cassette							
Roche Urisys 2400	-	-	2	9	2	-	-
Siemens Clinitek Atlas Reagent							
Siemens Clinitek Atlas	1	1	1	80	61	-	-
Siemens Clinitek Novus/Pro Cassette							
Siemens Clinitek Novus	1	-	-	75	13	-	-
Siemens Reagent Strips							
Siemens Clinitek 10 or 100	-	-	-	7	5	1	-
Siemens Clinitek 500, Advantus	-	-	1	181	395	-	-
Siemens Clinitek Status	1	-	1	541	195	-	1
Visual	-	-	1	9	94	2	2
Sysmex Reagent Strips							
Sysmex UC-3500	-	-	-	13	1	-	-

Blood or Hemoglobin, Method 2

CM-12

Method/Instrument	Negative	Trace	1+	2+	3+	4+	5+
77 Elektronika Reagent Strips							
77 Elektronika urine chemistry analyzers	19	-	-	-	-	-	-
ARKRAY Aution Sticks							
ARKRAY Aution Hybrid	45	-	-	-	-	-	-
ARKRAY Aution MAX	103	-	-	1	-	-	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips							
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	25	-	-	-	-	-	-
DIRUI H-800 series reagent strips							
DIRUI FUS systems	11	-	-	-	-	-	-
Eiken Uropaper							
Eiken US-3100R/3100Rplus/3500	35	-	-	-	-	-	-
Roche Chemstrip/Combur							
Roche Chemstrip Criterion/II	20	-	-	-	-	-	-
Roche cobas u411, Urisys 1800	113	-	-	-	-	-	-
Roche Urisys 1100	53	-	-	1	-	-	-
Visual	93	-	-	-	-	-	-
Roche cobas u Pack Cassette							
Roche cobas u601	37	-	-	-	-	-	-
Roche Urisys Cassette							
Roche Urisys 2400	13	-	-	-	-	-	-
Siemens Clinitek Atlas Reagent							
Siemens Clinitek Atlas	144	-	-	-	-	-	-
Siemens Clinitek Novus/Pro Cassette							
Siemens Clinitek Novus	88	-	-	1	-	-	-
Siemens Reagent Strips							
Siemens Clinitek 10 or 100	13	-	-	-	-	-	-
Siemens Clinitek 500, Advantus	574	2	-	-	1	-	-
Siemens Clinitek Status	724	11	3	1	1	-	-
Visual	107	1	-	-	-	-	-
Sysmex Reagent Strips							
Sysmex UC-3500	14	-	-	-	-	-	-

Blood or Hemoglobin, Method 3

CM-10

Method/Instrument	Negative	5 – 25 Ery/µL	50 – 150 Ery/µL	250 Ery/µL
Roche Chemstrip/Combur				
Roche Chemstrip Criterion/II	-	-	2	14
Roche cobas u411, Urisys 1800	-	-	5	148
Roche Urisys 1100	-	-	2	147
Visual	-	-	7	92
Roche cobas u Pack Cassette				
Roche cobas u601	-	-	1	23
Roche Urisys Cassette				
Roche Urisys 2400	-	-	2	40
Siemens Reagent Strips				
Siemens Clinitek 500, Advantus	-	1	10	36
Siemens Clinitek Status	-	1	102	47

CM-11

Method/Instrument	Negative	5 – 25 Ery/µL	50 – 150 Ery/µL	250 Ery/µL
Roche Chemstrip/Combur				
Roche Chemstrip Criterion/II	-	-	16	-
Roche cobas u411, Urisys 1800	-	-	150	3
Roche Urisys 1100	-	-	20	129
Visual	-	-	71	28
Roche cobas u Pack Cassette				
Roche cobas u601	-	-	24	-
Roche Urisys Cassette				
Roche Urisys 2400	1	1	40	-
Siemens Reagent Strips				
Siemens Clinitek 500, Advantus	-	1	19	27
Siemens Clinitek Status	-	-	125	25

CM-12

Method/Instrument	Negative	5 – 25 Ery/µL	50 – 150 Ery/µL	250 Ery/µL
Roche Chemstrip/Combur				
Roche Chemstrip Criterion/II	16	-	-	-
Roche cobas u411, Urisys 1800	153	-	-	-
Roche Urisys 1100	148	1	-	-
Visual	99	-	-	-
Roche cobas u Pack Cassette				
Roche cobas u601	24	-	-	-
Roche Urisys Cassette				
Roche Urisys 2400	42	-	-	-
Siemens Reagent Strips				
Siemens Clinitek 500, Advantus	47	-	-	-
Siemens Clinitek Status	150	2	-	-

Blood or Hemoglobin, Method 4

CM-10

Method/Instrument	Negative	±0.03 mg/dL	0.06 – 0.15 mg/dL	0.20 – 0.50 mg/dL	≥0.75 mg/dL
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	-	-	-	13	3
ARKRAY Aution MAX	-	-	-	29	1

CM-11

Method/Instrument	Negative	±0.03 mg/dL	0.06 – 0.15 mg/dL	0.20 – 0.50 mg/dL	≥0.75 mg/dL
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	-	-	-	14	2
ARKRAY Aution MAX	-	-	-	30	-

CM-12

Method/Instrument	Negative	±0.03 mg/dL	0.06 – 0.15 mg/dL	0.20 – 0.50 mg/dL	≥0.75 mg/dL
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	16	-	-	-	-
ARKRAY Aution MAX	30	-	-	-	-

Leukocyte Esterase, Method 1

CM-10

Method/Instrument	Negative	Trace	Small	Moderate	Large
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	-	-	-	1	46
ARKRAY Aution MAX	-	-	-	1	74
Roche Chemstrip/Combur					
Roche cobas u411, Urisys 1800	-	-	-	7	7
Visual	-	-	1	2	7
Siemens Clinitek Atlas Reagent					
Siemens Clinitek Atlas	2	-	-	5	201
Siemens Clinitek Novus/Pro Cassette					
Siemens Clinitek Novus	-	-	-	8	141
Siemens Reagent Strips					
Siemens Clinitek 10 or 100	1	-	5	7	1
Siemens Clinitek 50	-	1	14	-	15
Siemens Clinitek 500, Advantus	2	-	17	885	71
Siemens Clinitek Status	5	5	423	127	487
Visual	1	-	20	157	49

CM-11

Method/Instrument	Negative	Trace	Small	Moderate	Large
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	-	-	1	1	45
ARKRAY Aution MAX	-	-	1	2	72
Roche Chemstrip/Combur					
Roche cobas u411, Urisys 1800	-	-	-	7	7
Visual	-	1	-	5	4
Siemens Clinitek Atlas Reagent					
Siemens Clinitek Atlas	-	-	2	31	175
Siemens Clinitek Novus/Pro Cassette					
Siemens Clinitek Novus	-	-	-	81	68
Siemens Reagent Strips					
Siemens Clinitek 10 or 100	1	-	6	7	-
Siemens Clinitek 50	-	-	22	-	8
Siemens Clinitek 500, Advantus	3	1	105	857	9
Siemens Clinitek Status	5	61	816	49	115
Visual	1	9	85	121	11

Leukocyte Esterase, Method 1

CM-12

Method/Instrument	Negative	Trace	Small	Moderate	Large
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	47	-	-	-	-
ARKRAY Aution MAX	73	1	1	-	-
Roche Chemstrip/Combur					
Roche cobas u411, Urisys 1800	14	-	-	-	-
Visual	11	-	-	-	-
Siemens Clinitek Atlas Reagent					
Siemens Clinitek Atlas	207	-	-	-	1
Siemens Clinitek Novus/Pro Cassette					
Siemens Clinitek Novus	149	-	-	-	-
Siemens Reagent Strips					
Siemens Clinitek 10 or 100	14	-	-	-	-
Siemens Clinitek 50	30	-	-	-	-
Siemens Clinitek 500, Advantus	970	2	2	-	-
Siemens Clinitek Status	1044	-	1	-	1
Visual	223	2	-	2	-

Leukocyte Esterase, Method 2

CM-10

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	1	-	-	1	17	-
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	-	-	1	13	4
ARKRAY Aution MAX	-	-	1	2	84	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	-	6	19	-
DIRUI H-800 series reagent strips						
DIRUI FUS systems	-	-	-	-	11	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	-	-	-	-	31	-
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	-	-	-	18	-	-
Roche cobas u411, Urisys 1800	1	-	1	45	68	4
Roche Urisys 1100	-	-	-	11	44	-
Visual	-	-	10	130	47	1
Roche cobas u Pack Cassette						
Roche cobas u601	-	-	-	1	34	1
Roche Urisys Cassette						
Roche Urisys 2400	-	-	-	7	6	-
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	-	-	1	-	140	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	-	-	-	5	80	1
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	-	1	10	3	-
Siemens Clinitek 500, Advantus	-	1	4	529	37	-
Siemens Clinitek Status	3	3	308	126	303	2
Visual	-	-	3	83	22	-
Sysmex Reagent Strips						
Sysmex UC-3500	-	-	-	1	12	-

Leukocyte Esterase, Method 2

CM-11

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	1	-	-	1	16	1
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	-	-	-	1	13	4
ARKRAY Aution MAX	1	-	1	2	83	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	2	10	13	-
DIRUI H-800 series reagent strips						
DIRUI FUS systems	-	-	-	-	11	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	-	-	-	2	29	-
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	-	-	-	18	-	-
Roche cobas u411, Urisys 1800	-	-	-	46	70	3
Roche Urisys 1100	-	-	-	10	45	-
Visual	1	-	7	132	48	-
Roche cobas u Pack Cassette						
Roche cobas u601	-	-	-	1	34	1
Roche Urisys Cassette						
Roche Urisys 2400	-	-	-	7	6	-
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	-	-	-	21	120	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	1	-	-	48	37	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	-	-	5	7	2	-
Siemens Clinitek 500, Advantus	1	1	78	487	5	-
Siemens Clinitek Status	-	30	596	55	63	-
Visual	-	4	40	57	7	-
Sysmex Reagent Strips						
Sysmex UC-3500	-	-	-	4	9	-

Leukocyte Esterase, Method 2

CM-12

Method/Instrument	Negative	Trace	1+	2+	3+	4+
77 Elektronika Reagent Strips						
77 Elektronika urine chemistry analyzers	19	-	-	-	-	-
ARKRAY Aution Sticks						
ARKRAY Aution Hybrid	18	-	-	-	-	-
ARKRAY Aution MAX	85	-	-	1	1	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips						
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	25	-	-	-	-	-
DIRUI H-800 series reagent strips						
DIRUI FUS systems	11	-	-	-	-	-
Eiken Uropaper						
Eiken US-3100R/3100Rplus/3500	31	-	-	-	-	-
Roche Chemstrip/Combur						
Roche Chemstrip Criterion/II	18	-	-	-	-	-
Roche cobas u411, Urisys 1800	119	-	-	-	-	-
Roche Urisys 1100	54	-	-	-	-	-
Visual	187	-	-	1	-	-
Roche cobas u Pack Cassette						
Roche cobas u601	36	-	-	-	-	-
Roche Urisys Cassette						
Roche Urisys 2400	13	-	-	-	-	-
Siemens Clinitek Atlas Reagent						
Siemens Clinitek Atlas	141	-	-	-	-	-
Siemens Clinitek Novus/Pro Cassette						
Siemens Clinitek Novus	85	-	-	-	1	-
Siemens Reagent Strips						
Siemens Clinitek 10 or 100	14	-	-	-	-	-
Siemens Clinitek 500, Advantus	571	-	1	-	-	-
Siemens Clinitek Status	743	1	1	-	-	-
Visual	108	-	-	-	-	-
Sysmex Reagent Strips						
Sysmex UC-3500	13	-	-	-	-	-

Leukocyte Esterase, Method 3

CM-10

Method/Instrument	Negative	25 µL	75 or 100 µL	250 or 500 µL
ARKRAY Aution Sticks				
ARKRAY Aution Hybrid	-	-	-	39
ARKRAY Aution MAX	-	-	-	52
Roche Chemstrip/Combur				
Roche Chemstrip Criterion/II	-	-	-	17
Roche cobas u411, Urisys 1800	-	-	-	160
Roche Urisys 1100	-	-	3	146
Roche cobas u Pack Cassette				
Roche cobas u601	-	-	-	24
Roche Urisys Cassette				
Roche Urisys 2400	-	-	-	44
Siemens Clinitek Novus/Pro Cassette				
Siemens Clinitek Novus	-	-	-	15
Siemens Reagent Strips				
Siemens Clinitek 500, Advantus	-	-	41	5
Siemens Clinitek Status	-	1	88	51

CM-11

Method/Instrument	Negative	25 µL	75 or 100 µL	250 or 500 µL
ARKRAY Aution Sticks				
ARKRAY Aution Hybrid	-	-	-	39
ARKRAY Aution MAX	-	-	-	52
Roche Chemstrip/Combur				
Roche Chemstrip Criterion/II	-	-	-	17
Roche cobas u411, Urisys 1800	-	-	-	160
Roche Urisys 1100	-	-	1	148
Roche cobas u Pack Cassette				
Roche cobas u601	-	-	-	24
Roche Urisys Cassette				
Roche Urisys 2400	1	-	-	43
Siemens Clinitek Novus/Pro Cassette				
Siemens Clinitek Novus	-	-	6	9
Siemens Reagent Strips				
Siemens Clinitek 500, Advantus	-	1	44	1
Siemens Clinitek Status	-	2	132	6

Leukocyte Esterase, Method 3

CM-12

Method/Instrument	Negative	25 µL	75 or 100 µL	250 or 500 µL
ARKRAY Aution Sticks				
ARKRAY Aution Hybrid	39	-	-	-
ARKRAY Aution MAX	51	-	-	1
Roche Chemstrip/Combur				
Roche Chemstrip Criterion/II	17	-	-	-
Roche cobas u411, Urisys 1800	160	-	-	-
Roche Urisys 1100	149	-	-	-
Roche cobas u Pack Cassette				
Roche cobas u601	24	-	-	-
Roche Urisys Cassette				
Roche Urisys 2400	44	-	-	-
Siemens Clinitek Novus/Pro Cassette				
Siemens Clinitek Novus	15	-	-	-
Siemens Reagent Strips				
Siemens Clinitek 500, Advantus	46	-	-	-
Siemens Clinitek Status	142	-	-	-

Nitrite

Intended response was positive.

CM-10

99.8% consensus

Method/Instrument	Negative	Positive
77 Elektronika Reagent Strips		
77 Elektronika urine chemistry analyzers	-	23
ARKRAY Aution Sticks		
ARKRAY Aution Hybrid	-	104
ARKRAY Aution MAX	-	207
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips		
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	26
DIRUI H-800 series reagent strips		
DIRUI FUS systems	-	11
Eiken Uropaper		
Eiken US-3100R/3100Rplus/3500	-	31
Roche Chemstrip/Combur		
Roche Chemstrip Criterion/II	-	35
Roche cobas u411, Urisys 1800	1	291
Roche Urisys 1100	-	202
Visual	2	198
Roche cobas u Pack Cassette		
Roche cobas u601	-	60
Roche Urisys Cassette		
Roche Urisys 2400	-	61
Siemens Clinitek Atlas Reagent		
Siemens Clinitek Atlas	1	355
Siemens Clinitek Novus/Pro Cassette		
Siemens Clinitek Novus	-	246
Siemens Reagent Strips		
Siemens Clinitek 10 or 100	1	24
Siemens Clinitek 50	-	38
Siemens Clinitek 500, Advantus	3	1582
Siemens Clinitek Atlas	-	13
Siemens Clinitek Status	4	1927
Visual	-	339
Sysmex Reagent Strips		
Sysmex UC-3500	-	16

Nitrite

Intended response was positive.

CM-11

99.5% consensus

Method/Instrument	Negative	Positive
77 Elektronika Reagent Strips		
77 Elektronika urine chemistry analyzers	-	23
ARKRAY Aution Sticks		
ARKRAY Aution Hybrid	-	104
ARKRAY Aution MAX	1	206
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips		
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	1	25
DIRUI H-800 series reagent strips		
DIRUI FUS systems	-	11
Eiken Uropaper		
Eiken US-3100R/3100Rplus/3500	-	31
Roche Chemstrip/Combur		
Roche Chemstrip Criterion/II	-	35
Roche cobas u411, Urisys 1800	2	290
Roche Urisys 1100	1	201
Visual	1	199
Roche cobas u Pack Cassette		
Roche cobas u601	-	60
Roche Urisys Cassette		
Roche Urisys 2400	1	60
Siemens Clinitek Atlas Reagent		
Siemens Clinitek Atlas	2	353
Siemens Clinitek Novus/Pro Cassette		
Siemens Clinitek Novus	2	244
Siemens Reagent Strips		
Siemens Clinitek 10 or 100	1	24
Siemens Clinitek 50	-	38
Siemens Clinitek 500, Advantus	4	1581
Siemens Clinitek Atlas	-	13
Siemens Clinitek Status	4	1927
Visual	3	336
Sysmex Reagent Strips		
Sysmex UC-3500	-	16

Nitrite

Intended response was negative.

