

ADVISORY NOTICE

35_2024_ A compilation of urine colours which could induce improper performance

Dear customer,

Hereby we inform you, that potential interferences and improper performances on chemistry results induced by urine colours may occur during measurement on Laura XL devices. This guideline gives indications regarding these interferences.

Test with Distilled Water

The results were obtained on different dyes diluted at the same concentration into distilled water. Colour of reference is colourless and clarity reference is clear.

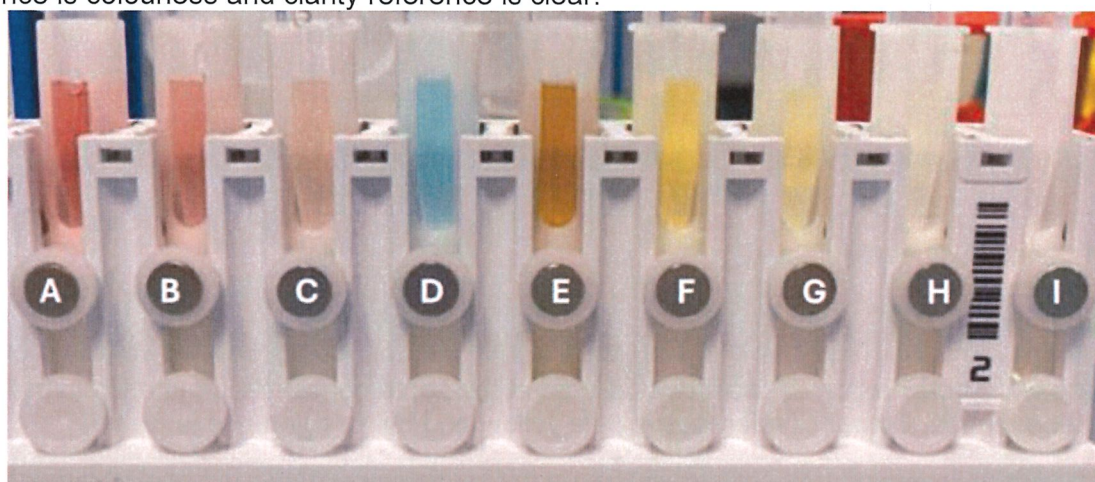


Figure 1. Diluted dyes in water; clear.

A: dark red – B: pink-red – C: amber – D: green blue – E: brown – F: dark yellow – G: yellow – H: pale-yellow – I: Di water.

The only interference detected during the study was with dark red colour (A) that may induce a positive bias result on LEU pad (25 Leu/μl instead of neg.).

Test with Urinorm N

The results were obtained on different dyes diluted at the same concentration into Urinorm N (negative control; urine matrix). Colour of reference is pale yellow and clarity reference is clear.

A: dark red – B: pink-red – C: amber – D: green blue – E: brown – F: dark yellow – G: yellow – H: pale-yellow – I: Urinorm N.

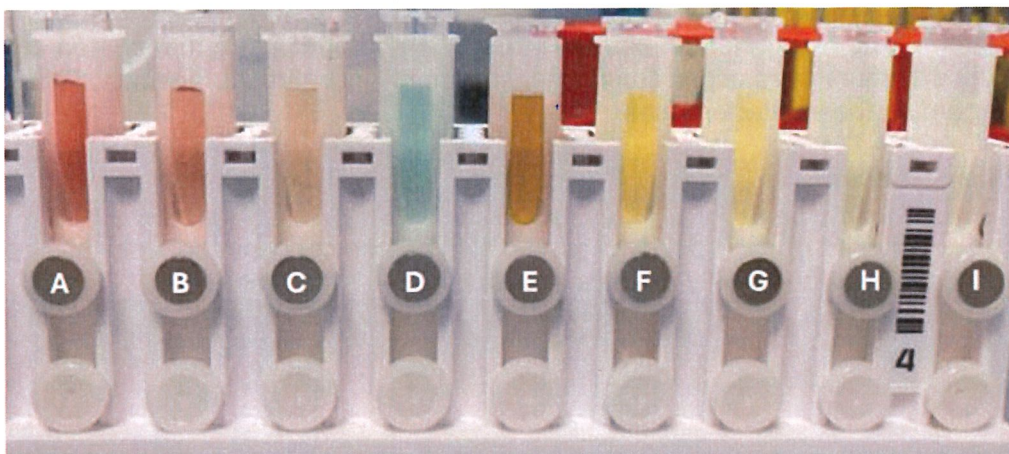


Figure 2. Urinorm N (1:7) and dyes; clear.

No interference has been detected.

Test with Urinorm P

The results were obtained on different dyes diluted at the same concentration into Urinorm P (positive control; urine matrix). Colour of reference is pale yellow and clarity reference is clear.

