

TUP Urine Test Strips Visual and Analyzer Reading

Comparison Report May 2008

Table of Contents

<i>I. ulti med TUP Urine Test Strips Visual and Analyzer Reading – Comparison Evaluation</i>	2
1. Objective.....	2
2. General Procedure.....	2
3. Materials.....	2
4. Results.....	2
4.1 Visual Test Comparison.....	2
4.2 Reading Comparison of the Clinitek 500 Analyzer.....	3
4.3 Reading Comparison of the Clinitek 100 Analyzer.....	3
4.2 Reading Comparison of the Clinitek Status Analyzer.....	4
5. Conclusion.....	4
<i>II. Appendix</i>	4
1. Cleared for US 510(k).....	4
2. CE Marked.....	4
3. Product Catalog Numbers.....	5
4. U120 Urine Analyzer.....	6

TUP Urine Test Strips

Visual and Analyzer Reading

I. ulti med TUP Urine Test Strips Visual and Analyzer Reading – Comparison Evaluation

1. Objective

To perform a clinical study including visual and analyzer testing to validate the accuracy of the ulti med TUP Urine Test Strips in comparison to the market leader Siemens Diagnostics (Bayer) Urine Strips.

2. General Procedure

Collect Clinical specimens from a hospital and test the specimens according to the procedures below.

- Visual Testing
Perform Visual Urine Strip comparison tests using the ulti med TUP and Siemens/Bayer Urine Strips. Then calculate the Percent Agreement of the results based on the ± 1 Color Block industry standard.
- Analyzer Testing
Perform Analyzer Urine Strip comparing tests using both the ulti med TUP and Siemens/Bayer Urine Strips on the Clinitek 500, Clinitek 100, and Clinitek Status Analyzers, and then compare the results.

3. Materials

- ulti med TUP Urine Test Strips
- Siemenst/Bayer Multistix 10 SG Urine Strips
 - Lot 1: 6L12D; Exp: 2008-05
 - Lot 2: 7B02D; Exp: 2008-08
- 300 Clinical Specimens collected from a Hospital
- Siemenst/Bayer Clinitek 100 Analyzer (SN024065)
- Siemenst/Bayer Clinitek Status Analyzer (SN10001)
- Siemenst/Bayer Clinitek 500 Analyzer (SN6470-1010472)

4. Results

4.1. Visual Test Comparison

ulti med TUP and Siemens/Bayer Visual Testing

Parameter	Total No. of Clinical Specimens	% Agreement ± 1 Color Block between Siemens/Bayer Strip Lot 1 & ulti med TUP	% Agreement ± 1 Color Block between Siemens/Bayer Strip Lot 2 & ulti med TUP	Average % Agreement ± 1 Color Block between Siemens/Bayer Strip Lot 1/2 & ulti med TUP	% Agreement ± 1 Color Block between Siemens (Bayer) Lot 1 & Siemens (Bayer) Lot 2
Leukocytes	300	100%	100%	100%	100%
Nitrite	300	99.67%	99.67%	100%	100%
Urobilinogen	300	100%	100%	100%	100%
Protein	300	100%	100%	100%	100%
pH	300	99%	99.33%	99%	99.67%
Blood	300	100%	100%	100%	100%
Specific Gravity	300	99.67%	99.67%	100%	100%
Ketone	300	100%	100%	100%	100%
Bilirubin	300	100%	100%	100%	100%
Glucose	300	100%	100%	100%	100%

According to the visual results in the above tables, the average percent agreement between the ulti med TUP with both Lots 1 and 2 of the Siemens/Bayer Strips was 99-100% for all parameters.

CONFIDENTIAL

For Customer Reference Use Only

ulti med Products (Deutschland) GmbH • Reeshoop 1 • 22926 Ahrensburg • Germany

Tel.: 04102 - 80090 • Fax: 04102 - 50082 • e-mail: info@ultimed.de • www.ultimed.org