CM-12

99.6% consensus

Method/Instrument	Negative	Positive
77 Elektronika Reagent Strips		
77 Elektronika urine chemistry analyzers	23	-
ARKRAY Aution Sticks		
ARKRAY Aution Hybrid	104	-
ARKRAY Aution MAX	206	1
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips		
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	26	-
DIRUI H-800 series reagent strips		
DIRUI FUS systems	10	-
Eiken Uropaper		
Eiken US-3100R/3100Rplus/3500	31	-
Roche Chemstrip/Combur		
Roche Chemstrip Criterion/II	34	-
Roche cobas u411, Urisys 1800	292	-
Roche Urisys 1100	200	2
Visual	198	2
Roche cobas u Pack Cassette		
Roche cobas u601	61	-
Roche Urisys Cassette		
Roche Urisys 2400	61	-
Siemens Clinitek Atlas Reagent		
Siemens Clinitek Atlas	355	1
Siemens Clinitek Novus/Pro Cassette		
Siemens Clinitek Novus	245	1
Siemens Reagent Strips		
Siemens Clinitek 10 or 100	25	-
Siemens Clinitek 50	38	-
Siemens Clinitek 500, Advantus	1577	7
Siemens Clinitek Atlas	13	-
Siemens Clinitek Status	1927	6
Visual	337	2
Sysmex Reagent Strips		
Sysmex UC-3500	16	-

Urobilinogen, Method 1

CM-10

Method/Instrument	Negative	1+	2+	3+	4+
77 Elektronika Reagent Strips					
77 Elektronika urine chemistry analyzers*	9	9	-	1	-
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	-	14	1	-	-
ARKRAY Aution MAX	1	28	2	-	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips					
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	4	6	10
Eiken Uropaper					
Eiken US-3100R/3100Rplus/3500	-	12	18	-	-
Roche Chemstrip/Combur					
Roche cobas u411, Urisys 1800	2	-	2	16	52
Roche Urisys 1100	-	1	-	2	46
Visual	1	7	27	24	6
Roche cobas u Pack Cassette					
Roche cobas u601	-	-	-	5	31
Siemens Reagent Strips					
Siemens Clinitek 500, Advantus	-	-	2	14	9
Siemens Clinitek Status	-	1	3	5	10
Visual	-	2	2	3	24
Sysmex Reagent Strips					
Sysmex UC-3500	-	14	-	-	-

*code 27 issued: Non-consensus

CM-11

Method/Instrument	Negative	1+	2+	3+	4+
77 Elektronika Reagent Strips					
77 Elektronika urine chemistry analyzers	1	12	5	1	-
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	-	10	5	-	-
ARKRAY Aution MAX	-	28	3	-	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips					
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	-	-	5	6	9
Eiken Uropaper					
Eiken US-3100R/3100Rplus/3500	-	12	18	-	-
Roche Chemstrip/Combur					
Roche cobas u411, Urisys 1800	-	1	1	10	60
Roche Urisys 1100	-	1	1	-	47
Visual	-	1	19	35	9
Roche cobas u Pack Cassette					
Roche cobas u601	-	-	-	4	32
Siemens Reagent Strips					
Siemens Clinitek 500, Advantus	-	-	2	14	9
Siemens Clinitek Status	-	1	3	5	10
Visual	-	-	3	6	22
Sysmex Reagent Strips					
Sysmex UC-3500	-	13	1	-	-

Urobilinogen, Method 1

CM-12

Method/Instrument	Negative	1+	2+	3+	4+
77 Elektronika Reagent Strips					
77 Elektronika urine chemistry analyzers	19	-	-	-	-
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	15	-	-	-	-
ARKRAY Aution MAX	31	-	-	-	-
BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips					
BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer	19	1	-	-	-
Eiken Uropaper					
Eiken US-3100R/3100Rplus/3500	29	-	-	-	-
Roche Chemstrip/Combur					
Roche cobas u411, Urisys 1800	72	-	-	-	-
Roche Urisys 1100	49	-	-	-	-
Visual	63	-	-	-	-
Roche cobas u Pack Cassette					
Roche cobas u601	36	-	-	-	-
Siemens Reagent Strips					
Siemens Clinitek 500, Advantus	25	-	-	-	-
Siemens Clinitek Status	19	-	-	-	-
Visual	31	-	-	-	-
Sysmex Reagent Strips					
Sysmex UC-3500	14	-	-	-	-

Urobilinogen, Method 2

CM-10

Method/Instrument	Negative or 0.0 - 0.2 mg/dL or <3.2 µmol/L	1.0 or <2.0 mg/dL or 16 µmol/L or <35** µmol/L	2.0/3.0 mg/dL or 34 or ≥35 or <70 µmol/L	4.0 or 4.0/6.0 mg/dL or ≥70 or <140 µmol/L	≥8.0 or 12.0 mg/dL or ≥140 or 200 µmol/L
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	-	2	79	2	1
ARKRAY Aution MAX	-	2	162	11	-
DIRUI H-800 series reagent strips					
DIRUI FUS systems	2	8	-	-	-
Roche Chemstrip/Combur					
Roche Chemstrip Criterion/II	-	1	-	-	30
Roche cobas u411, Urisys 1800	-	1	-	-	211
Roche Urisys 1100	-	-	-	1	140
Visual	-	4	1	35	82
Roche cobas u Pack Cassette					
Roche cobas u601	-	-	-	-	24
Roche Urisys Cassette					
Roche Urisys 2400	-	-	2	-	51
Siemens Clinitek Atlas Reagent					
Siemens Clinitek Atlas	1	-	20	288	2
Siemens Clinitek Novus/Pro Cassette					
Siemens Clinitek Novus	-	-	24	198	6
Siemens Reagent Strips					
Siemens Clinitek 10 or 100	-	-	-	1	18
Siemens Clinitek 50	-	-	-	4	30
Siemens Clinitek 500, Advantus	2	-	-	48	1300
Siemens Clinitek Status	3	-	2	97	1539
Visual	-	-	4	19	244

**Note: <35 µmol/L for ARKRAY Aution MAX users only.

Urobilinogen, Method 2

CM-11

Method/Instrument	Negative or 0.0 - 0.2 mg/dL or <3.2 µmol/L	1.0 or <2.0 mg/dL or 16 µmol/L or <35** µmol/L	2.0/3.0 mg/dL or 34 or ≥35 or <70 µmol/L	4.0 or 4.0/6.0 mg/dL or ≥70 or <140 µmol/L	≥8.0 or 12.0 mg/dL or ≥140 or 200 µmol/L
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	-	2	64	17	1
ARKRAY Aution MAX	2	1	138	34	-
DIRUI H-800 series reagent strips					
DIRUI FUS systems	2	8	-	-	-
Roche Chemstrip/Combur					
Roche Chemstrip Criterion/II	-	-	-	-	31
Roche cobas u411, Urisys 1800	-	-	-	1	211
Roche Urisys 1100	-	-	-	1	140
Visual	-	8	1	26	87
Roche cobas u Pack Cassette					
Roche cobas u601	-	-	-	-	24
Roche Urisys Cassette					
Roche Urisys 2400	-	1	2	-	50
Siemens Clinitek Atlas Reagent					
Siemens Clinitek Atlas	-	-	15	288	8
Siemens Clinitek Novus/Pro Cssette					
Siemens Clinitek Novus	1	-	12	183	32
Siemens Reagent Strips					
Siemens Clinitek 10 or 100	-	-	-	1	18
Siemens Clinitek 50	-	-	-	3	31
Siemens Clinitek 500, Advantus	2	-	-	45	1303
Siemens Clinitek Status	2	-	-	93	1545
Visual	1	1	2	19	244

**Note: <35 µmol/L for ARKRAY Aution MAX users only.

Urobilinogen, Method 2

CM-12

Method/Instrument	Negative or 0.0 - 0.2 mg/dL or <3.2 µmol/L	1.0 or <2.0 mg/dL or 16 µmol/L or <35** µmol/L	2.0/3.0 mg/dL or 34 or ≥35 or <70 µmol/L	4.0 or 4.0/6.0 mg/dL or ≥70 or <140 µmol/L	≥8.0 or 12.0 mg/dL or ≥140 or 200 µmol/L
ARKRAY Aution Sticks					
ARKRAY Aution Hybrid	69	15	-	-	-
ARKRAY Aution MAX	118	56	1	-	-
DIRUI H-800 series reagent strips					
DIRUI FUS systems	4	6	-	-	-
Roche Chemstrip/Combur					
Roche Chemstrip Criterion/II	31	-	-	-	-
Roche cobas u411, Urisys 1800	211	1	-	-	-
Roche Urisys 1100	141	-	-	-	-
Visual	121	-	-	-	1
Roche cobas u Pack Cassette					
Roche cobas u601	24	-	-	-	-
Roche Urisys Cassette					
Roche Urisys 2400	53	-	-	-	-
Siemens Clinitek Atlas Reagent					
Siemens Clinitek Atlas	309	1	1	-	-
Siemens Clinitek Novus/Pro Cassette					
Siemens Clinitek Novus	227	-	-	1	-
Siemens Reagent Strips					
Siemens Clinitek 10 or 100	19	-	-	-	-
Siemens Clinitek 50	34	-	-	-	-
Siemens Clinitek 500, Advantus	1346	2	1	-	1
Siemens Clinitek Status	1623	11	5	-	2
Visual	265	2	-	-	-

**Note: <35 µmol/L for ARKRAY Aution MAX users only.

Osmolality - mOsm/kg (mmol/kg)

		No. Labs	Mean	S.D.	C.V.
CMP1-10	Advanced Instruments	414	109.4	1.8	1.7
	Fiske	22	109.1	1.7	1.6
CMP1-11	Advanced Instruments	412	98.3	1.6	1.6
	Fiske	21	98.4	2.1	2.1
CMP1-12	Advanced Instruments	414	65.6	1.8	2.8
	Fiske	21	65.5	1.3	2.0

Urine hCG

The hCG level was intended to be positive.

CMP1-10

99.6% consensus

Manufacturer	Negative	Positive
Alere hCG Combo Cassette (20/10)	-	22
Alere hCG Combo Cassette (25) (Clearview)	-	10
Beckman Coulter ICON 20	-	48
Beckman Coulter ICON 25	-	69
Cardinal Health Cassette (waived)	1	49
Cardinal Health Combo	1	321
Meridian ImmunoCard STAT (waived)	-	12
Quidel QuickVue One-Step Combo	1	67
Quidel QuickVue One-Step Urine	-	50
Quidel QuickVue+ One-Step Combo	-	129
Quidel Sofia	-	15
Sekisui OSOM (waived)	-	11
Sekisui OSOM Combo	-	56
Siemens Clinitek Status	-	37
Stanbio QuPID PLUS	1	19
Sure-Vue	-	30
Sure-Vue (Serum/Urine)	-	86
Sure-Vue STAT (Serum/Urine)	-	115
Other and Methods with <10 responses	1	95

Note: The manufacturer's stated sensitivity level (mIU/mL) will no longer be displayed. Refer to the manufacturer package insert.

Urine hCG (cont'd)

The hCG level was intended to be positive.

CMP1-11

99.9% consensus

Manufacturer	Negative	Positive
Alere hCG Combo Cassette (20/10)	-	22
Alere hCG Combo Cassette (25) (Clearview)	-	10
Beckman Coulter ICON 20	-	48
Beckman Coulter ICON 25	-	69
Cardinal Health Cassette (waived)	-	50
Cardinal Health Combo	-	322
Meridian ImmunoCard STAT (waived)	-	12
Quidel QuickVue One-Step Combo	-	68
Quidel QuickVue One-Step Urine	-	50
Quidel QuickVue+ One-Step Combo	-	129
Quidel Sofia	-	15
Sekisui OSOM (waived)	-	11
Sekisui OSOM Combo	-	56
Siemens Clinitek Status	-	37
Stanbio QuPID PLUS	1	19
Sure-Vue	-	30
Sure-Vue (Serum/Urine)	-	86
Sure-Vue STAT (Serum/Urine)	-	115
Other and Methods with <10 responses	-	96

The hCG level was intended to be positive.

CMP1-12

99.2% consensus

Manufacturer	Negative	Positive
Alere hCG Combo Cassette (20/10)	-	22
Alere hCG Combo Cassette (25) (Clearview)	-	10
Beckman Coulter ICON 20	-	48
Beckman Coulter ICON 25	-	69
Cardinal Health Cassette (waived)	1	49
Cardinal Health Combo	1	321
Meridian ImmunoCard STAT (waived)	-	12
Quidel QuickVue One-Step Combo	2	66
Quidel QuickVue One-Step Urine	1	49
Quidel QuickVue+ One-Step Combo	1	128
Quidel Sofia	1	14
Sekisui OSOM (waived)	-	11
Sekisui OSOM Combo	-	56
Siemens Clinitek Status	-	37
Stanbio QuPID PLUS	1	19
Sure-Vue	-	30
Sure-Vue (Serum/Urine)	1	85
Sure-Vue STAT (Serum/Urine)	1	114
Other and Methods with <10 responses	-	96

Note: The manufacturer's stated sensitivity level (mIU/mL) will no longer be displayed. Refer to the manufacturer package insert.

Specific Gravity

CMP1-10

Method/Instrument	No. Labs	Mean	S.D.	C.V.
IRIS iChem Reagent Strips				
IRIS iChem 100	74	1.0050	0.0000	0.0
IRIS iChemVELOCITY Reagent Strips (800-7204)				
IRIS iChemVELOCITY	34	1.0023	0.0010	0.1
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	1144	1.0025	0.0008	0.1
IRIS Mass Gravity Meter				
IRIS iChemVELOCITY	44	1.0028	0.0008	0.1
Refractometer				
IRIS iChemVELOCITY	126	1.0026	0.0009	0.1

Method/Instrument	No. Labs	Median	Low	High
Less-Than Values				
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	71	1.005	1.002	1.005
Refractometer				
IRIS iChemVELOCITY	7	1.005	1.002	1.005

CMP1-11

Method/Instrument	No. Labs	Mean	S.D.	C.V.
IRIS iChem Reagent Strips				
IRIS iChem 100	74	1.0014	0.0023	0.2
IRIS iChemVELOCITY Reagent Strips (800-7204)				
IRIS iChemVELOCITY	33	1.0012	0.0007	0.1
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	1099	1.0019	0.0005	0.0
IRIS Mass Gravity Meter				
IRIS iChemVELOCITY	44	1.0019	0.0004	0.0
Refractometer				
IRIS iChemVELOCITY	125	1.0019	0.0006	0.1

Method/Instrument	No. Labs	Median	Low	High
Less-Than Values				
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	79	1.005	1.002	1.005
Refractometer				
IRIS iChemVELOCITY	8	1.005	1.002	1.005

Specific Gravity

CMP1-12

Method/Instrument	No. Labs	Mean	S.D.	C.V.
IRIS iChem Reagent Strips				
IRIS iChem 100	75	1.0016	0.0023	0.2
IRIS iChemVELOCITY Reagent Strips (800-7204)				
IRIS iChemVELOCITY	34	1.0022	0.0008	0.1
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	1124	1.0030	0.0004	0.0
IRIS Mass Gravity Meter				
IRIS iChemVELOCITY	43	1.0029	0.0004	0.0
Refractometer				
IRIS iChemVELOCITY	124	1.0029	0.0004	0.0

Method/Instrument	No. Labs	Median	Low	High
Less-Than Values				
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	73	1.005	1.003	1.005
Refractometer				
IRIS iChemVELOCITY	8	1.005	1.003	1.005

pH, Urine

CMP1-10

Method/Instrument	≤3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	≥9.0
IRIS iChem Reagent Strips												
IRIS iChem 100*	-	-	-	-	-	-	-	84	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7204)												
IRIS iChemVELOCITY	-	-	-	-	-	1	6	34	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)*												
IRIS iChemVELOCITY	-	-	-	1	-	4	-	1392	2	1	-	-

CMP1-11

Method/Instrument	≤3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	≥9.0
IRIS iChem Reagent Strips												
IRIS iChem 100*	-	-	-	-	-	-	-	-	-	65	-	19
IRIS iChemVELOCITY Reagent Strips (800-7204)												
IRIS iChemVELOCITY	-	-	-	-	-	-	-	-	1	12	27	1
IRIS iChemVELOCITY Reagent Strips (800-7212)*												
IRIS iChemVELOCITY	-	-	-	-	-	4	-	4	1	1128	1	260

CMP1-12

Method/Instrument	≤3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	≥9.0
IRIS iChem Reagent Strips												
IRIS iChem 100*	-	-	-	-	-	-	-	-	-	74	-	10
IRIS iChemVELOCITY Reagent Strips (800-7204)												
IRIS iChemVELOCITY	-	-	-	-	-	-	-	-	-	18	22	1
IRIS iChemVELOCITY Reagent Strips (800-7212)*												
IRIS iChemVELOCITY	-	-	-	-	-	-	-	5	1	1238	2	151

* iChem 100 instruments or 800-7212 strips users: Results should be reported in whole numbers from 5.0-≥9.0.

Protein – Qualitative, Method 1

CMP1-10

Method/Instrument	Negative	Trace	1+	2+	3+	4+
IRIS iChem Reagent Strips						
IRIS iChem 100	-	-	-	32	2	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	-	-	-	29	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	-	1	2	474	6	-

CMP1-11

Method/Instrument	Negative	Trace	1+	2+	3+	4+
IRIS iChem Reagent Strips						
IRIS iChem 100	-	-	-	33	1	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	-	-	-	29	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	-	-	1	473	9	-

CMP1-12

Method/Instrument	Negative	Trace	1+	2+	3+	4+
IRIS iChem Reagent Strips						
IRIS iChem 100	-	-	-	32	2	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	-	-	-	29	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	1	-	1	472	9	-

Protein – Qualitative, Method 2

Protein, Method 2 reporting options in SI units	
Conventional (mg/dL)	**SI (g/L)**
Negative	Negative
10-20	0.1 - 0.2
30-70	0.3 - 0.7
100 - 200	1.0 - 2.0
≥300	≥3.0 or >6.0 or ≥1000

CMP1-10

Method/Instrument	Negative	10-20 mg/dL	30-70 mg/dL	100-200 mg/dL	≥300 mg/dL
IRIS iChem Reagent Strips					
IRIS iChem 100	-	-	-	45	4
IRIS iChemVELOCITY Reagent Strips (800-7204)					
IRIS iChemVELOCITY	-	-	-	14	-
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	2	-	7	910	3

CMP1-11

Method/Instrument	Negative	10-20 mg/dL	30-70 mg/dL	100-200 mg/dL	≥300 mg/dL
IRIS iChem Reagent Strips					
IRIS iChem 100	-	-	-	45	4
IRIS iChemVELOCITY Reagent Strips (800-7204)					
IRIS iChemVELOCITY	-	-	-	14	-
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	1	-	4	894	23

CMP1-12

Method/Instrument	Negative	10-20 mg/dL	30-70 mg/dL	100-200 mg/dL	≥300 mg/dL
IRIS iChem Reagent Strips					
IRIS iChem 100	-	-	-	47	2
IRIS iChemVELOCITY Reagent Strips (800-7204)					
IRIS iChemVELOCITY	-	-	-	14	-
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	5	-	4	898	14

Glucose, Method 1

CMP1-10

Method/Instrument	Negative	Trace	1+	2+	3+	4+
IRIS iChem Reagent Strips						
IRIS iChem 100	-	-	-	4	21	9
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	-	-	-	-	16	13
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	-	-	-	9	447	8

CMP1-11

Method/Instrument	Negative	Trace	1+	2+	3+	4+
IRIS iChem Reagent Strips						
IRIS iChem 100	-	-	-	1	12	21
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	-	-	-	-	9	20
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	-	-	-	12	444	8

CMP1-12

Method/Instrument	Negative	Trace	1+	2+	3+	4+
IRIS iChem Reagent Strips						
IRIS iChem 100	34	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	29	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	461	1	-	1	1	-

Glucose, Method 2

Glucose, Method 2 reporting options in SI units	
Conventional (mg/dL)	**SI (mmol/L)**
Negative	Negative
30 - 100	1.6 - 6.0
150 - 300	8.3 - 16.6
500	28
> 500 or ≥ 1000 or ≥ 2000	> 28 or ≥ 55 or ≥ 111

CMP1-10

Method/Instrument	Negative	30-100 mg/dL	150-300 mg/dL	≥500 mg/dL
IRIS iChem Reagent Strips				
IRIS iChem 100	1	-	5	43
IRIS iChemVELOCITY Reagent Strips (800-7204)				
IRIS iChemVELOCITY	-	-	-	13
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	1	1	4	934

CMP1-11

Method/Instrument	Negative	30-100 mg/dL	150-300 mg/dL	≥500 mg/dL
IRIS iChem Reagent Strips				
IRIS iChem 100	-	-	3	46
IRIS iChemVELOCITY Reagent Strips (800-7204)				
IRIS iChemVELOCITY	-	-	-	13
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	3	1	7	929

CMP1-12

Method/Instrument	Negative	30-100 mg/dL	150-300 mg/dL	≥500 mg/dL
IRIS iChem Reagent Strips				
IRIS iChem 100	49	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7204)				
IRIS iChemVELOCITY	13	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	931	-	-	8

Reducing Substance

CMP1-10

Method	Negative	¼% (Trace)	½%	¾%	1%	≥2%
Bayer Clinitest, 5 Drop	1	3	13	48	32	11

CMP1-11

Method	Negative	¼% (Trace)	½%	¾%	1%	≥2%
Bayer Clinitest, 5 Drop	1	2	14	39	40	12

CMP1-12

Method	Negative	¼% (Trace)	½%	¾%	1%	≥2%
Bayer Clinitest, 5 Drop	107	-	-	1	-	-

* Please note ¾% is not an appropriate response for the Bayer Clinitest, 2-drop method.

