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Supplementary information

Implantable bioelectronics and wearable sensors for kidney health and disease

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Implantable bioelectronics and wearable sensors for renal health and disease

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Supplementary Table 1. Representative clinical studies on serum and urine diagnostic biomarkers in kidney diseases.

Kidney disease	Biofluid	Biomarker	Type	Marker of	Cut-off (≥)	Sensitivity	Specificity	Ref.
CKD	Blood	**Creatinine**	Waste product	Glomerular filtration	1 mg/dL	30.8% (women) 65.8% (men)	98.8% (women) 83.7% (men)	1
					1 mg/dL	63.5% (women) 94.5% (men)	96.3% (women) 63% (men)	2
					97 µmol/l	33%	78%	3
		Blood Urea Nitrogen (BUN)	Waste product	Glomerular filtration	NA	Associated with CKD progression (value NA)	Associated with CKD progression (value NA)	4
		Cystatin C	Protein	Glomerular function	NA	81-98%	67%-100%	5
					1.21 mg/L	82% (pediatric)	77%	6
		NGAL	Protein	Proximal tubular injury	435 ng/mL	83.9%	53.8%	7
					45 ng/mL	84%	77%	6
	Urine	**Proteinuria, albuminuria**	Protein	Glomerular permeability	NA	Association with CKD progression (value NA)	Association with CKD progression (value NA)	8, 9, 10
		NGAL	Protein	Proximal tubular injury	231 ng/mL	80.6%	73.8%	7
					20.5 µg/L	90.2%	67.9%	11
		NAG	Protein	Proximal tubular injury	9 U/gCr	82.4%	60.5%	11
AKI	Blood	**Creatinine**	Waste Product	Glomerular filtration	1.17 mg/dL	50%	52%	12
					0.6 mg/dL	32% (pediatric)	70% (pediatric)	13
					1.4 ng/mL	81%	82%	14
		Blood Urea Nitrogen (BUN)	Waste Product	Glomerular filtration	16.1 mmol/L	54.2% (Stage I)	77.5% (Stage I)	15
					16.76 mmol/L	71.7% (Stage II)	76% (Stage II)	
					17.19 mmol/L	82.9% (Stage III)	75.2% (Stage III)	
		Cystatin C	Protein	Glomerular filtration	0.94 mg/L	63%	66%	16
					0.85 mg/ml	89.5%	82.5%	17
		NGAL	Protein	Proximal tubular injury	90.5 ng/mL	61.7%	59.1 %	18
					154 ng/mL	59% (pediatric)	54% (pediatric)	13
					293 ng/mL	50%	82%	19
					150 µg/L (2hrs)	84%	94%	20
	Urine	**Proteinuria, albuminuria**	Proteins	Glomerular permeability	NA	Association with kidney disease progression after AKI (value NA)	Association with kidney disease progression after AKI (value NA)	21

		KIM-1	Protein	Proximal tubular injury	1412 pg/mL	87.5%	93.3%	22
					2.817 ng/mL	52%	79%	14
					0.42 ng/mg	92%	58%	23
					2 ng/mg uCr	65%	80%	24
					1.73 ng/mg	80%	99%	25
		IL-18	Protein	Inflammatio n	2.74 pg/mg	68%	95%	25
		NGAL	Protein	Proximal tubular injury	100 ng/mL	82%	90%	26
					104 ng/mL	68%	81%	14
					102 ng/mL	75% (pediatric)	65% (pediatric)	13
					102 ng/mL	46%	81%	19
					50 µg/L (2h)	100%	98%	27
					82.7 ng/mg	80%	96%	25
		NAG	Protein	Proximal tubular injury	18.5 U/g uCr (3h post op)	53.57%	70.59%	28
					40.0 U/mg uCr (12h post op)	84%	55%	24
					0.015 U/mg	80%	65%	25
		TIMP2*IGFBP	Proteins	Cell cycle arrest in renal tubular cells	0.39 (ng/ml)2 /1000	97%	72%	29
					0.817 (ng/ml)2/1000 (1d post op)	80%	81%	12
		L-FABP	Protein	Oxidative stress of proximal tubular cells	NA	74.5%	77.6%	30
					211 ng/mg Cr (4h)	95.2%	63.16%	31
					47.1 ng/mgCr	83%	90%	32
					33.9 ng/mL	50%	95%	33
					44.1 µg/g Cr	86%	100%	34
					24.5 µg/g Cr	82%	69%	35
					33.4 ng/ml (4h)	92.9%	44.9%	36
					12.9 ng/ml	50%	80%	14
		IL-18	Cytokine	Acute tubular necrosis after cardiac surgery	20 pg/mL	60% (24h)	89%(24h)	37
					49 pg/mL	96.6%	62.1%	38
					125 pg/mL	69% (pediatric)	68% (pediatric)	13
					0.065 ng/ml	43%	78%	14
					60 pg/ml	54%	82%	19
					92 pg/mg	75%	66%	23
					200 pg/ml	68%	95%	25

Abbreviations: References (Ref.), Not Available (NA), Chronic Kidney Disease (CKD), Acute Kidney Injury (AKI), Neutrophil gelatinase-associated lipocalin (NGAL), N-acetyl-glucosaminidase (NAG), Kidney Injury Molecule 1 (KIM-1), Interleukin-18 (IL-18), Tissue inhibitor of metalloproteinases-2 *Insulin-like growth factor-binding protein-7 (TIMP2*IGFBP), Liver-type fatty acid-binding protein (L-FABP), Creatinine (Cr).

