

Validation of IDEXX VetLab® UA™ Analyzer and IDEXX UA™ Strips for Veterinary Samples

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ABSTRACT: To validate IDEXX UA™ Strips and the IDEXX VetLab® UA™ Analyzer for veterinary samples against the reference instrument: Bayer CLINITEK Atlas® 5001B (Elkhart, IN). 203 urine samples (115 canine, 66 feline and 22 equine) were run on both systems. The agreement between the reference, the IDEXX UA strips visual read and the IDEXX VetLab® UA™ was greater than 90%.

INTRODUCTION: It is well established that urinalysis is a key component of the minimum diagnostic profile for all sick patients, along with chemistry and hematology. There is also general consensus that a urinalysis should be conducted as close as possible to the time of collection to increase the accuracy, thus making it an ideal in-house test. IDEXX UA™ Strips are the only urine dipsticks validated for veterinary use on canine, feline, and equine urine. The strips can be read visually or with the IDEXX VetLab® UA™ Analyzer. The objective of this study was to compare the IDEXX results (visual and reader) to the reference instrument (Bayer Atlas).

There are two types of results from a photometric test: quantitative and semi-quantitative. For quantitative tests such as blood glucose measurement meters, color development on the test area is directly proportional to the concentration of the analyte in the sample due to test device design and concentration calculation algorithm (see figure A). For semi-quantitative tests such as the urinalysis strip screening test, the development of the reaction color on the test pads is influenced by different variables, including sample handling, composition of the urine sample, intrinsic urine color, urine density, and urine volume on the test paper (see figure B). Although urine analyzers measure the color intensity of the test strip in reflectance units with high precision, they are not able to eliminate all influences on the color development as described above. Therefore, the urine analyzer indicates measurement results only in concentration ranges (semi-quantitative) in contrast to glucose meters or other instruments. Therefore, for this study, the acceptance criterion was that all compared test methods must have > 85% agreement of results within +/- 1 color block.

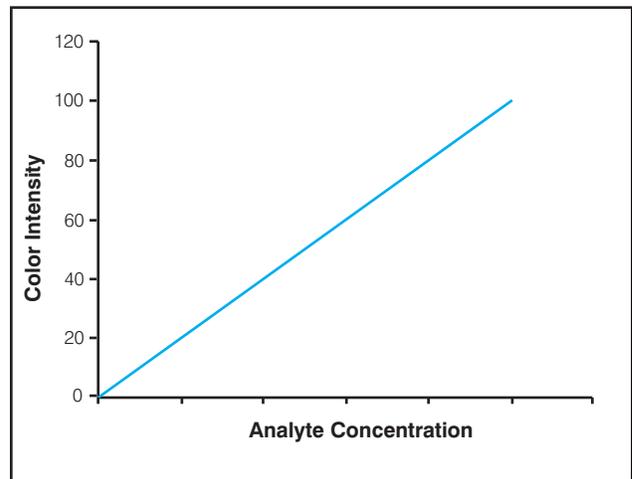


Figure A—A quantitative test showing the direct response between analyte concentration and color intensity.