Ketones, Method 1

CMP1-10

Method/Instrument	Negative	Trace	Small	Moderate	Large
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	-	1	78	31	3

CMP1-11

Method/Instrument	Negative	Trace	Small	Moderate	Large
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	113	-	-	-	-

CMP1-12

Method/Instrument	Negative	Trace	Small	Moderate	Large
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	113	-	-	-	-

Ketones, Method 2

CMP1-10

Method/Instrument	Negative	Trace	1+	2+	3+	4+
IRIS iChem Reagent Strips						
IRIS iChem 100	-	-	1	31	2	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	-	-	8	21	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	-	1	318	128	11	-

CMP1-11

Method/Instrument	Negative	Trace	1+	2+	3+	4+
IRIS iChem Reagent Strips						
IRIS iChem 100	34	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	29	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	457	-	1	-	-	-

CMP1-12

Method/Instrument	Negative	Trace	1+	2+	3+	4+
IRIS iChem Reagent Strips						
IRIS iChem 100	34	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	29	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	456	1	-	-	1	-

Ketones, Method 3

Ketones, Method 3 reporting options in SI units	
Conventional (mg/dL)	**SI (mmol/L)**
Negative	Negative
5 - 10	0.5 - 1.0
15 - 30	1.5 - 2.0
40 - 60	3.9 - 6.0
80 - 100	7.8 - 10.0
≥ 150	≥ 15.0

CMP1-10

Method/Instrument	Negative	5-10 mg/dL	15-30 mg/dL	40 - 60 mg/dL	80 - 100 mg/dL	≥150 mg/dL
IRIS iChem Reagent Strips						
IRIS iChem 100	-	-	-	2	44	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	-	-	3	7	1	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	3	1	600	7	218	1

CMP1-11

Method/Instrument	Negative	5-10 mg/dL	15-30 mg/dL	40 - 60 mg/dL	80 - 100 mg/dL	≥150 mg/dL
IRIS iChem Reagent Strips						
IRIS iChem 100	45	-	-	-	1	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	11	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	827	1	2	-	-	-

CMP1-12

Method/Instrument	Negative	5-10 mg/dL	15-30 mg/dL	40 - 60 mg/dL	80 - 100 mg/dL	≥150 mg/dL
IRIS iChem Reagent Strips						
IRIS iChem 100	46	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	11	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	827	1	1	-	-	-

Bilirubin, Method 1

CMP1-10

Method/Instrument	Negative	Trace/Small	Positive/Moderate	Large
IRIS iChem Reagent Strips				
IRIS iChem 100	-	-	11	15
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	9	12	795	24

CMP1-11

Method/Instrument	Negative	Trace/Small	Positive/Moderate	Large
IRIS iChem Reagent Strips				
IRIS iChem 100	26	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	841	-	-	-

CMP1-12

Method/Instrument	Negative	Trace/Small	Positive/Moderate	Large
IRIS iChem Reagent Strips				
IRIS iChem 100	26	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	839	-	1	-

Bilirubin, Method 2

CMP1-10

Method/Instrument	Negative	1+	2+	3+	4+
IRIS iChem Reagent Strips					
IRIS iChem 100	-	-	4	24	-
IRIS iChemVELOCITY Reagent Strips (800-7204)					
IRIS iChemVELOCITY	1	-	27	2	-
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	5	11	374	6	1

CMP1-11

Method/Instrument	Negative	1+	2+	3+	4+
IRIS iChem Reagent Strips					
IRIS iChem 100	28	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7204)					
IRIS iChemVELOCITY	30	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	395	-	1	1	-

CMP1-12

Method/Instrument	Negative	1+	2+	3+	4+
IRIS iChem Reagent Strips					
IRIS iChem 100	28	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7204)					
IRIS iChemVELOCITY	30	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	397	-	-	-	-

Bilirubin, Method 3

CMP1-10

Method/Instrument	Negative	0.5 - 1.0 mg/dL	2.0 - 4.0 mg/dL	6.0 - ≥8.0 mg/dL
IRIS iChem Reagent Strips				
IRIS iChem 100	-	-	28	1
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	-	-	131	2

CMP1-11

Method/Instrument	Negative	0.5 - 1.0 mg/dL	2.0 - 4.0 mg/dL	6.0 - ≥8.0 mg/dL
IRIS iChem Reagent Strips				
IRIS iChem 100	29	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	133	-	-	-

CMP1-12

Method/Instrument	Negative	0.5 - 1.0 mg/dL	2.0 - 4.0 mg/dL	6.0 - ≥8.0 mg/dL
IRIS iChem Reagent Strips				
IRIS iChem 100	29	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	133	-	-	-

Blood or Hemoglobin, Method 1

CMP1-10

Method/Instrument	Negative	Trace/Small	Positive/Moderate	Marked Positive/Large
IRIS iChem Reagent Strips				
IRIS iChem 100	-	1	-	29
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	-	-	7	808

CMP1-11

Method/Instrument	Negative	Trace/Small	Positive/Moderate	Marked Positive/Large
IRIS iChem Reagent Strips				
IRIS iChem 100	-	1	-	29
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	1	1	7	806

CMP1-12

Method/Instrument	Negative	Trace/Small	Positive/Moderate	Marked Positive/Large
IRIS iChem Reagent Strips				
IRIS iChem 100	-	1	-	29
IRIS iChemVELOCITY Reagent Strips (800-7212)				
IRIS iChemVELOCITY	6	-	3	805

Blood or Hemoglobin, Method 2

CMP1-10

Method/Instrument	Negative	Trace	1+	2+	3+	4+
IRIS iChem Reagent Strips						
IRIS iChem 100	-	-	-	-	34	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	-	-	-	4	25	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	-	-	-	9	478	2

CMP1-11

Method/Instrument	Negative	Trace	1+	2+	3+	4+
IRIS iChem Reagent Strips						
IRIS iChem 100	-	-	-	-	34	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	-	-	-	-	29	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	-	-	-	7	480	2

CMP1-12

Method/Instrument	Negative	Trace	1+	2+	3+	4+
IRIS iChem Reagent Strips						
IRIS iChem 100	-	-	-	-	34	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	-	-	-	2	27	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	2	-	-	6	479	2

Blood or Hemoglobin, Method 3

CMP1-10

Method/Instrument	Negative	5 – 25 Ery/µL	50 – 150 Ery/µL	250 Ery/µL	300 Ery/µL
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	-	-	-	2	3

CMP1-11

Method/Instrument	Negative	5 – 25 Ery/µL	50 – 150 Ery/µL	250 Ery/µL	300 Ery/µL
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	-	-	-	3	2

CMP1-12

Method/Instrument	Negative	5 – 25 Ery/µL	50 – 150 Ery/µL	250 Ery/µL	300 Ery/µL
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	-	-	-	2	3

Blood or Hemoglobin, Method 4

CMP1-10

Method/Instrument	Negative	±0.03 mg/dL	0.06 – 0.15 mg/dL	0.20 – 0.50 mg/dL	≥0.75 mg/dL
IRIS iChem Reagent Strips					
IRIS iChem 100	-	-	-	-	19
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	-	-	-	-	95

CMP1-11

Method/Instrument	Negative	±0.03 mg/dL	0.06 – 0.15 mg/dL	0.20 – 0.50 mg/dL	≥0.75 mg/dL
IRIS iChem Reagent Strips					
IRIS iChem 100	-	-	-	-	19
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	-	-	-	-	95

CMP1-12

Method/Instrument	Negative	±0.03 mg/dL	0.06 – 0.15 mg/dL	0.20 – 0.50 mg/dL	≥0.75 mg/dL
IRIS iChem Reagent Strips					
IRIS iChem 100	-	-	-	-	19
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	-	-	-	-	95

Leukocyte Esterase, Method 1

CMP1-10

Method/Instrument	Negative	Trace	Small	Moderate	Large	Positive
IRIS iChem Reagent Strips						
IRIS iChem 100	-	-	-	-	29	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	3	-	-	4	769	24

CMP1-11

Method/Instrument	Negative	Trace	Small	Moderate	Large	Positive
IRIS iChem Reagent Strips						
IRIS iChem 100	29	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	795	1	-	-	4	-

CMP1-12

Method/Instrument	Negative	Trace	Small	Moderate	Large	Positive
IRIS iChem Reagent Strips						
IRIS iChem 100	29	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	795	1	-	1	2	-

Leukocyte Esterase, Method 2

CMP1-10

Method/Instrument	Negative	Trace	1+	2+	3+	Positive
IRIS iChem Reagent Strips						
IRIS iChem 100	-	-	-	1	22	1
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	-	-	-	-	27	1
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	-	-	-	4	447	4

CMP1-11

Method/Instrument	Negative	Trace	1+	2+	3+	Positive
IRIS iChem Reagent Strips						
IRIS iChem 100	24	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	28	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	455	-	-	-	1	-

CMP1-12

Method/Instrument	Negative	Trace	1+	2+	3+	Positive
IRIS iChem Reagent Strips						
IRIS iChem 100	24	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7204)						
IRIS iChemVELOCITY	28	-	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)						
IRIS iChemVELOCITY	455	-	-	-	1	-

Leukocyte Esterase, Method 3

CMP1-10

Method/Instrument	Negative	25 µL	75 or 100 µL	250 or 500 µL	Positive
IRIS iChem Reagent Strips					
IRIS iChem 100	-	-	-	28	1
IRIS iChemVELOCITY Reagent Strips (800-7204)					
IRIS iChemVELOCITY	-	-	-	10	-
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	-	-	-	130	16

CMP1-11

Method/Instrument	Negative	25 µL	75 or 100 µL	250 or 500 µL	Positive
IRIS iChem Reagent Strips					
IRIS iChem 100	29	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7204)					
IRIS iChemVELOCITY	10	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	146	-	-	-	-

CMP1-12

Method/Instrument	Negative	25 µL	75 or 100 µL	250 or 500 µL	Positive
IRIS iChem Reagent Strips					
IRIS iChem 100	29	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7204)					
IRIS iChemVELOCITY	10	-	-	-	-
IRIS iChemVELOCITY Reagent Strips (800-7212)					
IRIS iChemVELOCITY	146	-	-	-	-

Nitrite

Intended response was positive.

CMP1-10

99.9% consensus

Method/Instrument	Negative	Positive
IRIS iChem Reagent Strips		
IRIS iChem 100	-	82
IRIS iChemVELOCITY Reagent Strips (800-7204)		
IRIS iChemVELOCITY	-	40
IRIS iChemVELOCITY Reagent Strips (800-7212)		
IRIS iChemVELOCITY	2	1393

Intended response was negative.

CMP1-11

99.6% consensus

Method/Instrument	Negative	Positive
IRIS iChem Reagent Strips		
IRIS iChem 100	81	1
IRIS iChemVELOCITY Reagent Strips (800-7204)		
IRIS iChemVELOCITY	40	-
IRIS iChemVELOCITY Reagent Strips (800-7212)		
IRIS iChemVELOCITY	1390	5

Intended response was negative.

CMP1-12

99.7% consensus

Method/Instrument	Negative	Positive
IRIS iChem Reagent Strips		
IRIS iChem 100	81	1
IRIS iChemVELOCITY Reagent Strips (800-7204)		
IRIS iChemVELOCITY	40	-
IRIS iChemVELOCITY Reagent Strips (800-7212)		
IRIS iChemVELOCITY	1391	3

Urobilinogen

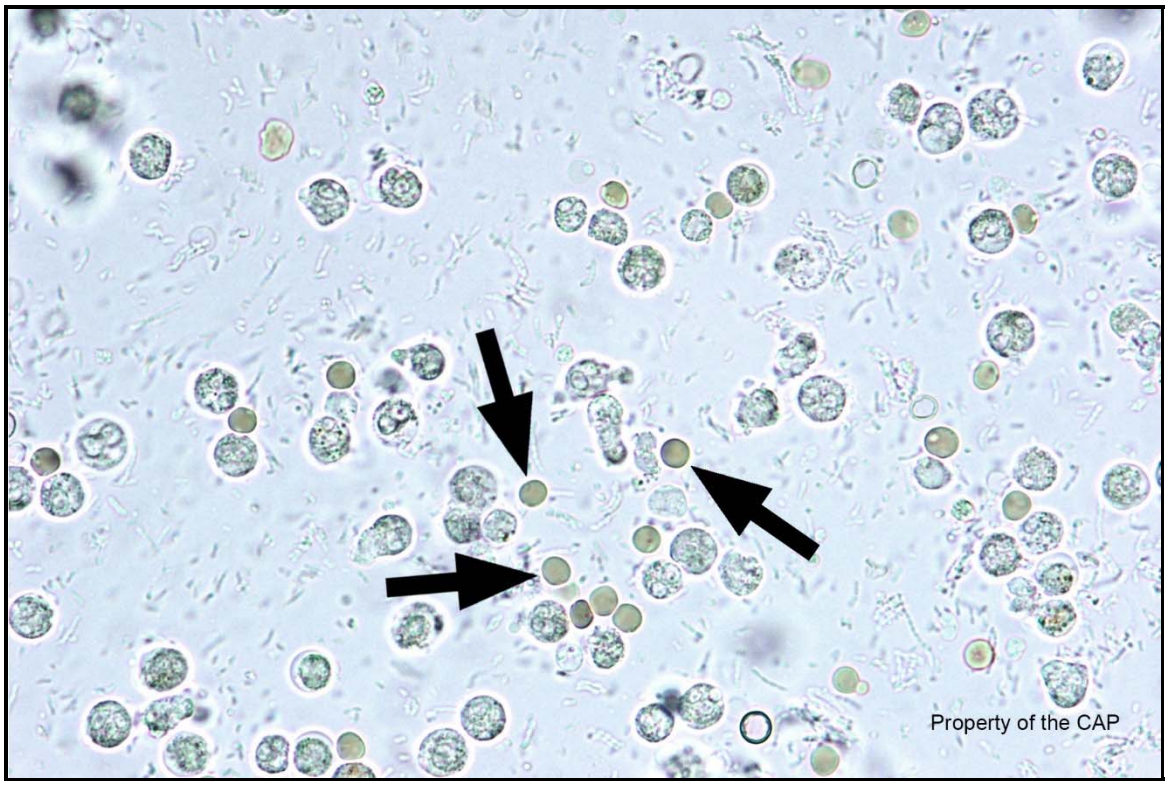
	Method/Instrument	Negative or 0.0 - 0.2 mg/dL or <3.2 µmol/L	1.0 or <2.0 mg/dL or 16 µmol/L or <35 µmol/L	2.0/3.0 mg/dL or 34 or ≥35 or <70 µmol/L	4.0 or 4.0/6.0 mg/dL or ≥70 or <140 µmol/L	≥8.0 or 12.0 mg/dL or ≥140 or 200 µmol/L	Positive
CMP1-10	**IRIS iChem Reagent Strips**						
	IRIS iChem 100	-	-	-	11	71	1
	IRIS iChemVELOCITY Reagent Strips (800-7204)						
	IRIS iChemVELOCITY	-	-	1	14	20	5
	IRIS iChemVELOCITY Reagent Strips (800-7212)						
	IRIS iChemVELOCITY	2	1	37	1263	3	27
CMP1-11	**IRIS iChem Reagent Strips**						
	IRIS iChem 100	68	15	-	-	-	-
	IRIS iChemVELOCITY Reagent Strips (800-7204)						
	IRIS iChemVELOCITY	34	6	-	-	-	-
	IRIS iChemVELOCITY Reagent Strips (800-7212)						
	IRIS iChemVELOCITY	953	370	4	6	-	-
CMP1-12	**IRIS iChem Reagent Strips**						
	IRIS iChem 100	67	16	-	-	-	-
	IRIS iChemVELOCITY Reagent Strips (800-7204)						
	IRIS iChemVELOCITY	34	6	-	-	-	-
	IRIS iChemVELOCITY Reagent Strips (800-7212)						
	IRIS iChemVELOCITY	956	373	1	2	-	-

Urine Sediment Photographs

Case History CMP-13 through CMP-15

This urine specimen is from a 13-year-old girl experiencing painful urination. Laboratory data include: specific gravity = 1.012; pH = 5.0; blood, protein, nitrite, and leukocyte esterase = positive; glucose, ketones, bilirubin, and urobilinogen = negative.

CMP-13



(URINE, UNSTAINED, HIGH POWER)

Identification	CMP Participants No.	%	Performance Evaluation
Erythrocytes	6162	99.5	Good

The arrowed objects are erythrocytes, as correctly identified by 99.5% of participants. Erythrocytes (RBCs) in urine are uniform round or oval biconcave discs. Erythrocytes contain variable amounts of hemoglobin and may be pale yellow orange or colorless. Hypertonic urines cause crenation of RBCs and hypotonic urine results in spherical “ghost “cells. Erythrocytes may be found in normal urine in small numbers, less than 5 per high power field. Erythrocytes are increased in urinary tract infections, trauma, urinary tract stone disease, glomerulonephritis, systemic anticoagulation and with vaginal contamination.

Erythrocytes in urine may resemble yeast, pollen, starch, air bubbles, fat droplets or monohydrate calcium oxalate crystals. Erythrocytes will be round and uniform, lacking the refractive membranes and budding seen in yeast and the central slit-like structure seen in starch. Pollen grains are nearly three times larger than erythrocytes, with a thick wall. Uniformity and color due to hemoglobin can be used to differentiate erythrocytes from fat droplets and air bubbles. Monohydrate calcium oxalate crystals are refractive, oval, round or dumbbell-shaped and usually accompanied by the more common dehydrate forms.