TUP Urine Test Strips Visual and Analyzer Reading

4.2. Reading Comparison on the Clinitek 500 Analyzer

ulti med TUP and Siemens/Bayer reading on Clinitek 500 Analyzer

Parameter	Total No. of Clinical Specimens	% Agreement between Siemens (Bayer) Lot 1 & ulti med TUP	% Agreement between Siemens (Bayer) Lot 2 & ulti med TUP	Average % Agreement \pm 1 Color Block between Siemens/Bayer Strip Lot 1/2 & ulti med TUP	% Agreement between Siemens (Bayer) Lot 1 & Siemens (Bayer) Lot 2
Leukocytes	300	100%	100%	100%	100%
Nitrite	300	93.33%	92.33%	92.83%	96.33%
Urobilinogen	300	100%	100%	100%	100%
Protein	300	100%	100%	100%	100%
pH	300	97%	99.67%	98.34%	99.33%
Blood	300	99.67%	100%	100%	100%
Specific Gravity	300	99.67%	100%	100%	99.67%
Ketone	300	100%	100%	100%	100%
Bilirubin	300	100%	100%	100%	100%
Glucose	300	100%	100%	100%	100%

According to the Clinitek 500 Analyzer results in the above tables, the average percent agreement between the *ulti med TUP* with both Lots 1 and 2 of the Siemens/Bayer Strips was 98-100% for all parameters, except Nitrite. The average Nitrite percent agreement between the *ulti med TUP* with both Lots 1 and 2 of the Siemens/Bayer Strips was 93% which may be due to the lot to lot variation of the Siemens/Bayer Strips which had a 96.33% between lot percent agreement.

4.3. Reading Comparison on the Clinitek 100 Analyzer

ulti med TUP and Siemens/Bayer reading on Clinitek 100 Analyzer

Parameter	Total No. of Clinical Specimens	% Agreement between Siemens (Bayer) Lot 1 & ulti med TUP	% Agreement between Siemens (Bayer) Lot 2 & ulti med TUP	Average % Agreement \pm 1 Color Block between Siemens/Bayer Strip Lot 1/2 & ulti med TUP	% Agreement between Siemens (Bayer) Lot 1 & Siemens (Bayer) Lot 2
Leukocytes	300	100%	100%	100%	100%
Nitrite	300	90.45%	91.36%	90.91%	92.73%
Urobilinogen	300	100%	100%	100%	100%
Protein	300	100%	100%	100%	100%
pH	300	99.09%	99.08%	99.09%	99.54%
Blood	300	100%	100%	100%	100%
Specific Gravity	300	99.55%	100%	100%	100%
Ketone	300	100%	100%	100%	100%
Bilirubin	300	100%	100%	100%	100%
Glucose	300	100%	100%	100%	100%

According to the Clinitek 100 Analyzer results in the above tables, the average percent agreement between the *ulti med TUP* with both Lots 1 and 2 of the Siemens/Bayer Strips was 98-100% for all parameters, except Nitrite. The average Nitrite percent agreement between the *ulti med TUP* with both Lots 1 and 2 of the Siemens/Bayer Strips was 91% which may be due to the lot to lot variation of the Siemens/Bayer Strips which had a 92.73% between lot percent agreement.

TUP Urine Test Strips Visual and Analyzer Reading

4.4. Reading Comparison on the Clinitek Status Analyzer

ulti med TUP and Siemens/Bayer reading on Clinitek Status Analyzer

Parameter	Total No. of Clinical Specimens	% Agreement between Siemens (Bayer) Lot 1 & ulti med TUP	% Agreement between Siemens (Bayer) Lot 2 & ulti med TUP	Average % Agreement \pm 1 Color Block between Siemens/Bayer Strip Lot 1/2 & ulti med TUP	% Agreement between Siemens (Bayer) Lot 1 & Siemens (Bayer) Lot 2
Leukocytes	300	100%	100%	100%	100%
Nitrite	300	95.67%	97%	96%	96%
Urobilinogen	300	100%	100%	100%	100%
Protein	300	98.33%	99%	99%	99.33%
pH	300	99%	99.67%	99%	99.33%
Blood	300	99.33%	99.33%	99%	100%
Specific Gravity	300	99.33%	99%	99%	99.67%
Ketone	300	100%	100%	100%	100%
Bilirubin	300	100%	100%	100%	100%
Glucose	300	100%	100%	100%	100%

According to the Clinitek Status Analyzer results in the above tables, the average percent agreement between the *ulti med TUP* with both Lots 1 and 2 of the Siemens/Bayer Strips was 98-100% for all parameters, except Nitrite. The average Nitrite percent agreement between the *ulti med TUP* with both Lots 1 and 2 of the Siemens/Bayer Strips was 96% which may be due to the lot to lot variation of the Siemens/Bayer Strips which had a 96% between lot percent agreement.

5. Conclusion

This study demonstrates that the ulti med TUP Urine Test Strips are substantially equivalent to the Siemens/Bayer Strips when read visually and when read on the Clinitek 500, 100 and Status Analyzers.

