BIOLOGIE D'URGENCE & GAZ DU SANG

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CRITICAL CARE TESTING & BLOOD GASES

EVALUATION OF A LUMIRADx™ ANALYZER FOR DECENTRALIZED CRP TESTING

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INTRODUCTION

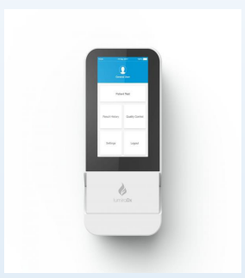
The availability of CRP blood testing is important in emergency medicine to ensure the relevance of the antibiotic therapy prescription. Its use in decentralized laboratory testing requires comparing the methods to the laboratory reference technique. The LumiraDx™ CRP test is a microfluidic immunoassay to quantify CRP levels in whole blood and plasma samples in 4 minutes.

OBJECTIVE

The objective of this study is to validate the analytical performance of the LumiraDx™ CRP test, establish correlations with the Siemens Atellica® CH technique from the central laboratory and evaluate its handling.

METHODS

Precision tests were carried out using 2 levels of CQI Multi LumiraDx™.



The comparison was made using 63 samples (CRP LumiraDx™ on whole blood followed by the assay on Atellica® CH (plasma after centrifugation) and evaluated using the Plever Viscali software.

The clinical concordance was verified *by* calculating the kappa coefficient (GraphPad) for thresholds <10 (gr.A), 10-40 (gr.B), 40-100 (gr.C) and >100 mg/L (gr.D).

Use was assessed during the correlation study using a questionnaire.

RESULTS

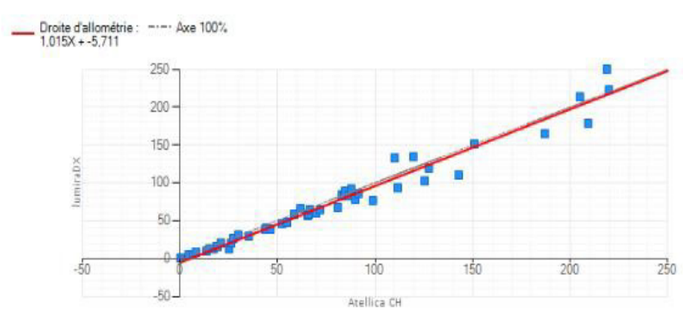
ANALYTICAL PERFORMANCE OF THE LUMIRADx™ CRP TEST: PRECISION STUDY

Intermediate precision				LumiraDx™ Multi Quality Control (ref.L020080101003)	n	Repeatability			
Mean (SD), mg/L	CV, %	CV objective				Mean (SD), mg/L	CV, %	CV objective	
		SFBC (*Société Française de Biologie Clinique* [French Society of Clinical Biology])	Ricos optimal					SFBC	FI Ricos optimal*0.75
20.3 (0.48)	2.4	12	10.6	Control 1 (batch 1009 0003 21000 161)	30	19.7 (0.52)	2.65	9	7.95
97.0 (4.51)	4.6	5	10.6	Control 2 (batch 1009 0003 21000 162)	30	97.2 (4.66)	4.79	3.8	7.95

✓The repeatability results are consistent with the Ricos optimal objectives and non-consistent with the SFBC objective only for the high level: without impact (use of unit cards)
✓Intermediate precision results are consistent with the Ricos optimal and SFBC objectives

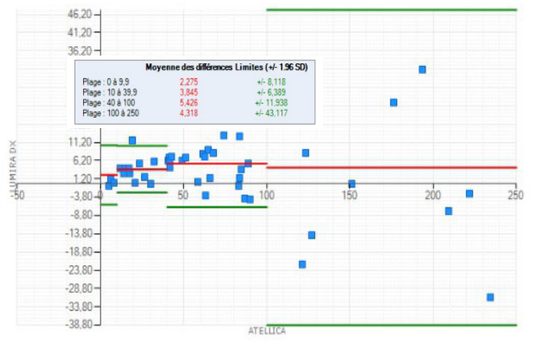
CRP CORRELATION RESULTS BETWEEN LUMIRADx™ and ATELLICA® CH

Smallest rectangles regression - Atellica CH vs. LumiraDx



✓ CRP Atellica® = 1.015 x CRP LumiraDx™ – 5.711.
✓ 8 samples with values <5 mg/L and 6 samples >250 mg/L obtained on LumiraDx™ were detected correctly except for one discordant point (193.6 mg/L on Atellica® vs. >250 mg/L on LumiraDx™)

Bland & Altmann - Atellica CH vs. LumiraDx



✓The Bland & Altman graph reveals only 2 points outside the limits +/-1.96 SD (24.9 and 99 mg/L on Atellica® CH vs respectively 13.2 and 76.4 mg/L on LumiraDx™).

CLINICAL CONCORDANCE STUDY RESULTS

	A	B	C	D	Total
A	10	0	0	0	10
B	1	10	0	0	11
C	0	5	18	0	23
D	0	0	1	18	19
Total	11	15	19	18	63

✓ A strong clinical concordance between the 2 techniques was demonstrated:
- Kappa coefficient = 0.849
- SE Kappa=0.054
- 95% CI: 0.744-0.954

USERS' APPRECIATION OF THE LumiraDx™ ANALYZER

✓Many strengths were highlighted during use:
- LumiraDx™ functionality,
- simplicity and intuitiveness of the interface,
- completeness and clarity of ticket information,
- safety of the transfer devices provided.

CONCLUSIONS

- Analytical performance of the LumiraDx™ CRP test is comparable to that of the central laboratory
- LumiraDx™ is well correlated with Atellica® CH for the CRP assay
- Its ergonomics, functional capacity, connectivity and safety for users are suitable for implementation in decentralized laboratory testing.