Urine Sediment Photographs

CMP-14

(URINE, UNSTAINED, HIGH POWER)

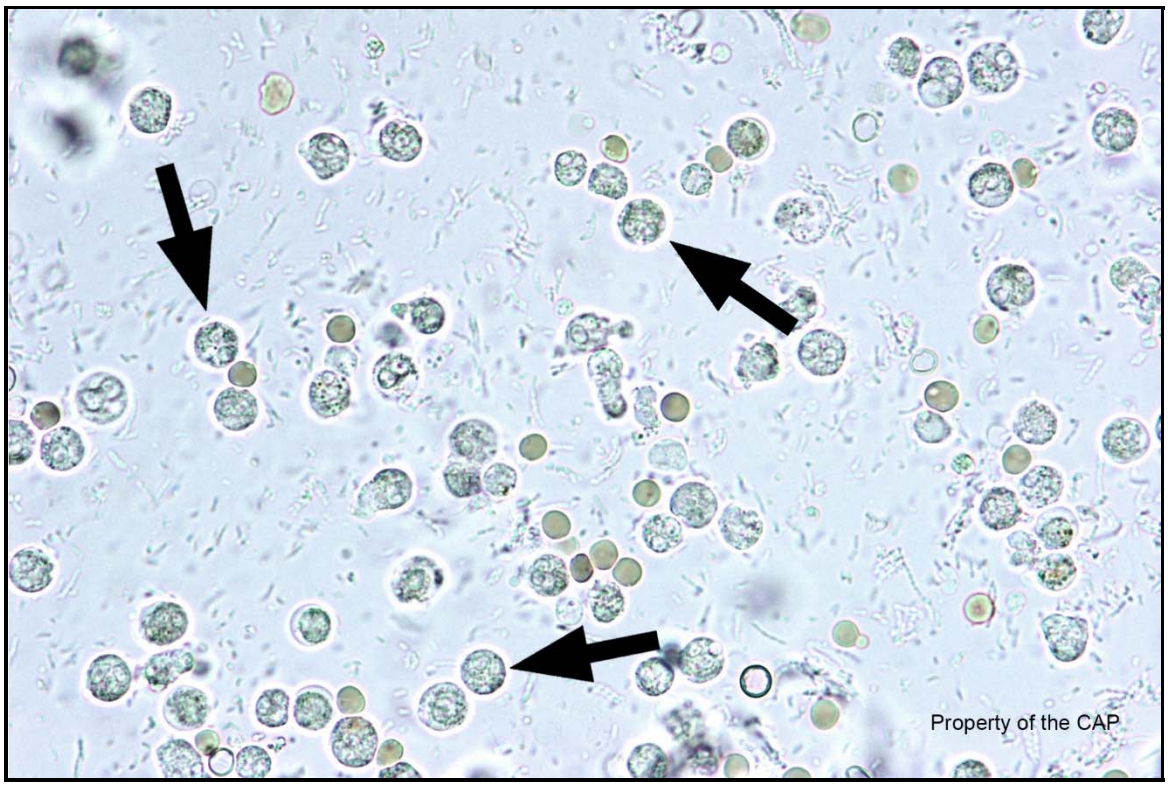
Identification	CMP Participants No.	%	Performance Evaluation
Bacteria	5983	96.6	Good

The arrowed objects are bacteria, as identified by 96.6% of participants. The urinary tract is normally sterile, but bacterial contamination of urine from the vagina or rectum is common due to imperfect collection technique. The bacteria in a contaminated specimen are usually a mixture of rods and cocci and are not accompanied by increased leukocytes. The presence of bacteria with a single morphology accompanied by increased leukocytes indicates urinary tract infection. In patients receiving antibiotics for a urinary tract infection, elongated bacilli with focally swollen walls, called protoplasts, may be seen. These represent bacilli with mural damage due to the antibiotics.

Bacteria, especially larger numbers of cocci, may resemble amorphous urates or phosphates. Particles of amorphous urates and phosphates show variable size and morphology, whereas most bacteria can be identified as rods and/or cocci. Gram stains of urine sediment are useful when differentiation is difficult.

Urine Sediment Photographs

CMP-15



(URINE, UNSTAINED, HIGH POWER)

Identification	CMP Participants No.	%	Performance Evaluation
Leukocyte (neutrophil, eosinophil, lymphocyte)	6024	97.2	Good

The arrowed objects are neutrophils, as correctly identified by 97.2% of participants. Leukocytes in urine are most often neutrophils. Leukocytes, or PMNs, are colorless cells averaging 10 - 12 µm in diameter, with finely granular cytoplasm and rarely preserved nuclear detail. Some nuclear structure is usually visible. Leukocytes swell or shrink depending on the concentration of the urine. Leukocytes may be confused with renal tubular epithelial cells. However, renal tubular epithelial cells have a large single central nucleus and lack cytoplasmic granules.

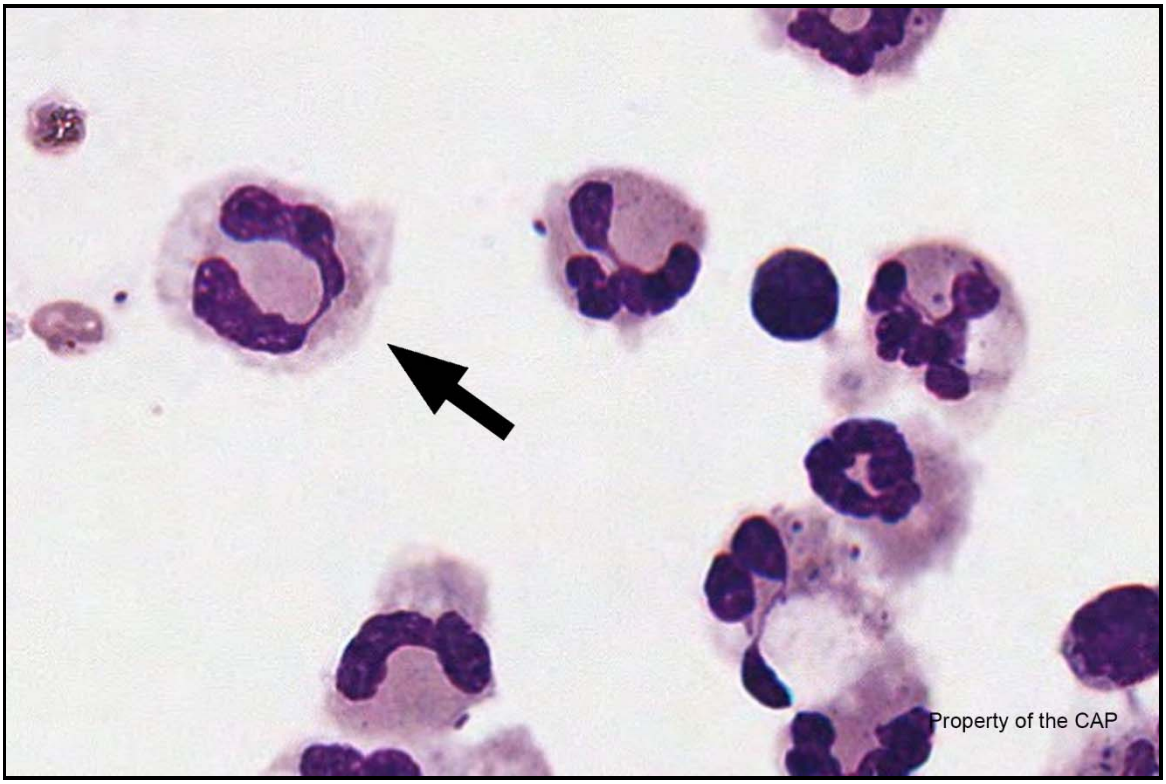
Leukocytes may be present in normal urine in small numbers, up to 5 per high power field. Leukocytes are increased in infection, urinary tract stone disease, glomerulonephritis and interstitial nephritis.

Body Fluid Photographs

Case History CMP-16 through CMP-18

This patient is a 48-year-old woman being seen in the emergency room for severe headaches, stiff neck, confusion, and irritability. Cerebrospinal fluid specimen laboratory findings include: WBC = 10,000/µL (10.000 × 10E3/µL) and RBC = 65/µL (0.065 × 10E3/µL).

CMP-16



(CSF, CYTOCENTRIFUGE, WRIGHT-GIEMSA, 100X)

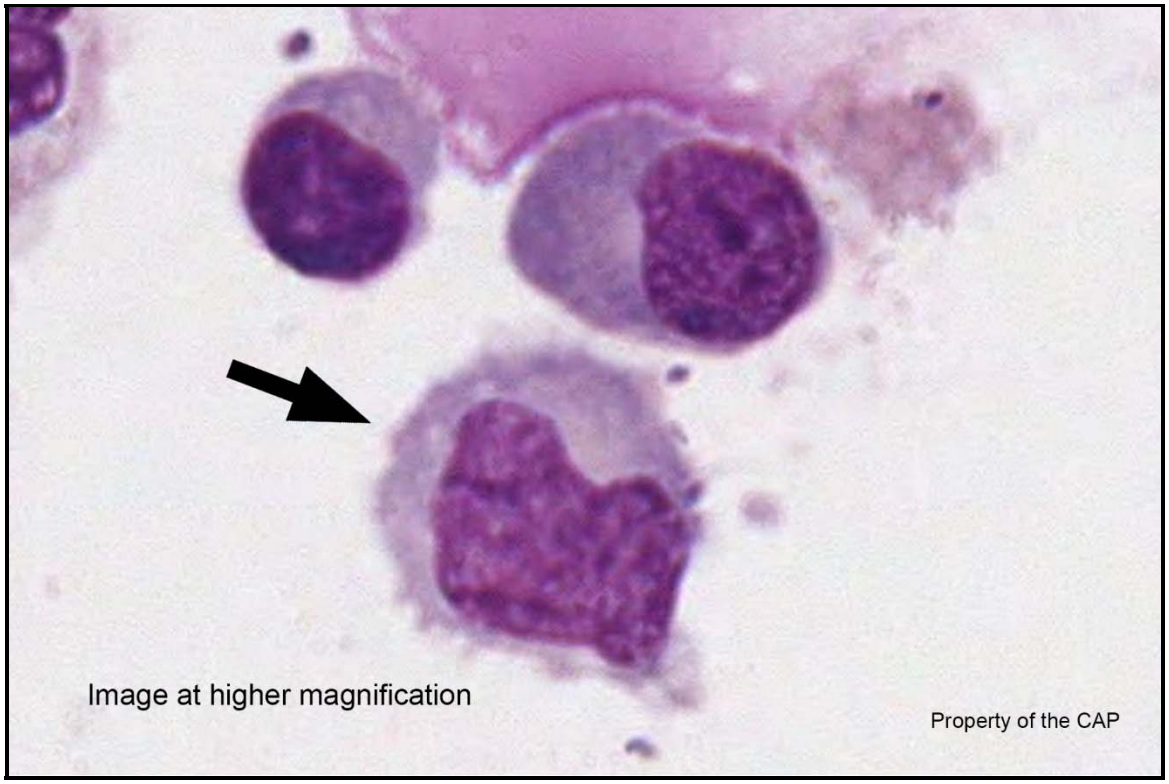
Identification	CMP Participants No.	%	Performance Evaluation
Neutrophil, segmented or band	3869	98.8	Good

The arrowed cell is a neutrophil, as correctly identified by 98.8% of participants. Neutrophils are usually easily recognized. In the context of inflammation, the cytoplasm may contain toxic granules or be vacuolated. Intracellular bacteria, crystals, or debris may be seen in pathologic conditions. If inclusions are present, the more specific identifications such as “neutrophil/macrophage with phagocytized bacteria” or “neutrophil/macrophage containing crystal” should be used.

Neutrophils in various fluid specimens (especially in samples from the stomach, intestine, or stool) can show morphologic change due to autolysis, including nuclear pyknosis and fragmentation, making recognition of cell type difficult. Autolytic neutrophils can be mistakenly identified as nucleated red blood cells; however, persistence of a few specific granules in the cytoplasm provides a clue to neutrophilic origin. For the purpose of proficiency testing, the identification “degenerative cell, NOS” should be chosen if the cell of origin can no longer be recognized.

Body Fluid Photographs

CMP-17



(CSF, CYTOCENTRIFUGE, WRIGHT-GIEMSA, 100X)

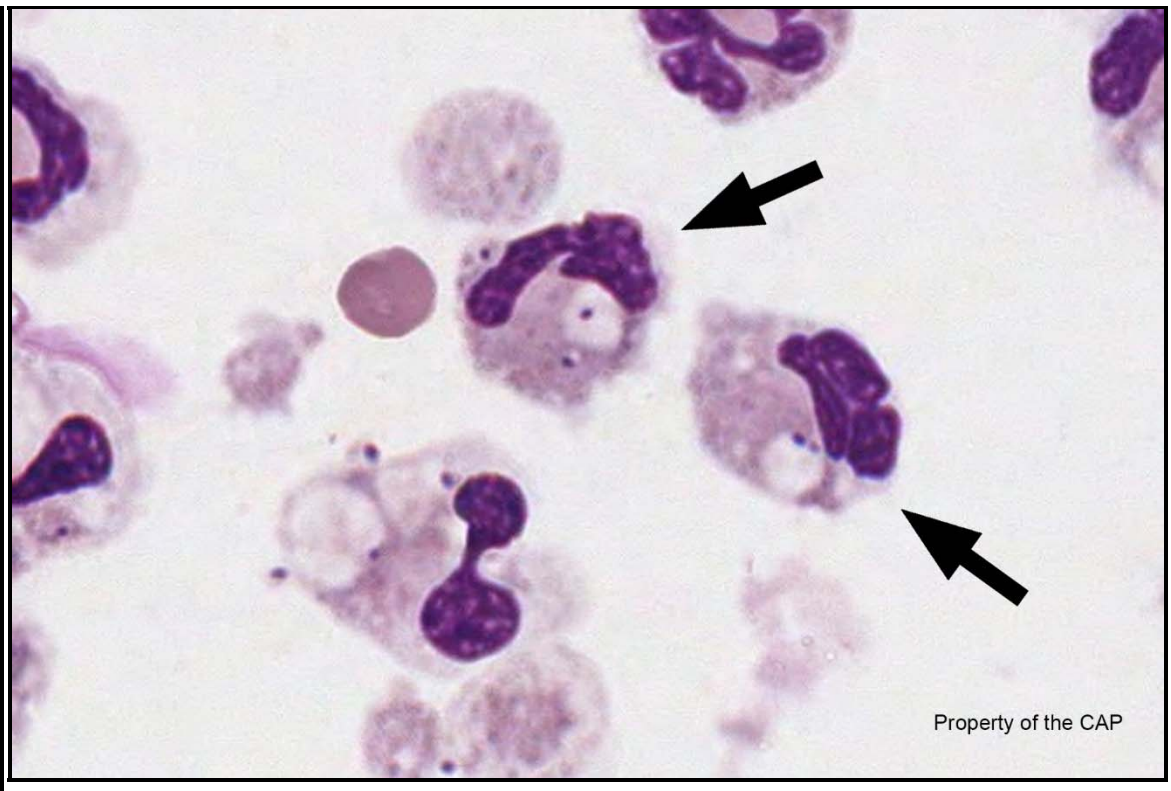
Identification	CMP Participants No.	%	Performance Evaluation
Monocyte/macrophage	3535	90.3	Good

The arrowed cell is a monocyte/macrophage, as correctly identified by 90.3% of participants. Monocytes are bone marrow derived cells that circulate in the blood; in contrast, macrophages arise from bone marrow derived cells that migrate into tissues. Monocyte/macrophage morphology in fluids may be variable, ranging along a continuum from the typical blood monocyte of the peripheral blood to a vacuolated, activated stage with the morphology of a typical macrophage.

Further, a variety of cytoplasmic bodies/features may be seen in macrophages. When macrophages are seen to contain uniform, small lipid vacuoles that completely fill the cytoplasm, such a macrophage would be more appropriately termed a “Macrophage containing abundant uniform small lipid vacuoles/droplets (Lipophage).” When a macrophage is seen to contain ingested red blood cells, such a macrophage would be more appropriately termed a “Macrophage containing erythrocyte(s) (Erythrophage);” similar logic applies to macrophages containing neutrophil(s) (Neutrophage), macrophage containing hemosiderin (a Siderophage), or a neutrophil/macrophage containing crystals.

Body Fluid Photographs

CMP-18



(CSF, CYTOCENTRIFUGE, WRIGHT-GIEMSA, 100X)

Identification	CMP Participants No.	%	Performance Evaluation
Neutrophil/macrophage containing bacteria	3179	81.2	Good
Neutrophils, segmented or band	482	12.3	Unacceptable

The arrowed cells are neutrophils/macrophages containing phagocytized bacteria, as correctly identified by 81.2% of participants. Bacteria within a neutrophil or macrophage typically have a uniform appearance, usually round or rod-shaped, single, diploid, or in small chains, depending upon the species. It is important to distinguish bacteria from the normal cytoplasmic granules, debris present within a neutrophil or macrophage, pigment or hemosiderin.

12.3% of participants incorrectly identified the arrowed images as neutrophils, segmented or band. Please refer to image CMP-16 and its discussion to note the differences between a neutrophil containing bacteria and a neutrophil, segmented or band.

Case Presentation:

This cerebrospinal fluid (CSF) originates from a 48-year-old woman being seen in the emergency room for severe headaches, stiff neck, confusion and irritability. CSF findings include: WBC = 10,000/µL (10.000 × 10E3/µL); and RBC = 65/µL (0.065 × 10E3/µL).

(CSF, CYTOCENTRIFUGE, WRIGHT-GIEMSA, 100X)

Case Discussion: *Streptococcus pneumonia* meningitis

Meningitis refers to inflammation of the meninges, which may be caused by a number of conditions, both infectious and otherwise.[1] The vast majority of patients with underlying meningitis present with a combination of two or more conditions: headache, fever, neck stiffness, and/or altered level of consciousness.[2] As these may be relatively non-specific clinical features, the vast majority of cases will require sampling of the cerebrospinal fluid (CSF) for diagnosis; CSF sampling can provide essential materials for cytological, microbiological, and molecular studies.[1] The urgency of CSF sampling and laboratory assessment relates mainly to the need to exclude bacterial meningitis; left untreated, bacterial meningitis typically demonstrates rapid clinical deterioration.[1]

In most Western countries, acute bacterial meningitis is relatively rare in modern times; in comparison to the higher incidence of acute bacterial meningitis in developing countries, the reduction in Western incidence might be attributable to immunization practices.[2] From a global perspective, the most frequently reported cause of adult acute bacterial meningitis is *Streptococcus pneumoniae.*[2] *S. pneumoniae* is the cause of a number of bacterial infections, and may exist as a commensal or colonizing organism in both children and adults.[3]

The importance of cytological evaluation in the work-up of a putative case of meningitis, including white cell counts, cannot be overstated. Indeed, recently proposed clinical decision algorithms underscore the importance of the combination of peripheral and CSF leukocytosis, high CSF total protein, CSF lactate, and CSF glucose as highly predictive of acute bacterial meningitis.[4] Not surprisingly, higher white cell counts are associated with a higher likelihood of acute bacterial meningitis.[4] Most acute bacterial meningitides will demonstrate a profound predominance of neutrophils; in contrast, in viral entities, the predominant cell type is often lymphoid.[2]

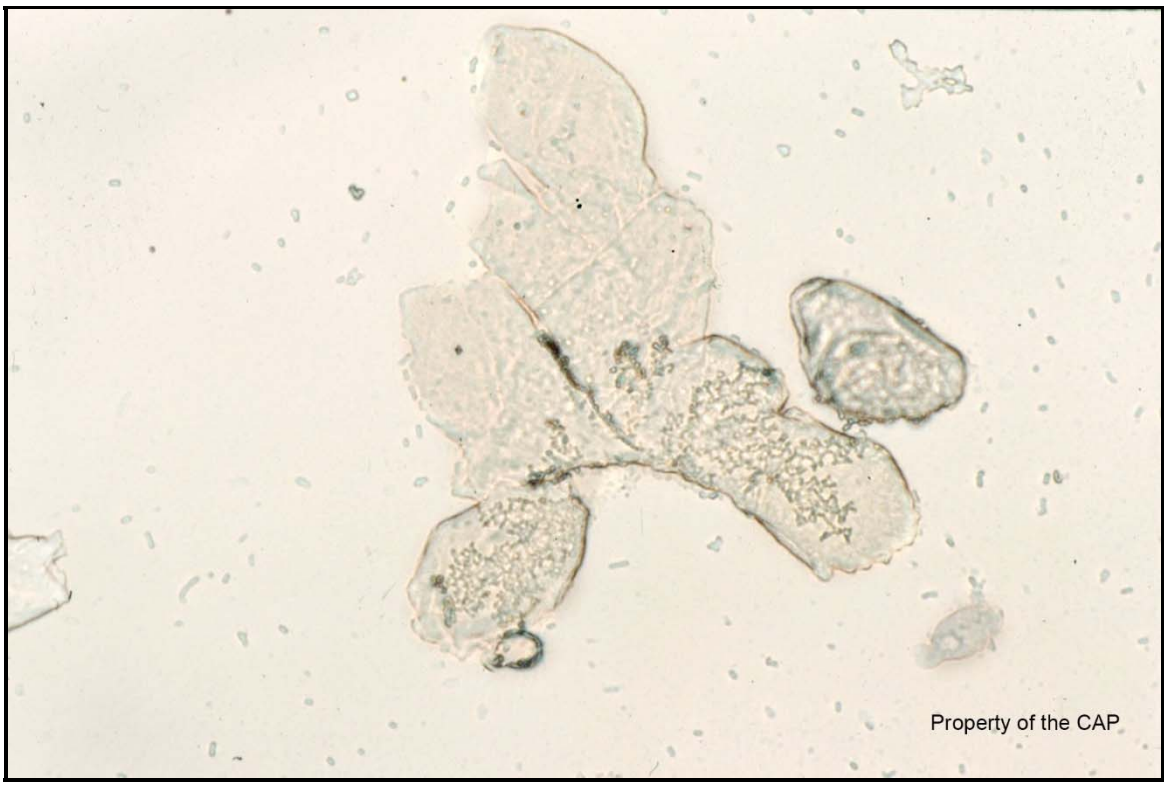
Etienne Mahé, MD, MSc, FRCPC, FCAP
Hematology and Clinical Microscopy Resource Committee

References:

1. Logan SA, MacMahon E. Viral meningitis. *BMJ*. 2008;336(7634):36–40.
2. McGill F, Heyderman RS, Panagiotou S, Tunkel AR, Solomon T. Acute bacterial meningitis in adults. *Lancet*. 2016;388(10063):3036–3047.
3. Weiser JN, Ferreira DM, Paton JC. *Streptococcus pneumoniae*: transmission, colonization and invasion. *Nat Rev Microbiol.* 2018;16(6):355–367.
4. Lagi F, Bartalesi F, Pecile P, et al. Proposal for a New Score-Based Approach To Improve Efficiency of Diagnostic Laboratory Workflow for Acute Bacterial Meningitis in Adults. *J Clin Microbiol.* 2016;54(7):1851–1854.

