



Rapport Etude Lumini



Population

Adult patients (men, and women) with a urinalysis prescription

Inclusion criteria:

- Fresh urine sample
- Volume of urine sample > 20mL after collection of the tubes necessary for Cobas/Microbiology analysis

Exclusion criteria:

- Samples for which an STI search is requested

Methodology

1. Sample anonymization
2. Sample analysis with Usense Jimini device (3 repetitions)
3. Analysis with Biogroup reference method

Primary objectives

Analytical performance in humans of the DM-DIV LUMINI on the urinary parameters listed in Appendix 4, with superiority over the urine dipstick (GOLD STANDARD: laboratory reference technique) on fresh urine aliquots (<12H) collected during a routine urine assessment.



Preliminary results obtained – Lumini compared to each target per sitetype

site	siteType	target	TEST															
			SUPPORT		CONFUSION MATRIX				METRICS									
			supportNeg	supportPos	tp	tn	fn	fp	tnr	tp	fnr	fpr	recall	precision	accuracy	bAcc	f1	AUC
metz	platform	bacterialPresenceBin	66	21	21	55	0	11	0.833	1	0	0.167	1	0.656	0.874	0.917	0.792	0.917
		leukocytes(dipstick)Bin	142	66	39	126	27	16	0.887	0.591	0.409	0.113	0.591	0.709	0.793	0.739	0.645	0.739
		leukocytesBin	131	85	57	122	28	9	0.931	0.671	0.329	0.069	0.671	0.864	0.829	0.801	0.755	0.801
		nitrites(dipstick)Bin	192	22	12	186	10	6	0.969	0.545	0.455	0.031	0.545	0.667	0.925	0.757	0.6	0.757
		redBloodCells(dipstick)Bin	167	47	29	141	18	26	0.844	0.617	0.383	0.156	0.617	0.527	0.794	0.731	0.569	0.731
		redBloodCellsBin	158	58	35	136	23	22	0.861	0.603	0.397	0.139	0.603	0.614	0.792	0.732	0.609	0.732
	prePost	bacterialPresenceBin	41	14	14	32	0	9	0.78	1	0	0.22	1	0.609	0.836	0.89	0.757	0.89
		leukocytes(dipstick)Bin	86	51	30	69	21	17	0.802	0.588	0.412	0.198	0.588	0.638	0.723	0.695	0.612	0.695
		leukocytesBin	81	56	41	74	15	7	0.914	0.732	0.268	0.086	0.732	0.854	0.839	0.823	0.788	0.823
		nitrites(dipstick)Bin	129	8	6	121	2	8	0.938	0.75	0.25	0.062	0.75	0.429	0.927	0.844	0.545	0.844
		redBloodCells(dipstick)Bin	95	42	13	70	29	25	0.737	0.31	0.69	0.263	0.31	0.342	0.606	0.523	0.325	0.523
		redBloodCellsBin	102	35	23	91	12	11	0.892	0.657	0.343	0.108	0.657	0.676	0.832	0.775	0.667	0.775
saintDenis	prePost	bacterialPresenceBin	30	45	25	26	20	4	0.867	0.556	0.444	0.133	0.556	0.862	0.68	0.711	0.676	0.711
		leukocytesBin	162	62	37	130	25	32	0.802	0.597	0.403	0.198	0.597	0.536	0.746	0.7	0.565	0.7
		nitrites(dipstick)Bin	221	3	3	185	0	36	0.837	1	0	0.163	1	0.077	0.839	0.919	0.143	0.919
		redBloodCellsBin	187	37	24	161	13	26	0.861	0.649	0.351	0.139	0.649	0.48	0.826	0.755	0.552	0.755

INTERPRETATION

The initial results show encouraging performance on urinary tract infection markers, however, there is variability between sites. A significant difference is noted between models developed in pre-post site and technical platform.

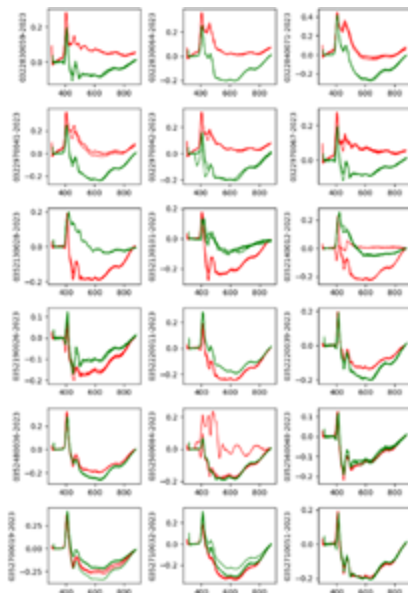


Limit

Impact on raw signals

Large diversity of responses across samples. However, in most cases we can observe significant differences in raw signals measured on technical platform vs pre-post sites. The origin of this variability has yet to be explained (impact of logistic, evolution of urine, Jimini...)

➡ Differences in signals measured on « plateau » vs « pre-post »

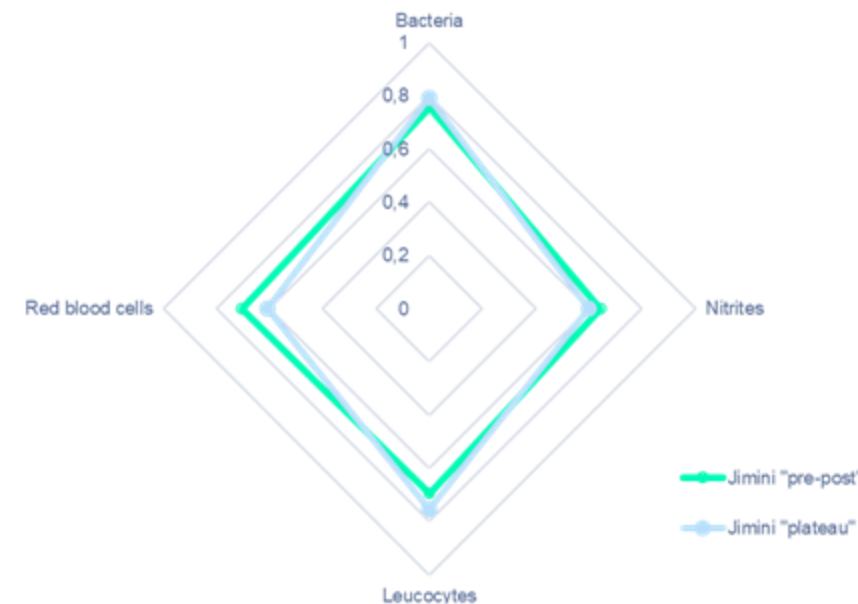


Normalized visible spectra on platform site (red) and pre-post sites (green)

Initial results show comparable level of performance on the 2 type of sites. However, we observe a very large variability due to the low number of positive cases.

➡ Comparable first results but high variability

Impact on models



F1 score "plateau technique" vs "pre-post"

CONCLUSION

The differences observed on raw signals seem to indicate that JIMINI signals should be collected as close as possible to the gold standard measurements (on the platform site) to lower the impact of uncontrollable variables



From Lumini1 to Jimini2:

- The first models developed are encouraging and show results close to or better than those of the urine dipstick.
- Need to integrate more samples into the database and activate other Jimini technology modules to improve models
- Need to uniform data collection as close as possible to the gold standard measurements (on the platform site) to lower the impact of uncontrollable variables