II. Appendix

1. Cleared for US 510(k)

The *ulti med TUP Urine Test Strips* are cleared for US 510(k). For more information visit the following website: www.ultimed.org

2. CE Marked

The *ulti med TUP Urine Test Strips* and *ulti med TUP U120 Urine Analyzer* are CE Marked for sale in Europe as of January 17, 2006 and August 10, 2006, respectively. The following table lists the available languages.

Product Name	Available Languages
ulti med TUP Urinalysis Reagent Strips	Package Insert: German, English, French, Polish, Netherlands Kit Box: German, English
ulti med TUP U120 Urine Analyzer	Instruction Manual: German, English, French, Polish, Netherlands Carton Label: German, English

CONFIDENTIAL

For Customer Reference Use Only

ulti med Products (Deutschland) GmbH • Reeshoop 1 • 22926 Ahrensburg • Germany
Tel.: 04102 - 80090 • Fax: 04102 - 50082 • e-mail: info@ultimed.de • www.ultimed.org

TUP Urine Test Strips

Visual and Analyzer Reading

3. Product Catalog Numbers

ulti med TUP UrineTest Strips

Catalog No.	No. of Parameters	Strips per Canister [◇]	Individually Pouched Strips per Kit	Available Strips		Parameters List											
				Visual-Read and Analyzer-Read Strips	Visual-Read Strips	ASC	GLU	BIL	KET	SG	BLO	pH	PRO	URO	NIT	LEU	
U031-111 [†]	11	100	1, 3, 6	√	√	*	*	*	*	*	*	*	*	*	*	*	*
U031-101 [†]	10	100	1, 3, 6	√	√		*	*	*	*	*	*	*	*	*	*	*
				NA	√	*	*	*	*	*	*	*	*	*	*	*	*
U031-091 [†]	9	100	1, 3, 6	√	√		*	*	*	*	*	*	*	*	*	*	*
U031-081 [†]	8	100	1, 3, 6	√	√		*	*	*	*	*	*	*	*	*	*	*
				NA	√	*	*	*	*	*	*	*	*	*	*	*	
U031-071 [†]	7	100	1, 3, 6	NA	√		*		*		*	*	*		*	*	*
U031-061 [†]	6	100	1, 3, 6	NA	√		*				*	*	*		*	*	*
					√		*		*	*	*	*	*	*	*	*	
U031-051 [†]	5	100	1, 3, 6	NA	√		*		*		*	*	*		*	*	*
					√		*			*	*	*		*	*	*	
					√		*		*	*	*	*	*	*	*	*	
					√		*	*	*	*	*	*	*	*	*	*	
U031-041 [†]	4	100	1, 3, 6	NA	√		*			*		*	*		*	*	*
					√		*			*	*	*	*	*	*		
					√		*	*	*	*	*	*	*	*	*		
U031-031 [†]	3	100	1, 3, 6	NA	√		*					*	*		*	*	*
					√		*		*			*	*	*	*		
					√		*	*	*		*	*	*	*	*		
					√		*			*	*	*	*	*	*		
U031-021 [†]	2	100	1, 3, 6	NA	√		*					*	*		*	*	*
					√		*	*			*	*	*	*	*		
					√		*	*	*		*	*	*	*	*		
					√		*	*	*	*	*	*	*	*	*		
U031-011 [†]	1	100	1, 3, 6	NA	√												
					√												
					√												
					√												
					√									*			

◇ Also available in canisters of 25, 50 and 150 strips
 √ CE Marked for Sale in the European Community

Other combinations available soon!
 † Cleared for US 510 (k) and CLIA Waived

CONFIDENTIAL

For Customer Reference Use Only

ulti med Products (Deutschland) GmbH • Reeshoop 1 • 22926 Ahrensburg • Germany
 Tel.: 04102 - 80090 • Fax: 04102 - 50082 • e-mail: info@ultimed.de • www.ultimed.org

TUP Urine Test Strips

Visual and Analyzer Reading

ulti med TUP U120 Urine Analyzer

Product Name	Catalog No.	Components	Quantity
U120 Urine Analyzer	U111-101 ^{√†}	Urine Analyzer	1
		Strip Holder	1
		Printer Paper Rolls	2
		Fuses (2.0A)	2
		Power Cord	1
		Instruction Manual	1
Printer Paper Rolls	U121-101	Printer Paper Rolls	4

√ CE Marked for Sale in the European Community

† Cleared for US 510 (k)