CMMP – Clinical Microscopy Miscellaneous Photographs

CMMP-30



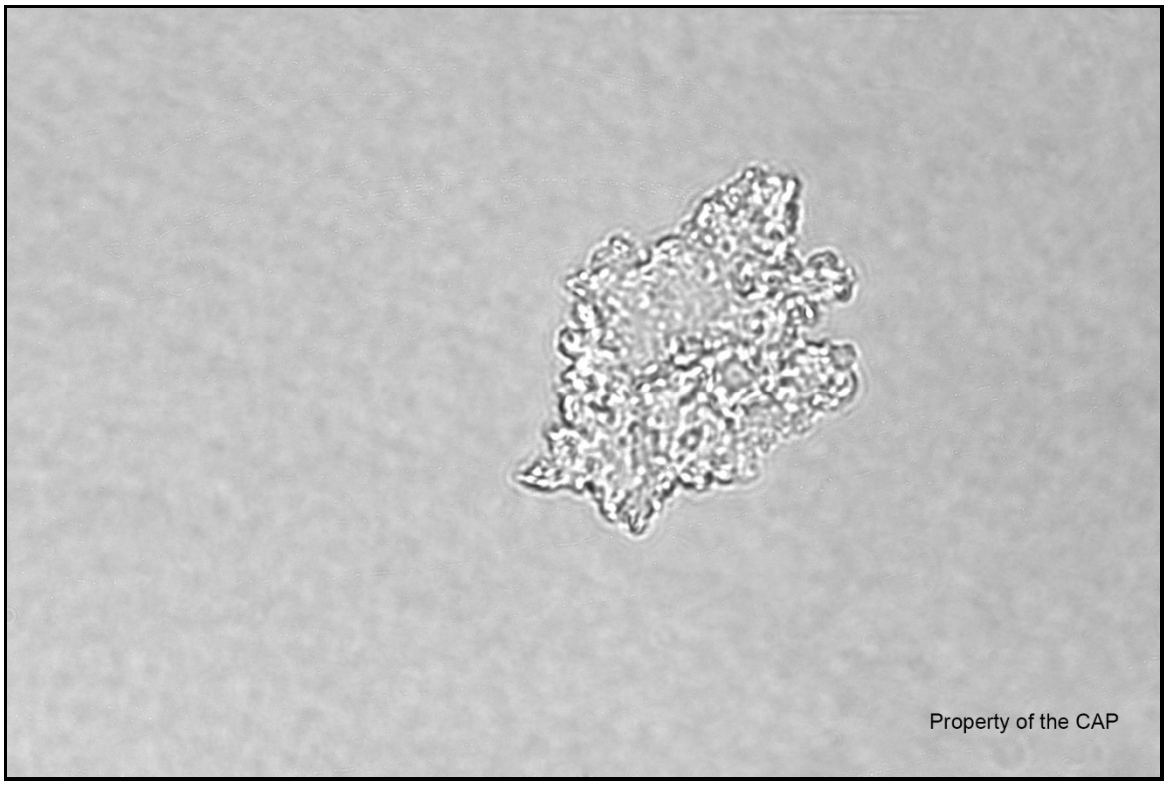
(VAGINAL, UNSTAINED) High power magnification

Identification	CMMP Participants No.	%	Performance Evaluation
Ferning is absent	1896	94.5	Good

Ferning is absent in this vaginal fluid preparation. The fern test is used to detect ruptured amniotic membranes and the early onset of labor. A vaginal pool sample is collected and the fluid is allowed to air dry on a glass slide. The slide is examined using a microscope to detect ferning, an elaborate arborized crystallization pattern.

CMMP – Clinical Microscopy Miscellaneous Photographs

CMMP-31



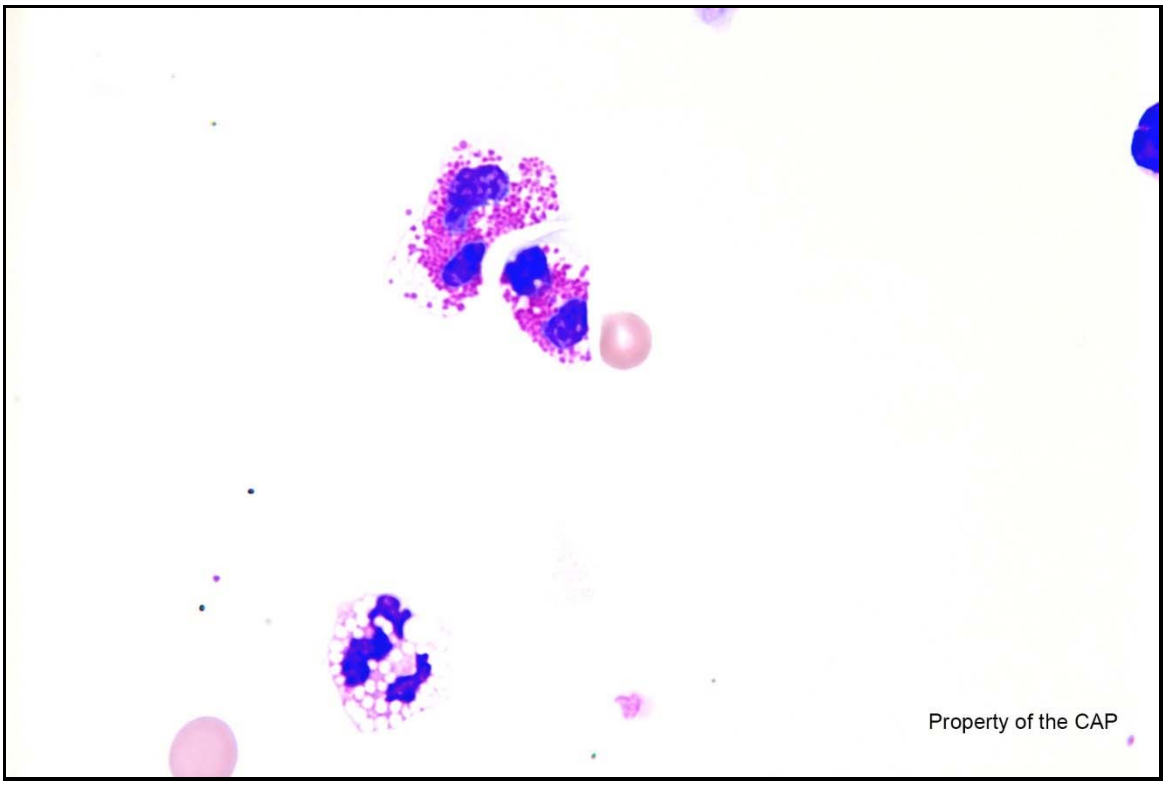
(SKIN, KOH) High power magnification

Identification	CMMP Participants No.	%	Performance Evaluation
Yeast/fungi are absent	3501	99.0	Good

This photomicrograph demonstrates an unstained skin KOH smear in which no yeast or fungal hyphae are seen. Use of a 10% KOH (potassium hydroxide) solution can assist in the detection of fungi. KOH disrupts proteinaceous material and dissolves cellular more material more rapidly than it does the chitinous cell wall of fungi. The resulting cleared background enables the detection of fungal hyphal elements, yeast cells, and arthrospores.

CMMP – Clinical Microscopy Miscellaneous Photographs

CMMP-32



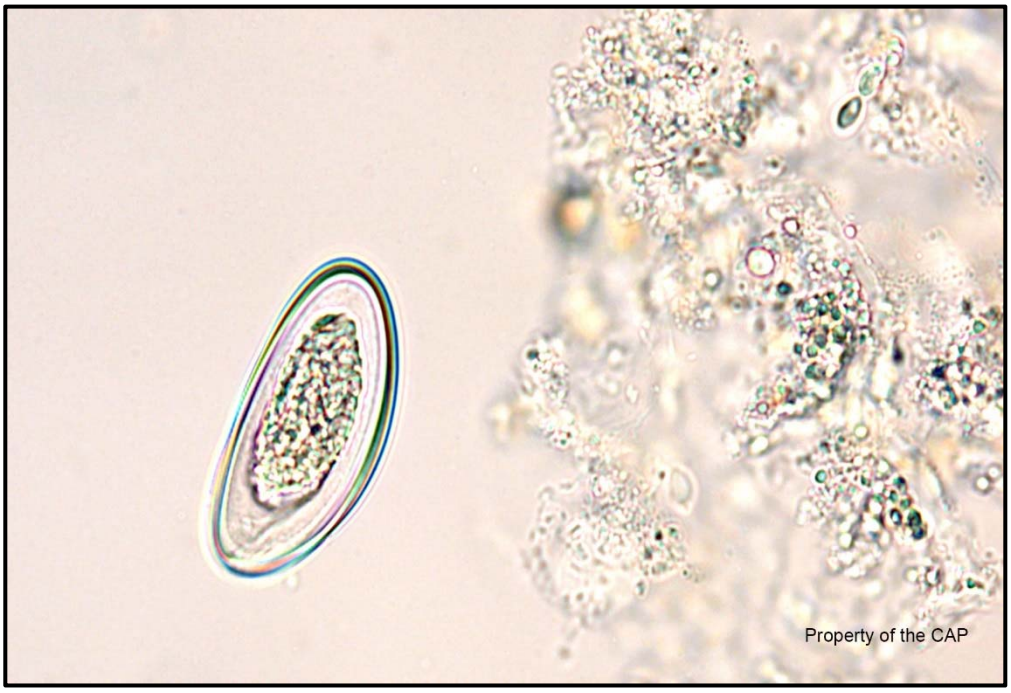
(NASAL, WRIGHT-GIEMSA) High power magnification

Identification	CMMP Participants No.	%	Performance Evaluation
Eosinophils are present	2163	99.9	Good

This photomicrograph demonstrates a Wright-Giemsa stained nasal smear. Two eosinophils with bright orange-red spherical granules are seen near the middle top of the image. The finding of nasal eosinophils is supportive of the diagnosis of allergic rhinitis. These cells have nuclei with two lobes separated by a thin filament. Non-allergic causes of nasal discharge will typically be acellular or show a predominance of neutrophils rather than eosinophils.

CMMP – Clinical Microscopy Miscellaneous Photographs

CMMP-33



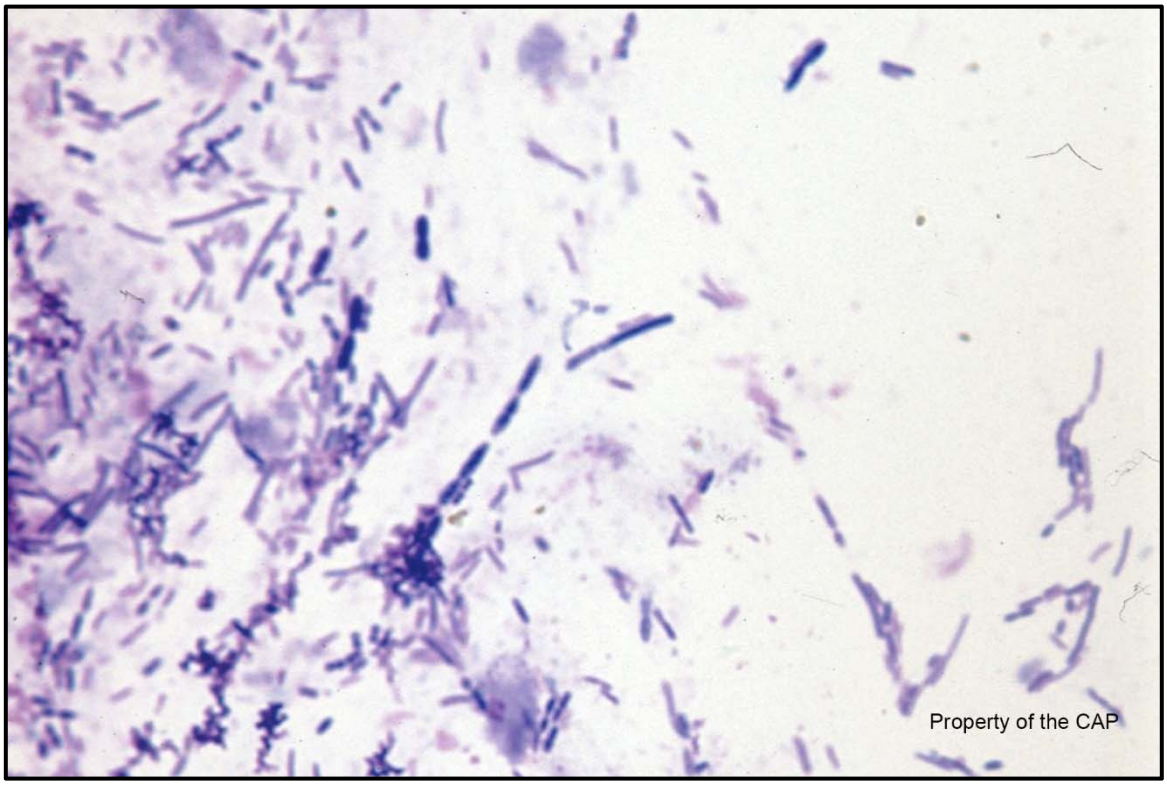
(PINWORM PREP, UNSTAINED, 66X) High power magnification

Identification	CMMP Participants No.	%	Performance Evaluation
Pinworm/pinworm eggs are present	2284	99.9	Good

This unstained preparation demonstrates an egg of *Enterobius vermicularis*, commonly known as pinworm. Pinworm preparations are performed on patients presenting with anal itching by placing either a piece of transparent tape or a pinworm paddle on the anal skin. The tape is then applied to a glass slide. The eggs are elongated, flattened on one side, 50 - 60 mm long by 20 - 32 mm wide, with a thick shell. Multiple samples may be required to make the diagnosis. Humans are considered to be the only hosts of *Enterobius vermicularis*. Transmission occurs by transferring eggs to the mouth via hands that scratch the perianal region. Person-to-person transmission can occur through handling of infected bed linens or clothes.

CMMP – Clinical Microscopy Miscellaneous Photographs

CMMP-34



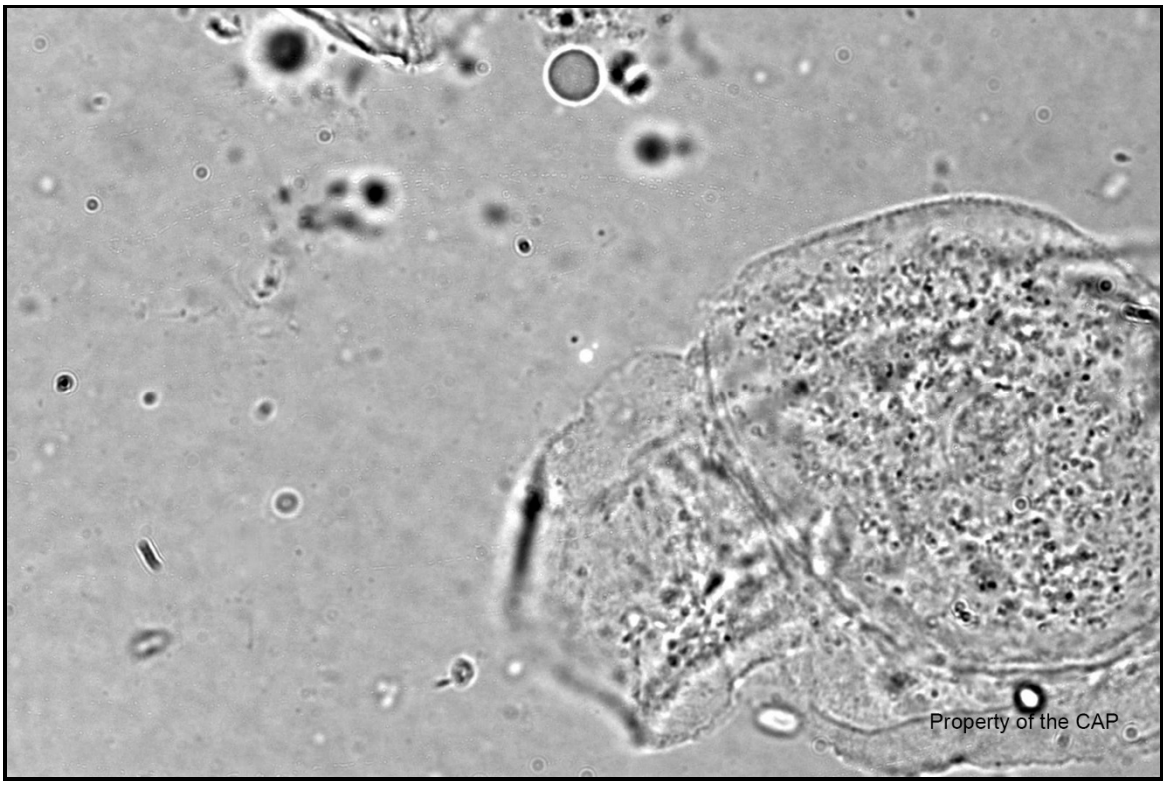
(STOOL, WRIGHT-GIEMSA) High power magnification

Identification	CMMP Participants No.	%	Performance Evaluation
Leukocytes are absent	2492	99.3	Good

No neutrophils are present in this stool smear which contains only bacteria. Assessment of stool specimens for neutrophils is a test that can be used in conjunction with a bacterial culture in the evaluation of enteritis/colitis. While the presence of neutrophils is consistent with a bacterial infection, the findings are not specific. Stool cultures are more sensitive and specific for the evaluation of enteric pathogens.