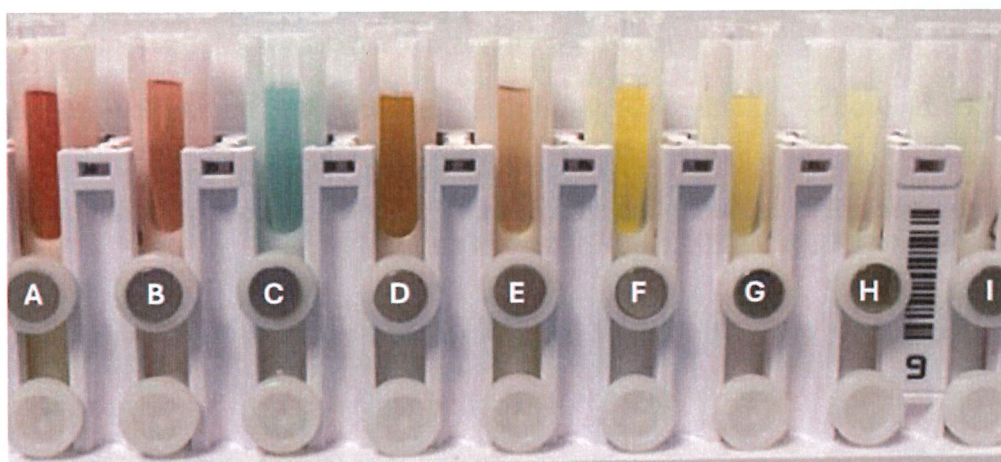


Figure 3. Urinorm P (1:7) and dyes; clear.

A: dark red – B: pink-red – C: green blue – D: brown – E: amber – F: dark yellow – G: yellow – H: pale-yellow – I: Urinorm P.

Colour B (pink-red) impacts on LEU pad interpretation, indeed there is a negative bias (75 Leu/ μ l for pink-red colour instead of 500 Leu/ μ l). Finally, pH interpretation may be impacted by brown colour (D) as a positive bias (pH=8 instead of 7). No impact on colours C, E, F, G, H, and I, on any of the 11 chemistry pads.

Turbidity impact

Coloured samples were diluted in a turbidity solution to obtain turbid (A, B and C), cloudy (D as limit between turbid and cloudy, and E), and clear samples (F and G). Three main colours were tested: dark yellow, green-blue, and pink-red.

Clarity reference can be made with a paper and a text, indeed if letters are visible then the sample is clear, if the letters are trouble but still visible then the sample is cloudy, if nothing is visible through the sample then it is turbid.

To prepare these solutions proceed as follows: add 100 µL of coloured solution into the stock solution, and then proceed with dilution 1/2 into Di water for the rest of solutions until obtention of clear solution.

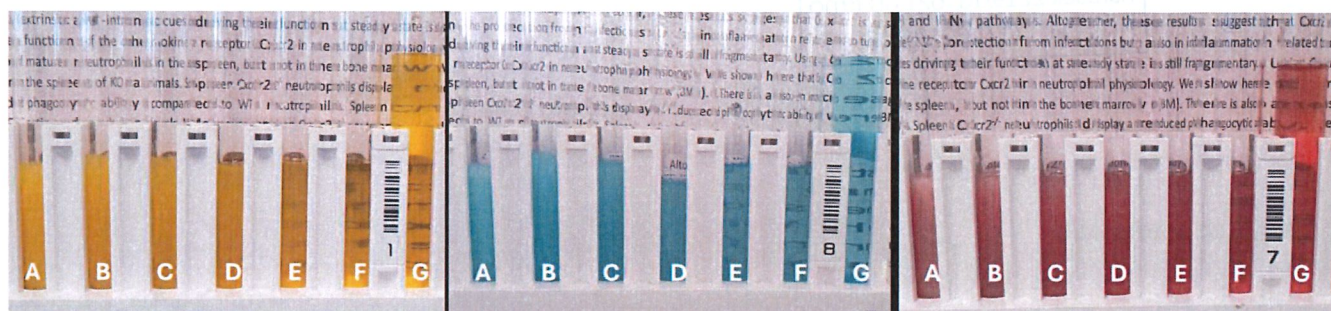


Figure 4. Turbid, cloudy, and clear samples associated with colour.

Clarity \ Color	A	B	C	D	E	F	G
Dark yellow	Green	✓	✓	✓	✓	✓	✓
Green-Blue	N/A	✓	✓	✓	✓	✓	✓
Pink-Red	Colorless	✓	✓	✓	✓	✓	✓

The results show that when a sample has a high turbidity for yellowish colour (pale yellow, yellow, and dark yellow) and pink-red colour, the result is wrongly detected, indeed for dark yellow result is green, and colourless for pink-red. For a blue urine sample, the result of a very turbid sample is out of range.

To conclude, in this document were presented a compilation of colour and the impact only for 2 chemistry pads.

- For LEU pad:
 - False positive with dark red colour (in distilled water only)
 - Negative bias with pink-red colour
- For pH pad:
 - Slight positive bias with brown colour

Our recommendations are:

- For red colour urines:
 - Check the presence of Leukocytes by microscopic method (Laura XL or manual microscopy).
 - If required, urine sample can be diluted with NaCl 0.9%, and run it in hybrid and calculate results with the dilution coefficient.
- In case of strong colour or turbidity, identify urine colour and clarity visually.

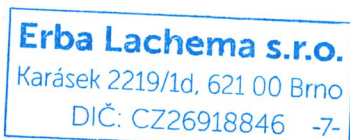
Erba Lachema s.r.o.



In case you have any additional question, please do not hesitate to contact us.

Best regards,

A handwritten signature in blue ink, appearing to be a stylized "A" or "B" followed by a flourish.



Erba Lachema s.r.o.

Brno, 5th November 2024

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