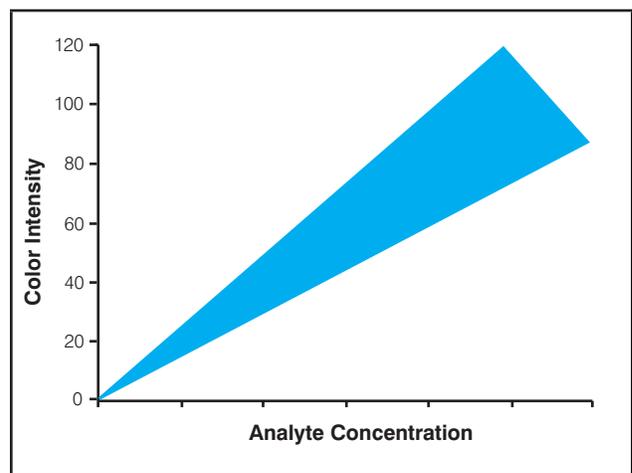
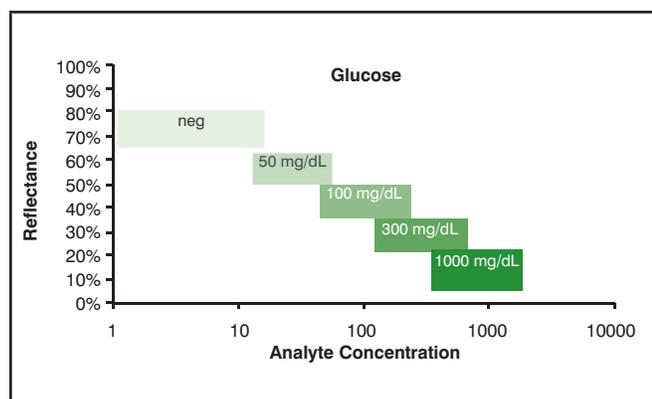


Figure B—A semi-quantitative test showing that the color intensity that develops in response to analyte concentration is not very precise because of the influence of external factors such as the intrinsic color of the urine sample and sample handling.

MATERIALS AND METHODS: Samples of canine, feline and equine urine (~ 3 mls each) were collected at three veterinary clinics. A total of 203 samples were analyzed (115 canine, 66 feline and 22 equine). These samples were from healthy as well as sick patients. For each sample, 2 IDEXX UA strips were analyzed: one for a visual read and one for an instrument read (UA Analyzer).

The samples were also run on the reference instrument (Bayer Atlas). To run the Atlas, the samples were dispensed into Urin-Tek sample tubes and loaded onto the sample carousel. After the sample IDs were entered into the instrument, the sample was automatically dispensed onto the reagent strips, the strips were incubated and the results printed.

RESULTS: The results from the IDEXX UA Analyzer are semi-quantitative in nature and are therefore given in result ranges or color blocks. Since these result ranges for each analyte are overlapping (see the example below), results in the expected concentration range and in both neighboring ranges (+/- 1 color block) are considered acceptable.



The agreement between the IDEXX UA™ Strips visual result, the IDEXX VetLab® UA™ analyzer result and the reference instrument result are all summarized in the following table:

	Visual vs. UA Analyzer	Visual vs. Atlas	UA Analyzer vs. Atlas
Bilirubin	94%	98%	99%
Blood	99%	94%	92%
Glucose	99%	97%	98%
Ketone	99%	100%	100%
Leukocytes	98%	97%	98%
Protein	96%	97%	90%
Urobilinogen	98%	100%	96%
pH	100%	96%	98%

DISCUSSION: There was a high level of agreement between the results from the IDEXX UA Analyzer and the visually read UA Strips as well as to the reference instrument, the Bayer Atlas. In two cases, there were gross disagreements between the IDEXX UA Analyzer and the Bayer Atlas. For bilirubin, the UA Analyzer had a negative result, while the Atlas's result was "large," a 3- concentration range difference. When the sample was sent to a reference lab for analysis, the results confirmed the UA Analyzer's result. The second case in which there was a disagreement between the two analyzers involved Protein. The UA Analyzer had a negative result, while the Atlas had a ">300" result, a 4- concentration range difference. Again, the reference lab result confirmed the UA result.

Because all the comparative results had a greater than 85% agreement, the acceptance criteria have been met for the validation of canine, feline and equine urine samples for IDEXX UA™ Strips and the IDEXX VetLab® UA Analyzer against the reference instrument, Bayer Atlas.

CONCLUSION: The IDEXX UA Analyzer and UA Strips provide accurate and reliable semi-quantitative urinalysis test results compared to the Bayer Atlas reference method for canine, feline and equine samples. The IDEXX VetLab UA Analyzer and UA Strips allow practitioners to offer their clients a more complete diagnostic profile by running a quick and easy in-house urinalysis test.



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