CMMP – Clinical Microscopy Miscellaneous Photographs

CMMP-35



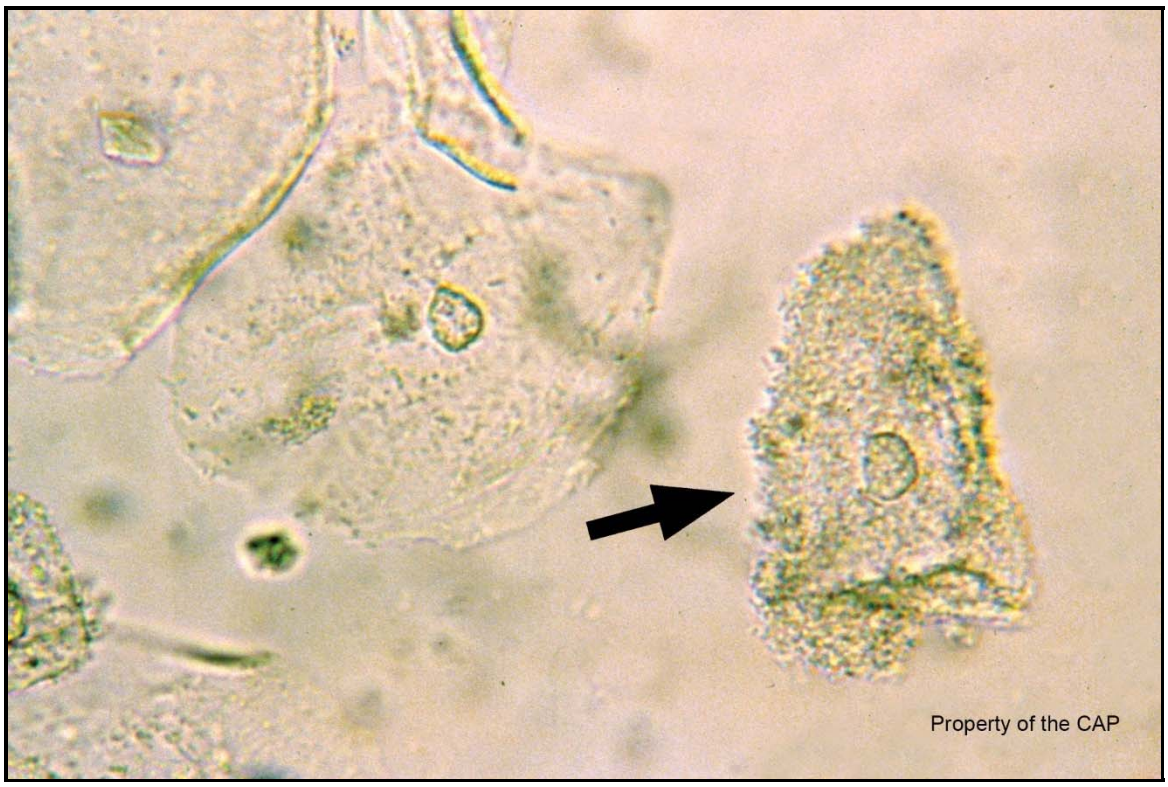
(VAGINAL, UNSTAINED) High power magnification

Identification	CMMP Participants No.	%	Performance Evaluation
Spermatozoa are absent	2752	99.3	Good

No spermatozoa are present on this vaginal wet preparation. A sperm head is about 4 - 6 µm in length while the slender tail is about 40 - 60 µm in length.

CMMP – Clinical Microscopy Miscellaneous Photographs

CMMP-36



(VAGINAL, UNSTAINED) High power magnification

Identification	CMMP Participants No.	%	Performance Evaluation
Clue cell(s) (squamous epithelial cell containing bacteria) are present	3965	97.3	Good

The arrowed object in this unstained vaginal wet preparation is a clue cell. Vaginal wet prep secretions are often examined to diagnose causes of vaginal discharge. Clue cells are squamous epithelial cells covered in bacteria. They are large (30 - 50 µm) and are derived from the lining of the female vagina and cervix. Clue cells have a stippled or granular, very refractile cytoplasm with shaggy borders due to the presence of numerous coccobacillary bacteria and are one diagnostic finding seen in bacterial vaginosis. Bacterial vaginosis is a clinical syndrome resulting from replacement of the normal *Lactobacillus* species in the vagina with high concentrations of anaerobic bacteria, *Gardnerella vaginalis* and *Mycoplasma hominis*. Bacterial vaginosis is the most prevalent cause of vaginal discharge or malodor; however, up to 50% of women with bacterial vaginosis may not report symptoms. There are no *Trichomonas vaginalis* in this sample. This trophozoite can be up to 23 µm in length with an undulating membrane that extends only half the length of the body. Yeast and non-clue cell squamous epithelial cells are also not present.

CMMP – Urine Sediment Color Photographs

Case History USP-04 and USP-06

This urine specimen is from a 30-year-old woman as part of a routine exam. Laboratory data include: specific gravity = 1.020; pH = 6.5; protein and blood = positive; glucose, ketones, leukocyte esterase, and nitrite = negative.

USP-04

(URINE, UNSTAINED, HIGH POWER) High power magnification

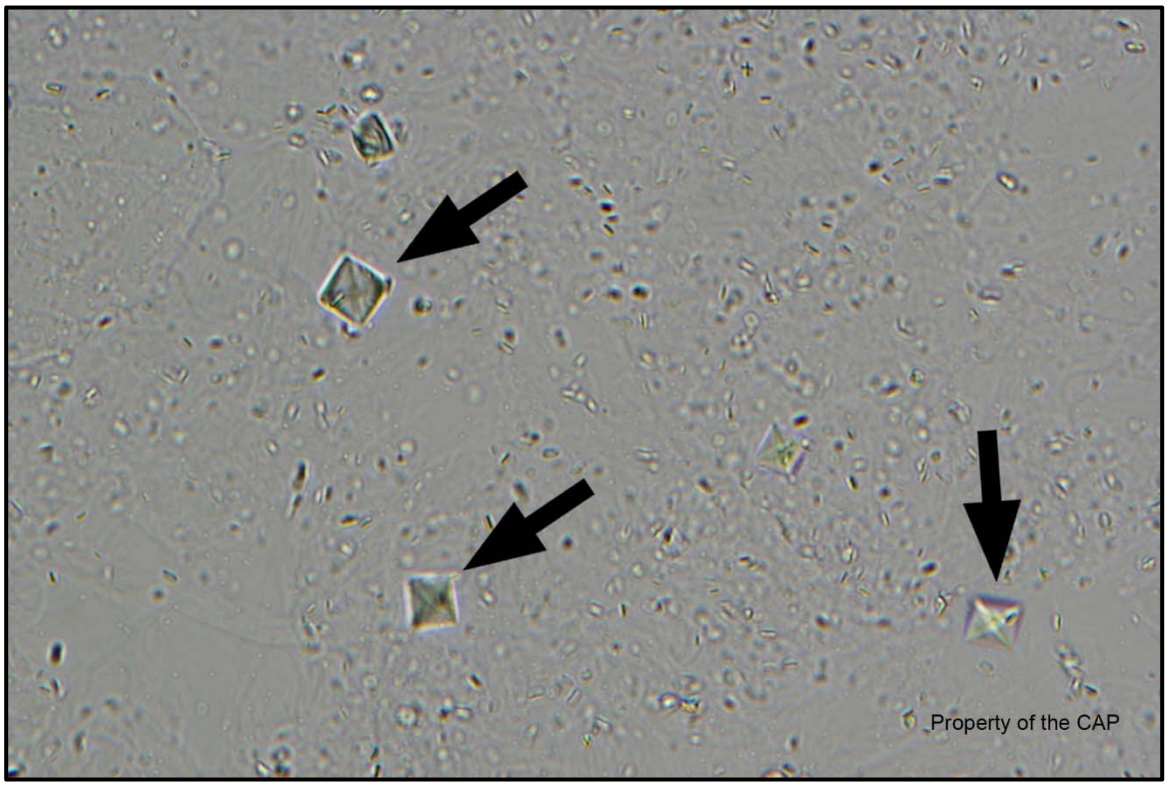
Identification	CMMP Participants No.	%	CMMP Referees No.	%	Performance Evaluation
Squamous epithelial cell	3107	73.0	34	69.4	Non-consensus
Squamous epithelial cell containing bacteria (clue cell)	1105	26.0	15	30.6	Non-consensus

The arrowed object is a squamous epithelial cell, as correctly identified by 73.0% of participants and 69.4% of referees. Squamous cells are the most common epithelial cells in the urine. Like transitional epithelial cells, they have a low nuclear-to-cytoplasmic ratio. The nucleus is small and round nucleus with dense chromatin and abundant cytoplasm. Small keratohyaline granules may be found in the cytoplasm. As is seen in most epithelial cells in the urine, the indicated cell does not have a perfectly regular cytoplasmic membrane. There are also a few refractile keratohyaline particles present.

26.0% of participants and 30.6% of referees incorrectly identified the indicated cell as a clue cell. Clue cells are squamous epithelial cells covered with numerous bacteria present in bacterial vaginosis, which are best appreciated on vaginal wet prep, although they may be present in urine as a contaminant. The squamous epithelial cells in this image can be distinguished from clue cells in that the latter have numerous small attached bacteria, which are so plentiful as the make the entire cytoplasm appear finely granular and obscure the cytoplasmic border, making it "shaggy" in appearance (refer to CMMP-36).

CMMP – Urine Sediment Color Photographs

USP-05



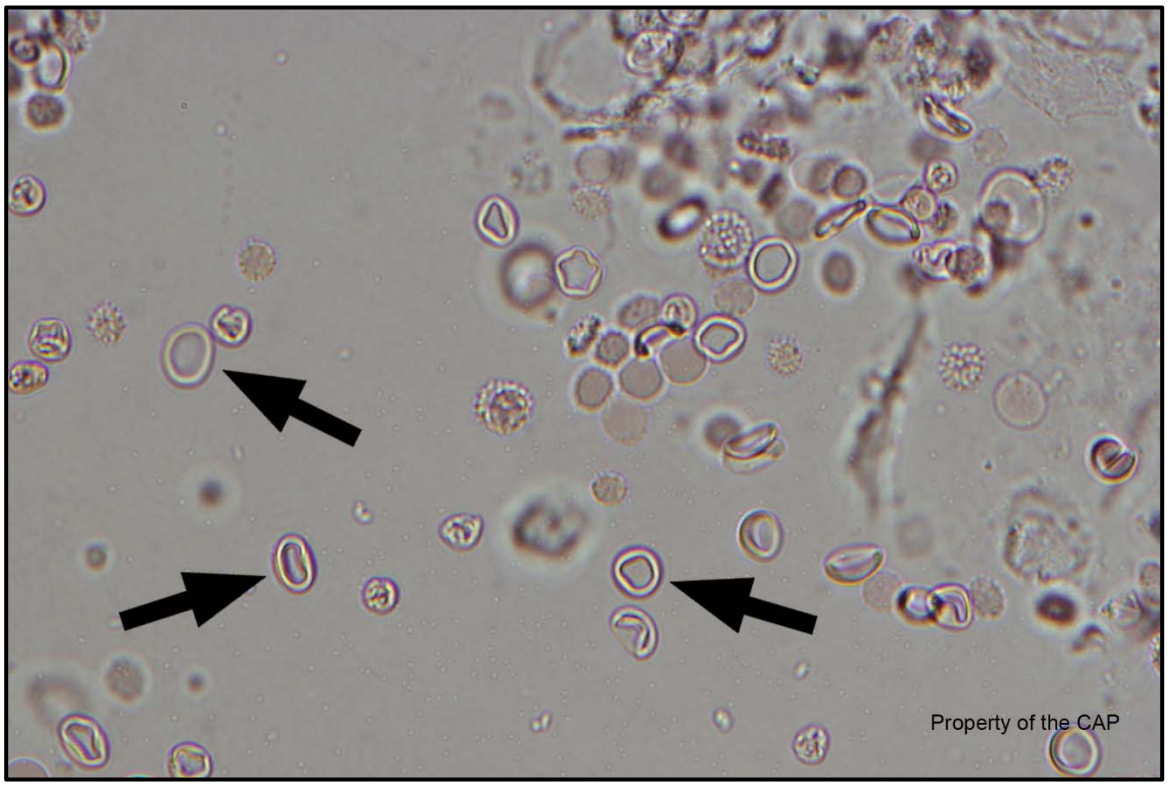
(URINE, UNSTAINED, HIGH POWER)

Identification	CMMP Participants No.	%	Performance Evaluation
Calcium oxalate crystals	4230	99.4	Good

The arrowed objects are calcium oxalate crystals, as correctly identified by 99.4% of participants. Calcium oxalate crystals are found in neutral or acid pH and vary in size. They may be smaller than red blood cells. Dihydrate calcium oxalate forms small colorless octahedrons that resemble stars, envelopes, or two pyramids joined at the base. All forms of calcium oxalate crystals are birefringent. Oval, elliptical, or dumbbell monohydrate forms are less commonly seen than the dihydrate form. Oxalate crystals are not usually abnormal findings, especially in patients who consume foods rich in oxalic acid, such as tomatoes, apples, asparagus, oranges, or carbonated beverages. However, in some circumstances they may suggest the cause of renal calculi.

CMMP – Urine Sediment Color Photographs

USP-06



(URINE, UNSTAINED, HIGH POWER)

Identification	CMMP Participants No.	%	Performance Evaluation
Erythrocytes	3780	88.8	Good

The arrowed objects are erythrocytes, as correctly identified by 88.8% of participants. Erythrocytes, or red blood cells, are round with no nucleus. They are 7 to 8 µm in diameter and appear as pale yellow-orange discs in unstained specimens, however if the sample is old or hypotonic they may be colorless and fainter. In hypertonic urine red blood cells may become crenated.

Small numbers of erythrocytes may be found in the urine sediment of otherwise normal patients. Larger numbers may indicate disease anywhere in the kidney or urinary tract. Hematuria can also be seen in patients with bleeding disorders or iatrogenic anticoagulation or trauma. Contamination of the urine by menstrual blood frequently causes falsely positive test results.

OCB – Occult Blood

Intended response was positive.

OCB-04

99.5% consensus

Method	Negative	Positive
ABON FOB	-	29
Aerscher Diagnostics HemaPrompt	1	14
Aerscher Diagnostics HemaPrompt FG	-	159
Beckman Coulter Hemoccult ICT	2	365
Beckman Coulter Hemoccult/II/SENSA	7	2471
BioMerieux bioNexia	-	13
Cenogenics Corp.	-	23
Consult Diagnostics	1	22
Dipro Hemdetect	-	13
Helena ColoScreen/ColoScreen-ES	-	131
Hemosure iFOB	1	382
Immunostics Hema Screen/Specific	1	106
Polymedco OC-Auto Micro 80	1	256
Polymedco OC-Light/OC-Light S	1	158
Polymedco OC-Sensor Diana	-	51
Propper Seracult/Seracult Plus	2	301
Quidel QuickVue iFOB	6	85
Siemens Hema-Chek slide	-	17
Stanbio	-	18
Starline ColoScan/ColoScan-ES	-	29
Sure-Vue/Sure-Vue ES	-	96
Other and Methods with <10 responses	2	214

Intended response was positive.

OCB-05

99.2% consensus

Method	Negative	Positive
ABON FOB	-	29
Aerscher Diagnostics HemaPrompt	-	15
Aerscher Diagnostics HemaPrompt FG	2	157
Beckman Coulter Hemoccult ICT	2	365
Beckman Coulter Hemoccult/II/SENSA	19	2459
BioMerieux bioNexia	-	13
Cenogenics Corp.	-	23
Consult Diagnostics	1	22
Dipro Hemdetect	-	13
Helena ColoScreen/ColoScreen-ES	2	129
Hemosure iFOB	5	378
Immunostics Hema Screen/Specific	3	103
Polymedco OC-Auto Micro 80	1	256
Polymedco OC-Light/OC-Light S	1	158
Polymedco OC-Sensor Diana	-	51
Propper Seracult/Seracult Plus	1	302
Quidel QuickVue iFOB	2	89
Siemens Hema-Chek slide	-	17
Stanbio	-	18
Starline ColoScan/ColoScan-ES	-	29
Sure-Vue/Sure-Vue ES	-	96
Other and Methods with <10 responses	2	214

OCB – Occult Blood

Intended response was negative.

OCB-06

99.0% consensus

Method	Negative	Positive
ABON FOB	29	-
Aerscher Diagnostics HemaPrompt	15	-
Aerscher Diagnostics HemaPrompt FG	157	2
Beckman Coulter Hemoccult ICT	363	4
Beckman Coulter Hemoccult/II/SENSA	2452	26
BioMerieux bioNexia	13	-
Cenogenics Corp.	23	-
Consult Diagnostics	23	-
Dipro Hemdetect	13	-
Helena ColoScreen/ColoScreen-ES	129	2
Hemosure iFOB	379	5
Immunostics Hema Screen/Specific	106	1
Polymedco OC-Auto Micro 80	255	2
Polymedco OC-Light/OC-Light S	157	2
Polymedco OC-Sensor Diana	51	-
Propper Seracult/Seracult Plus	299	4
Quidel QuickVue iFOB	91	-
Siemens Hema-Chek slide	17	-
Stanbio	18	-
Starline ColoScan/ColoScan-ES	29	-
Sure-Vue/Sure-Vue ES	95	1
Other and Methods with <10 responses	214	2

GOCB – Gastric Occult Blood

Intended response was positive.

GOCB-04

99.3% consensus

Method	Negative	Positive
Aerscher Diagnostics HemaPrompt FG	-	140
Beckman Coulter Gastroccult	13	1834
Other	-	11

Intended response was negative.

GOCB-05

97.8% consensus

Method	Negative	Positive
Aerscher Diagnostics HemaPrompt FG	139	1
Beckman Coulter Gastroccult	1805	42
Other	11	-

Intended response was positive.

GOCB-06

98.5% consensus

Method	Negative	Positive
Aerscher Diagnostics HemaPrompt FG	1	139
Beckman Coulter Gastroccult	28	1819
Other	-	11

GOCB – Gastric pH, Quantitative

GOCB-04

Method	No. Labs	Mean	S.D.	C.V.
pH dipstick without reader	33	8.53	0.72	8.4
pH meter	14	9.16	0.23	2.5
pH paper	104	8.38	0.67	7.9

GOCB-05

Method	No. Labs	Mean	S.D.	C.V.
pH dipstick without reader	32	2.55	0.88	34.7
pH meter	13	2.44	0.08	3.1
pH paper	103	2.59	0.76	29.2

GOCB-06

Method	No. Labs	Mean	S.D.	C.V.
pH dipstick without reader	34	8.53	0.66	7.8
pH meter	13	9.17	0.24	2.6
pH paper	103	8.43	0.72	8.5

GOCB – Gastric pH, Qualitative

GOCB-04

98.1% consensus

Method	1	2	3	4	5-7	7+
Beckman Coulter Gastroccult	16	2	2	8	72	1373

GOCB-05

98.7% consensus

Method	1	2	3	4	5-7	7+
Beckman Coulter Gastroccult	-	573	860	22	12	7

GOCB-06

98.0% consensus

Method	1	2	3	4	5-7	7+
Beckman Coulter Gastroccult	14	1	8	7	70	1373

DSC – Bilirubin, Confirmatory

Intended response was negative.

DSC-03

97.3% consensus

Method	Negative	Positive
Biorex DIAZO-CHEK	62	2
Siemens Ictotest	694	19
Other	8	-

Intended response was positive.

DSC-04

95.4% consensus

Method	Negative	Positive
Biorex DIAZO-CHEK	10	54
Siemens Ictotest	24	689
Other	2	6

DSC – Protein, Confirmatory, Method 1

Intended response was negative.

DSC-03

100.0% consensus

Method/Instrument	Negative	Positive
Sulfosalicylic Acid (SSA)		
Visual	54	-

Intended response was positive.

DSC-04

98.2% consensus

Method/Instrument	Negative	Positive
Sulfosalicylic Acid (SSA)		
Visual	1	53

DSC – Protein, Confirmatory, Method 2

DSC-03

99.4% consensus

Method/Instrument	Negative	1+	2+	3+	4+
Sulfosalicylic Acid (SSA)					
Visual	170	-	1	-	-

DSC-04

100.0% consensus

Method/Instrument	Negative	1+	2+	3+	4+
Sulfosalicylic Acid (SSA)					
Visual	-	33	71	50	17

DSC – Protein, Confirmatory, Method 3

DSC-03

100.0% consensus

Method/Instrument	Negative	Trace	30 mg/dL	≥100 or >600 mg/dL
Sulfosalicylic Acid (SSA)				
Visual	11	-	-	-

DSC-04

90.9% consensus

Method/Instrument	Negative	Trace	30 mg/dL	≥100 or >600 mg/dL
Sulfosalicylic Acid (SSA)				
Visual	-	1	1	9

Actions Laboratories Should Take when a PT Result is Not Graded

The College uses Exception Reason Codes that signify the proficiency testing (PT) for an analyte has not been graded. The Exception Reason Code is located on the evaluation report in brackets to the right of the result. Your laboratory must identify all analytes with an exception reason code, review and document the acceptability of performance as outlined below and retain documentation of review for at least 2 years. The actions laboratories should take include but are not limited to:

Code	***Exception Reason Code Description***	***Action Required***
11	Unable to analyze.	Document why the specimens were not analyzed (eg, instrument not functioning or reagents not available). Perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
20	No appropriate target/response; cannot be graded.	Applies to a response that is not formally evaluated when a peer group is not established due to fewer than 10 laboratories reporting. Document that the laboratory performed a self-evaluation using the data presented in the Participant Summary and compared its results to a similar method, or all method, or all participant statistics if provided. Perform and document the corrective action of any unacceptable results. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
21	Specimen problem.	Document that the laboratory has reviewed the proper statistics supplied in the Participant Summary. Perform and document alternative assessment for the period that commercial PT was not tested to the same level and extent that would have been tested. Credit is not awarded in these cases.
22	Result is outside the method/ instrument reportable range.	Document the comparison of results to the proper statistics supplied in the Participant Summary. Verify detection limits. Perform and document the corrective action of any unacceptable results.
24	Incorrect response due to failure to provide a valid response code.	Document the laboratory's self-evaluation against the proper statistics and evaluation criteria supplied in the Participant Summary. Perform and document the corrective action of any unacceptable results. Document corrective action to prevent future failures.
25	Inappropriate use of antimicrobial.	Document the investigation of the results as if they were unacceptable and review the proper reference documents to gain knowledge of the reason your response is not appropriate.
26	Educational challenge.	Review participant summary report for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation. Response to the CAP is not required.
27,31	Lack of participant or referee consensus.	Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the Participant Summary. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested.
28	Response qualified with a greater than or less than sign; unable to quantitate.	Applies to a response that is not formally evaluated when a less than or greater than sign is reported. Document that the laboratory performed a self-evaluation and compared its results to the proper statistics supplied in the Participant Summary. Verify detection limits. Perform and document the corrective action of any unacceptable results.
30	Scientific Committee decision.	Applies to a response that is not penalized based on Scientific Committee Decision. Document that the laboratory has reviewed the proper statistics supplied in the Participant Summary.

Actions Laboratories Should Take when a PT Result is Not Graded

The College uses Exception Reason Codes that signify the proficiency testing (PT) for an analyte has not been graded. The Exception Reason Code is located on the evaluation report in brackets to the right of the result. Your laboratory must identify all analytes with an exception reason code, review and document the acceptability of performance as outlined below and retain documentation of review for at least 2 years. The actions laboratories should take include but are not limited to:

Code	***Exception Reason Code Description***	***Action Required***
33	Specimen determined to be unsatisfactory after contacting the CAP.	Document that the laboratory has contacted the CAP and no replacements specimens were available. Perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
40 41	Results for this kit were not received. Results for this kit were received past the evaluation cut-off date.	Document why results were not received, corrective action to prevent recurrence and the laboratory's self-evaluation of the results by comparing results to the proper statistics and evaluation criteria supplied in the Participant Summary. If PT specimens were not analyzed, perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
42	No credit assigned due to absence of response.	The Participant Summary indicates which tests are graded (see evaluation criteria) and which tests are Not Evaluated/Educational. Updates to grading will also be noted. If a test is educational, the laboratory is not penalized for leaving a result(s) blank. The code 42 that appears on the evaluation is **not** a penalty. However, if a test is graded (regulated and non-regulated analytes) and your laboratory performs that test, results cannot be left blank. The laboratory is required to submit results for **all** challenges within that test or use an appropriate exception code or indicate test not performed/not applicable/not indicated. Exceptions may be noted in the Kit Instructions and/or the Result Form. Document corrective actions to prevent future failures.
44	This drug is not included in our test menu. Use of this code counts as a correct response.	Verify that the drug is not tested on patient samples and document to ensure proper future reporting.
45	Antimicrobial agent is likely ineffective for this organism or site of infection	Document that the laboratory performed a self-evaluation of written protocols and practices for routine reporting of antimicrobial susceptibility reports to patient medical records. Document that routine reporting of this result to clinicians for patient care is compliant with specific recommendations of relevant Medical Staff and Committees (eg, infectious Diseases, Pharmacy and Therapeutics, Infection Control). Response to the CAP is not required.
77	Improper use of the exception code for this mailing.	Document the identification of the correct code to use for future mailings.
91	There was an insufficient number of contributing challenges to establish a composite grade.	Document the investigation of the result as if it were an unacceptable result. Perform and document the corrective action if required.
35, 43, 88, 92, 46	Various codes.	No action required.

COLLEGE of AMERICAN PATHOLOGISTS

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CM-B 2018: Neutrophilia

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This activity is approved for continuing education credit in the states of California and Florida.

Disclosure Statement

The following authors/planners have no financial relationships to disclose:
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None

The following In-Kind Support has been received for this activity:
None

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Learning Objectives

Upon completing the reading and answering the learning assessment questions, you should be able to:

1. Be familiar with the differential diagnosis of neutrophilia.
2. Know the clinical significance of bands and the conditions for which they are relevant.
3. Understand the clinical significance of immature granulocytes (IG).

CM-B 2018: Neutrophilia

INTRODUCTION

A complete blood count (**CBC**) is a blood test used to broadly evaluate the health status and can detect a wide range of disorders, including anemia, infection, and leukemia. A complete blood count measures red blood cells, which carry oxygen; white blood cells (WBCs)/leukocytes, which fight infection; and platelets, which help with blood clotting. Additional measures include hemoglobin, the oxygen-carrying protein in red blood cells and hematocrit, the proportion of red blood cells to the fluid component/plasma in blood.

Leukocytosis refers to an increase in the total number of WBCs due to any cause. It can be classified according to the component of white cells that contribute to an increase in the total number of WBCs. Therefore, leukocytosis may be caused by an increase in the granulocytes (neutrophils, monocytes, eosinophils, basophils), or lymphocytes or immature cells (eg, blasts). A combination of any of the above may be involved. Leukocytosis is a reflection of an underlying condition rather than a disease itself and is a nonspecific finding that can result from a variety of reactive and neoplastic causes. It may be present as a result of infection, such as bacterial, viral, or parasitic infections; inflammatory conditions such as chronic inflammation or autoimmune disorders; or medication (eg, steroids). It may also be seen with bone marrow involvement by a metastatic malignancy as well as primary marrow neoplasms such as leukemia. This continuing education activity will focus on neutrophilia, a specific type of leukocytosis, with the following objectives.

Case History:

A 40-year-old female presents with fever and cough. No hepatosplenomegaly is identified on physical exam. A CBC is performed and shows WBC = 24.06 x10E9/L, Hg = 6.5 g/dL, Platelets = 407x10E9/L. The instrument flags the case for manual review due to leukocytosis and immature granulocytes (IGs). A peripheral smear is made. The red blood cells show slight anisopoikilocytosis, echinocytes, and basophilic stippling. The platelets show normal morphology. No blood parasites are seen. The granulocytes show toxic granulation with Döhle bodies. A 200 WBC manual differential count is performed due to the increased WBC. Neutrophils and bands = 72%; metamyelocytes = 6%; myelocytes = 14%; promyelocytes = 2%; blasts = 1%; lymphocytes = 2%; monocytes = 1%; eosinophils = 2%; and basophils = 0%.

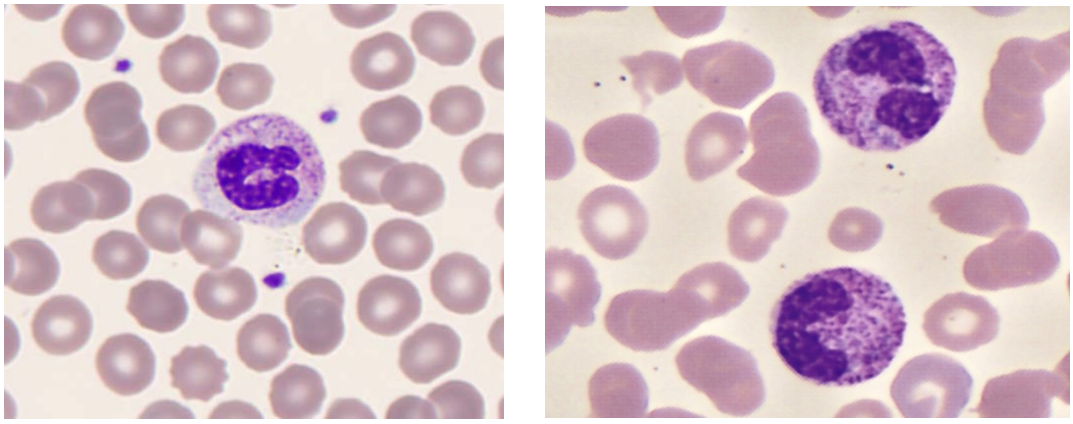


Figure 1: Peripheral smear showing neutrophils with toxic granulation (oil 1000x)

The differential diagnosis for this presentation includes a leukemoid reaction and also a myeloproliferative neoplasm such as chronic myeloid leukemia (CML). The clinical presentation and morphology of the granulocytes are compatible with a leukemoid reaction. Note that the manual differential performed included both bands and neutrophils under the same denomination. Should they have been counted separately? The automated instrument flagged “Immature granulocytes (IGs)”. What are IGs?

DISCUSSION

Neutrophils

Neutrophils are the most abundant human immune cells. They are rapidly recruited to sites of infection, where they perform lifesaving antimicrobial functions. Although reference ranges differ between laboratories, an absolute neutrophil count reference range somewhere near 2.0–7.7×10E9/L (40% – 80% of WBC)[1, 30]. People of African and Middle Eastern descent may have lower counts, which are still normal. The normal absolute neutrophil count is highest at birth (5.7-20.7x10E9/L at 0-3 days) and slowly declines; infants and children (<5 years) have slightly higher normal levels (1.5-8.5x10E9/L) than adults ranges.[31] Reference ranges are even more difficult to establish for preterm babies, term babies, or the ranges at the first 48 -72 hours. Particularly given these normal variations, age specific reference ranges must be established/verified and appropriate for the population served by the testing laboratory.

Neutrophils develop in the bone marrow from hematopoietic stem cells in a process called “granulopoiesis,” which normally takes 10-14 days. Bone marrow neutrophil also considered the “storage pool” can be divided into 3 compartments: (i) the stem cell compartment composed of hematopoietic stem cells and pluripotent progenitors; (ii) the mitotic compartment composed of proliferating, lineage-committed myeloblasts, promyelocytes, and myelocytes; and (iii) the post-mitotic compartment composed of metamyelocytes, band cells, and mature neutrophils. The post-mitotic cells (metamyelocytes, band cells, and neutrophils) constitute 95% of the circulating neutrophils in the body. Mature neutrophils are short-lived (with a life span up to 5 days) and highly motile, as they can enter parts of tissue where other cells/molecules cannot.[1,2] A neutrophil is usually 10-15 µm in diameter with N:C ratio of 1:3. Normally, neutrophils contain a nucleus divided into 2–5 segments connected by a filament. The neutrophil’s nuclear chromatin is clumped with no discernible nucleoli. The cytoplasm contains at least four different types of granules:

(1) primary granules, also known as azurophilic granules; (2) secondary granules, also known as specific granules; (3) tertiary granules; and (4) secretory vesicles. The granules are formed through a continuous process of vesicles budding from the Golgi apparatus. The content of these structures change during the development of the granulocyte resulting in a continuum of granule development with overlapping contents.[3,26] The Wright-Giemsa and other modifications of the Romanowsky cytochemical stains used in the laboratory are designed to stain the primary and secondary granules. The primary granules are the main storage site of the most toxic mediators, including elastase, myeloperoxidase, cathepsins, and defensins. The secondary and tertiary granules contain lactoferrin and lysozyme among other substances. The secretory vesicles in human neutrophils contain human serum albumin, suggesting that they contain extracellular fluid that was derived from endocytosis of the plasma membrane. Granules are released only when receptors in the plasma membrane or phagosomal membrane are activated, triggering movement of the granules to the cell membrane for secretion of their contents by degranulation. This control mechanism is important to minimize tissue damage, as the neutrophil is highly enriched in tissue-destructive proteases. Upon stimulation, neutrophils quickly migrate out of circulation into targeted tissue and congregate at a focus of infection. This extravasation and tissue localization is mediated by cytokines expressed by activated endothelium, mast cells, and macrophages including tumor necrosis factor (TNF) alpha, TNF beta, G-CSF, GM-CSF, IL-8, and C5a. Neutrophils express and release cytokines, which in turn amplify inflammatory reactions by recruiting several other cell types.

In addition to activating other cells of the immune system, neutrophils play a key role in the front-line defense against invading pathogens. Neutrophils have 3 methods for directly attacking micro-organisms: phagocytosis (ingestion), degranulation (release of soluble anti-microbials), and generation of neutrophil extracellular traps (NETs). In degranulation, the neutrophil release a diverse array of antimicrobial proteins and enzymes intracellularly into membrane-bound organelles, called phagosomes, which contain engulfed small microorganisms. At the same time, neutrophils release reactive oxygen species and cytokines outside the cells to kill extracellular bacteria and recruit additional leukocytes to the region of infection or inflammation. A study by Brinkmann[4] and colleagues described a novel mechanism by which neutrophils eliminate bacteria. Neutrophils, on activation by a range of mediators such as interleukin-8 (IL-8), lipopolysaccharide, and interferon-α generate a web of extracellular fibers known as NETs, composed of deoxyribonucleic acid (DNA), histones, and antimicrobial granule proteins. These are highly effective at trapping and killing invasive bacteria. Neutrophils from this “storage pool” in the bone marrow are released into the circulation—“circulating pool” by the actions of chemokine receptor signaling involving CXCR4 and CXCR2. In the periphery neutrophils are stored in the “marginated pools,” or vascular pools located in the lungs, spleen, and liver.[3-5] Demargination or mobilization of neutrophils into the circulation or tissues from the marginated pools is promoted by inflammatory reactions by cytokines and other cell signaling proteins plus environmental factors like hypoxia. During infections, the mitotic/proliferative compartment increases the cell divisions that can double the number of mature neutrophils produced. A small fraction of these neutrophil precursors escape the marrow and are found in the blood, and can be measured by the IG%. Another mechanism involves the release of postmitotic cells (neutrophils, bands, metamyelocytes) from the marrow into the circulation. This leads to an increase in the I/T ratio.[11]

Bands

The morphologic definition of band is a granulocyte with condensed chromatin and a nucleus that is indented to more than half of the distance to the farthest nuclear margin, but in no area is the chromatin condensed to a single filament. Bands are round to oval and 10-18 µm in diameter, with a nuclear to cytoplasmic ratio of 1:1.5 to 1: 2. The shape of the nucleus can be a curved or coiled band with no limits on the level of indentation as long as it does not completely segment the nucleus into lobes connected by a filament. Bands normally constitute 5%-10% of the nucleated cells in the blood. Other names for bands include schilling, band cell, stab cell, stab neutrophil, and staff cell. Experimental studies show that the some of the granulocytic lineage functionalities such as the chemotaxis, and oxygen-dependent bacterial killing develop in the later stage of granulocyte differentiation and are seen at both the band and neutrophil stage, suggesting similar functional capabilities for these 2 cell types. In current literature, band and segmented neutrophil are both considered within the category of "neutrophil."[1,23]

Flagging

Flagging is an indication from the instrument that a reported result is abnormal and the cells in question are quantitatively or qualitatively outside the established normal ranges programmed into the instrument or the instrument detects a technical problem with the sample. Therefore, all immature cells are flagged as they are not an expected finding in the peripheral blood. In the current context, immature cells were perhaps previously classified under "left shift" or monocytes. A manual review is required for further delineation. The criteria for manual review can be chosen judiciouly based on scientific literature, striking the right balance for manual smear reviews, that can optimize use of resources—the most scarce being medical technologists. The consensus guidelines from *International Society for Laboratory Hematology* can be used to generate criteria for manual review.[28]

Performing differentials: Band vs. Segmented Neutrophils

The impetus for delineating bands came from its utility in diagnosis of sepsis, for which band count was considered an important parameter especially in the neonate population.[9] The band count is used widely in various established diagnostic algorithms to diagnose bacterial infection in newborns and infants less than 3 months of age. The neonatologists use the I/T Neutrophil Ratio, calculated as the total number of immature cells (promyelocytes + myelocytes + metamyelocytes + bands) divided by the total number of cells in the neutrophils cell line (immature + segmented neutrophils).[10] One can see that to determine the I/T ratio a manual differential must be performed. There are several major technical limitations of the manual band count. Lack of consistent interpretation of the band cell identification criteria leads to considerable variation in reference ranges.[6,7,8,21] Distinction between these cell types can be particularly difficult when the nucleus is twisted or folded. Precision of the band count is poor due to both limited counting sample (100-200 cells) and individual technologist variation. The 95% confidence limits for a standard 100-cell differential count are unacceptably wide—for 5% bands the 95% confidence limits are 1%-12%, for 10% bands the limits are 4%-18%, and for 15% bands the limits are 8%-24%.[22] In the study by Manroe et al[9] which established the reference ranges in infants and is considered a classic reference in the field, the investigators relied on a single experienced technologist to perform more than 90% of the manual differential counts. This practice is not practical in a laboratory that depends on several medical technologists to perform differentials. Although a 500 cell differential can decrease this variability, routine counting of 500 cells is also not practical in a busy hematology laboratory. Further, we now know that elevation of the band count is not specific for infection, and may be secondary to inflammatory processes, tissue damage or necrosis,

neoplasia, intoxication, metabolic abnormalities, hemorrhage, hemolysis, or drugs. Conditions in infants that can result in increased bands without infection include meconium aspiration, hypoglycemia, prolonged labor, oxytocin induction, pneumothorax, and/or asphyxia. The College of American Pathologists Hematology & Clinical Microscopy Committee and the Clinical and Laboratory Standards Institute recommend reporting bands with segmented neutrophils to represent the total absolute neutrophil count (ANC).[19] In the case study presented above, while performing a differential the bands and neutrophils were counted together.

The total WBC and ANC have repeatedly shown to be much better predictors of bacterial infection, to which the band count adds no additional useful information. The current recommendations include the use of WBC, total ANC, and IGs (described in the next paragraph). Critical values for leukocytes are generally determined from the total WBC with both a low and high value along with the ANC.

(Neutrophil% +Band%) x WBC = ANC

The ANC Critical low value, when a patient cannot adequately fight infection, for most laboratories is less than 0.500 x 10E9/L. Current guidelines for the management of severe sepsis and septic shock[27] include the following inflammatory variables for diagnosis of sepsis:

1. WBC count > 12,000/ µL (12 x 10E9/L)
2. Leukopenia < 4,000/ µL (4 x 10E9/L)
3. Normal WBC count with >10% immature forms

Severe neutropenia can be seen in overwhelming sepsis due to absolute depletion of cells in the bone marrow storage pool in association with increased loss from blood into tissues. It can also be seen in significant viral infections as well as post chemotherapy treatment.

IGs

IGs are generally used to denote cells more immature than a band neutrophil and include metamyelocytes, myelocytes, and promyelocytes. Although myeloblasts are immature granulocytes, they are not included in this definition. IG counts can be performed both manually and by automated instruments. Modern automated hematology analyzers are capable of performing CBCs and differential leukocyte counts (DIFFs) where large numbers of leukocytes are categorized by flow cytometric techniques according to their size and cytoplasmic and nuclear characteristics. DIFF results generated by these analyzers from evaluation of at least 10,000 leukocytes include both the percentages and absolute numbers of neutrophils, lymphocytes, monocytes, eosinophils, and basophils, and flags for the potential presence of immature/abnormal/atypical white cells. Some automated instruments like the Sysmex hematology analyzer (Sysmex Corporation, Mundelein, IL) additionally measures IGs in percent and absolute number.[12,25] The IG count is performed in differential channels of the analyzer. A specific surfactant induces hemolysis of erythrocytes and the formation of ultramicroscopic pores in the leukocyte cell membrane. The increased permeability of leukocytes allows a polymethine dye with high affinity for nucleic acid to enter the cells. Subsequently, the cells are analyzed by nucleic acid fluorescence and side scatter. When excited by a 633-nm laser beam, the stained cells emit fluorescence proportional to their content of nucleic acid (ribonucleic acid [RNA] or DNA). IGs with an increased DNA content show an intense fluorescence that permits their separation from mature neutrophils. Of note, Sysmex is the only instrument, in our knowledge

that provides the IG count.

Quantitation of Immature Granulocytes: Comparison of automated counts with manual differentials

A manual differential count, once seen as the best method to review a patient's peripheral blood cells and provide the necessary numbers, is now challenged by the accuracy, precision, and turnaround time of automated differentials. Flow cytometry based methods are considered most sensitive and a gold standard for enumerating IGs.[20] Normal ranges for automated immature granulocyte counts (IG%) are described in adults and children as <1%, maximal IG concentrations of 0.5% or 0.03 × 10E9/L.[15,29] Studies comparing automated IG counts to manual 400 cell counts have found good correlation. Studies performed to see the degree of correlation between the automated and manual IG percentages when the latter is obtained from the conventional 100-cell manual differential[24] show that automated IG% and corresponding manual IG% group means are similar when the IG% are below 10. However, the difference between the automated and manual IG% grows larger when the manual IG% exceeds 10. CBC specimens that have a large number of hyper segmented neutrophils or cells with toxic granulation may give falsely increased IG values. Given these limitations and since increased IG% can raise suspicion for infection, one should consider scanning a smear to manually verify the count prior to reporting values when IG% exceeds a certain level. Automated IG counts at low levels (<5% in our experience) are reproducible, and have the potential to decrease the turnaround time of reporting CBCs. There is no consensus on the number at which a smear review is generated, therefore it is recommended that laboratories perform their own validation studies to compare automated vs manual counts for IGs. When combined with validated/verified auto verification protocols, automated differentials have the advantage that a blood smear is not needed, and technologist time is not required to perform a microscopic analysis, thereby conserving materials and reducing technologist time.

IG use in sepsis

Automated IG counts are useful in detecting infection and sepsis.[14,16,17] Ansari-Lari et al showed that the percentage of IGs correlates better with infection and positive blood culture results than the WBC count and is comparable to the ANC. The larger WBC sampling size and consistent parameters used to discriminate between cell populations used in automated differential counts allow for very accurate IG values even in the very low numbers. All of these parameters have low sensitivity and, therefore, are not individually useful as screening tests for infection. High cutoff levels for the percentage of immature granulocytes (in their study it is reported at >3%) may predict positive blood culture results. This may result in lower sensitivity but increases the specificity. IGs can be used to aid the diagnosis of sepsis in the adult population and infants >3 months based on as reference ranges that are established by manufactures and validated by laboratories based on current CAP guidelines.

Challenges in infants

Enumerating ANC and IG% in the infants poses some special challenges. It is difficult to determine reference ranges for immature granulocytes (IGs) in neonates due to rapid fluctuations during the first 5 days of postnatal life. Obtaining adequate samples to establish reference ranges can also be a challenge given that sample volume is usually limited and obtaining samples specifically for reference ranges is difficult in this population. It can also be difficult to establish a reference range in this population since IGs and ANC values in the first 48 hours of life are commonly increased for many reasons, including nonspecific stressors related to the delivery and steroid use, which is common in the setting of prematurity. Wiland EL et al[13] showed that IG counts in newborns (48 hours of life) appeared to be higher than reported for other age groups. IG% ranged from 0%-8.4% (95th percentile 5.2%).

At <12 h, 70% of samples had IG% >1%. IG% appears to decrease over time. Earlier hour of life and higher birth weight were independently associated with higher IG%. The study by MacQueen and Christensen et al, 2016[11], looked at 10,000 CBCs performed on neonates at 10 different institutions, compared automated vs manual leukocyte differential counts and established IGs reference ranges. They showed that the upper reference limit for absolute IG count during the first 48 hours was 1,460 per µL and thereafter (48 hours to 90 days) was 613 per µL. Lower reference limits were essentially zero in all cases. In the first 48 hours of life IG% were between 0%-6.2% and post 48 hours (48 hours to 90 days of life) the IG% were between 0%-4.2%. Further the ability of IT ratios and IG% to identify infants with both blood culture confirmed and clinically suspected sepsis were compared. Using the 95th percentile of IG% as the upper limit of normal (6.2% for newborns $\leq$ 48 hours of age, and 4.2% for those > than 48th of age) they found that IT ratios and IG% were similarly predictive. Some laboratories are using these numbers as guidelines. IG% greater than 6.2% in the first 48 hours of life and greater than 4.2% after 48 hours of age are likely to have similar information regarding the possibility of sepsis as an IT ratio of 0.30. As always, decision making regarding the possibility of sepsis should not be dependent solely upon information available from a CBC but instead must incorporate relevant historical and clinical information. Finally, use of adult and pediatric reference ranges for IG% would not be appropriate for newborns, particularly in those being evaluated for early-onset sepsis, and laboratories should establish age-specific reference ranges.

Neutrophilia: Causes and differential diagnosis

Neutrophilia or the increase of neutrophils in the blood is the most common form of leukocytosis. Neutrophilia is defined as an increased absolute neutrophil count (ANC) in PB above 2SD of the mean value for healthy individuals, ie, above 7.7 × 10E9/L. Mild neutrophilia may sometimes still be within spectrum of normal for an individual as we should remember that the neutrophil count in 2.5% of the general population is >2 standard deviations above the mean. Neutrophilia can be secondary to demargination or physiologic/shift /pseudo-neutrophilia when the neutrophils move from the marginated/storage pools to the circulating pools. This may happen in pregnancy, labor, newborns, strenuous exercise, emotional states, and vomiting. In this condition the total number of granulocytes does not increase. In true neutrophilia the granulocyte count increases as a result of increased release of neutrophils from the bone marrow or increase in the production of neutrophils in the bone marrow. There are several causes of true neutrophilia such as acute bacterial infection, inflammation that results from burns, post-operative, autoimmune conditions, acute myocardial infarction, trauma or tissue damage that induces an inflammatory reaction, conditions of abnormal metabolism such as diabetic ketoacidosis, uremia and eclampsia, acute hemorrhage, sepsis, cigarette smoking, and stress. Drugs such as steroids cause elevation of neutrophil count. Malignancy such as carcinoma, sarcoma, etc, can cause reactive neutrophilia. Finally primary hematologic malignancies can result in neutrophilia. **Left shift** or increase in circulating precursors is often seen in neutrophilia. **Toxic granulation** described as dark blue to purple lysosomal granules containing myleoperoxidase can be seen in these conditions and indicate a shortened maturation and activation or early release from the neutrophilic storage pool. This can be seen in neutrophils in leukemoid reactions, acute inflammation, as well as when granulocyte colony stimulating factors (G-CSF) has been administered. **Döhle bodies**, also seen in neutrophilia are RNA containing structures derived from endoplasmic reticulum. They are oval to round bodies that range in size from barely visible to 2 mcm. These are generally found in patients with infections, burns, trauma, pregnancy, and administration of G-CSF. They are also seen in a benign inherited condition called May-Hegglin anomaly.

Leukemoid reaction describes an increased WBC count, or leukocytosis, which is a physiological response to stress or infection or other medical conditions as mentioned above, except a primary blood malignancy such as acute or chronic leukemia. There can be presence of immature cells such as myeloblasts, promyelocytes, myelocyte or metamyelocytes along with bands and neutrophils showing toxic granulation or Döhle bodies in the peripheral blood. Nucleated red blood cells/erythroid precursors can also be seen. It is important to distinguish a leukemoid reaction from leukocytosis due to malignancy such as chronic myeloid leukemia or Chronic Neutrophilic leukemia.

CML is a malignancy characterized by an increased and unregulated growth of predominantly myeloid cells in the bone marrow and the accumulation of these cells in the peripheral blood.[18] Myeloid cells arise from stem cells that give rise to granulocytes, erythrocytes, or platelets. This clonal disorder primarily manifests as a proliferation of maturing granulocytes (neutrophils, eosinophils, and basophils and precursors). In most patients it presents with an insidious onset and approximately 50% will be aymptomatic and is discovered when the WBC performed in routine medical examination is found to be abnormal. In contrast, most times, a patient with leukemoid reaction will present with signs and symptoms of infection, sepsis, or inflammatory disorders. Other presentations include fatigue, malaise, weight loss, or symptoms of anemia; about 50% will present with massive splenomegaly. CML typically presents in chronic phase and may progress to accelerated phase or blast phase. Rarely, the initial presentation can be accelerated or blast phase. When the disease is progressive the signs and symptoms include bleeding, petechiae, and ecchymosis, bone pain and fever (transformation to acute leukemia-blast phase), increasing anemia, thrombocytopenia, basophilia, and a rapidly enlarging spleen in blast crisis. The diagnosis of CML is suggested based on peripheral blood counts and smear review. It is confirmed and staged with bone marrow biopsy histology and demonstration of t(9;22) and/or *BCR/ABL1* fusion by molecular and cytogenetic analysis. CBC with differential on the peripheral blood smear often shows a total WBC count 20,000-60,000 cells/µL, with mildly increased basophils and eosinophils. There can be mild to moderate anemia. The platelet counts can be low, normal, or markedly increased. Peripheral blood leukocytosis shows a prominent left shift, including granulocyte precursors (eg, myeloblasts, myelocytes, metamyelocytes with a relative increase in myelocytes is seen along with nucleated red blood cells. Toxic granulation or Döhle bodies are usually not appreciated. In chronic phase, blasts are not significantly increased as a percentage of WBCs in peripheral blood or bone marrow, but are often higher than seen in reactive conditions. Bone marrow analysis shows an increased cellular marrow with an increased granulocyte: erythroid ratio. The granulocytes usually display a left shift with increase in myelocytes. Erythroid precursors are relatively decreased. Megakaryocytes include small abnormal hypolobated forms (so called “dwarf” megakaryocytes). The confirmatory analysis is the presence of the Philadelphia (Ph) chromosome in bone marrow cells by conventional cytogenetic karyotyping or demonstration of *BCR/ABL1* fusion by fluorescent in situ hybridization (FISH) or polymerase chain reaction (PCR) analysis. This abnormality is associated with the chromosomal translocation t (9; 22) (q34.1; q11.2), which results in the formation of the Philadelphia (Ph) chromosome. Conventional karyotyping detects 90%-95% of the cases Philadelphia Chromosome (fusion between Chromosome 9 and 22). Cryptic translocations can further be delineated by FISH. Multiplex PCR tests that detect multiple fusion partners are often used at diagnosis to determine which specific fusion is present, and quantitative RT-PCR is routinely performed to effectiveness of ongoing therapy. FISH and PCR can be performed on peripheral blood specimens, while cytogenetic karyotyping is performed on bone marrow. These tests are used in various combinations at different points in the clinical

course for initial diagnosis, therapeutic monitoring, and evaluation for progression and/or resistance. The fusion protein exhibit deregulated protein tyrosine kinase (PTK) activity compared to normal ABL. As a result, there is excessive tyrosine phosphorylation of many intracellular proteins including the BCR-ABL protein itself. The abnormal tyrosine kinase receptor is constitutively expressed and causes abnormal cell growth and proliferation. In the 1990s, imatinib, a specific inhibitor of the unique BCR-ABL tyrosine kinase receptor was designed, and indeed was the first drug treatment targeted to molecular abnormality responsible for the pathogenesis of disease.[18]

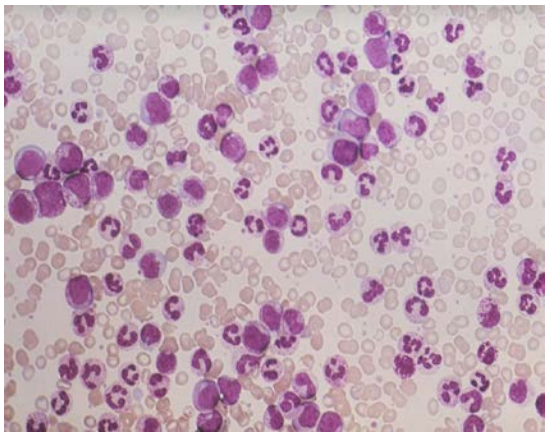
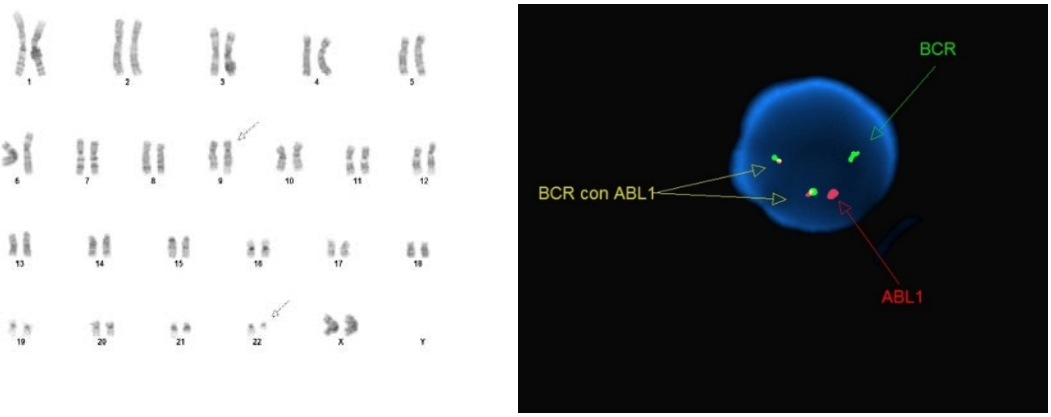


Figure 2: Peripheral blood showing leukocytosis with granulocyte left shift (oil 500x).



Left panel: Cytogenetic/karyotypic analysis that shows translocation of genetic material between the chromosome 9 and 22.

The right panel: FISH studies (fluorescently labeled- in-situ- the genes of interest. Here BCR gene is labeled green and ABL gene is labeled red; when there is translocation that brings genetic material from 2 separate genes together, in this example BCR and ABL; the overlap signal shows as yellow that confirms the presence of the translocation.

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Chronic Neutrophilic Leukemia is another rare myeloproliferative neoplasm that presents with neutrophilia. Clinically, patients maybe asymptomatic or present with fatigue, easy bruising, or bone pain. Hepatosplenomegaly maybe seen. There is leukocytosis with counts of ≥25 x 10E9/L. The peripheral blood shows increased

segmented neutrophils/bands which comprise > 80% of the leukocytes. This is often referred to as “right” shifted. IGs usually account for <10% of leukocytes with myeloblasts <1% of leukocytes. The bone marrow is hyper cellular with an increased number and percentage of neutrophilic granulocytes. Again, myeloblasts account for <5% of the marrow cellularity. A normal neutrophilic maturation pattern is seen. Cytogenetics can show abnormalities in 10% of the cases with karyotype abnormalities that include deletions in Chromosome 20 or chromosome 11; gains in chromosome 8, 9, 21, and sometimes a complex karyotype. By definition there is no Philadelphia chromosome or *bcr/abl* fusion gene. All other causes of neutrophilia are ruled out such as infection or inflammatory process. There is no evidence of another myeloproliferative disease or myelodysplastic disease. This morphology can be seen in plasma cell neoplasm in a significant subset of cases; therefore plasma cell neoplasm should be excluded as the cause of neutrophilia or clonality must be established in the myeloid cells to consider the diagnosis of concurrent 2 neoplasms (plasma cell neoplasm and CNL) in the same specimen. CNL is now known to be strongly associated with CSF3R (receptor for Colony-Stimulating Factor 3) mutation, SETBP1 (SET Binding Protein 1) mutations, ASXL1(Additional Sex Combs-like 1) mutations, or JAK2 (Janus Kinase 2) mutations. The knowledge of these mutations is useful not only diagnostic but also for therapeutic purposes. For example CSF3R has been shown to signal through downstream SRC family and JAK-kinase pathways and makes these attractive markers for treatment with tyrosine kinase inhibitors such as Desatinib or JAK inhibitor Ruxolitinib. There is ongoing investigation on the use of these tyrosine kinase inhibitors for the treatment of patients with neutrophilic leukemia with CSF3R mutations.[18]

KEY POINTS

1. Automated differentials have better precision and accuracy of WBCs due to the large number of cells (at least 10,000) counted than the traditional visual 100-cell differential, which shows high imprecision due to the small number of cells counted, low reproducibility and a relatively wide inter-examiner variability.

2. As automation continues to increase and more hematology vendors provide IG counts, the use of automated IG counts instead of manual IGs will increase. The enumeration of band counts as an indicator of left shift should cease altogether. This will decrease the workload on the hematology technologists.

SUMMARY

Neutrophilia can be seen in several medical conditions. Clinical and laboratory correlation helps in the final delineation of the disease. Optimal use of automated technology can assist in optimal use of technologist time for more productive activities.

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