Supplementary Table 2. Representative clinical studies on serum and urine diagnostic biomarkers in kidney injury and rejection after transplant.

Biofluid	Biomarker	Type	Marker of	Cut-off (≥)	Sensitivity	Specificity	Ref.
Blood	**Creatinine**	Waste Product	Glomerular filtration, allograft dysfunction	NA	75%	72%	39
				1.20 mg/dL	83%	54%	40
	Blood Urea Nitrogen (BUN)	Waste Product	Glomerular filtration, allograft dysfunction	NA	Late diagnosis (value NA)	Late diagnosis (value NA)	41_42
	Cystatin C	Protein	Glomerular filtration, allograft dysfunction	1.27 mg/L	77.8%	78.8%	40
				NA	Diagnostic accuracy better than serum creatinine	Diagnostic accuracy better than serum creatinine	43
	NGAL	Protein	Proximal tubular injury, allograft rejection	6865 pg/mL	60%	73%	44
				309 ng/mL	AKI and graft rejection (12h) 100%	92%	45
	KIM-1	Protein	Allograft rejection	153 pg/mL (1d post-transplant)	84.4%	86.7%	46
	Donor Specific Antibody (DSA)	Antibodies	Allograft rejection	MFI>500	78% (Immucor) 88% (One Lambda)	86% (Immucor) 68% (One Lambda)	47
	Donor-derived cell-free DNA (dd-cfDNA)	Next-generation sequencing assay to quantify dd-cfDNA	Allograft rejection	1%	59%	85%	48
	Tutivia	17 gene GEP RNASeq	Allograft rejection	Risk score > 50	51%	85%	49
	Trugraf	57 gene GEP microarray	Allograft rejection	0.375	64%	87%	50
	Cylex-Immuknow	CD4+ lymphocytes ATP production	Allograft rejection	NA	51%	90%	51
	Proteinuria, albuminuria	Proteins	Death-censored graft loss	NA	50.0%	79.8%	52
	Urinary-cell mRNA profiling (CTOT-04 study)	CD3Ɛ, IP10 (mRNAs), and 18S (rRNA)	Allograft rejection	−1.213	79%	78%	53

Urine	**Urine mRNA assay (QSant)**	Urine cell-free DNA, methylated cell-free DNA, clusterin, CXCL10, creatinine and total protein	Allograft rejection	Q-Score 32	95.8%	99.3%	54
	qPCR exosomes GEP (BioTechne)	Urinary exosomal mRNAs	Allograft rejection	NA	84.7%	94%	55
	miRNA-210	Urinary microRNA	Allograft rejection	Ratio of 7.9×10^{-6}	52%	74%	56
	NGAL	Protein	Proximal tubular injury	100 ng/mL 350 ng/mL (1d post-transplant)	100% 77% (dialysis within 1-week post- transplant)	93% 74%	57 58
	KIM-1	mRNA	Proximal tubular injury, allograft dysfunction Allograft rejection Long-term graft dysfunction	923.43 pg/mg (18h post-transplant) 153 pg/mL (24h post-transplant) 3.98 ng/mmol (1d post-op)	89.9% 84.4% 90%	100% 86.7% 51.66%	59 60 61
	CXCL9	Chemokine	Allograft rejection	37.8 pg/mL NA	86% 58.8% (T-cell rejection: 80%)	80% 84.5% 87%	39 62
	CXCL10	Chemokine	Allograft rejection	28 pg/mL NA	80% 59%	76% 83.3%	39 62
	IL-18	Cytokine	Allograft dysfunction	90 pg/mL	83% (dialysis within 1 week of transplant)	75%	58

Abbreviations: References (Ref.), Not Available (NA), Chronic Kidney Disease (CKD), Acute Kidney Injury (AKI), Blood Urea Nitrogen (BUN), Neutrophil gelatinase-associated lipocalin (NGAL), Kidney Injury Molecule 1 (KIM-1), Donor Specific Antibody (DSA), Donor-derived cell-free DNA (dd-cfDNA), Interleukin-18 (IL-18), Gene expression profile (GEP), RNA sequencing (RNAseq), Adenosine triphosphate (ATP), messenger RNA (mRNA), Clinical Trials in Organ Transplantation (CTOT), C-X-C motif chemokine ligand 9 (CXCL9), C-X-C motif chemokine ligand 10 (CXCL10), Interferon-inducible protein 10 (IP-10), Quantitative polymerase chain reaction (qPCR), microRNA (miRNA), ribosomal RNA (rRNA), 18S ribosomal RNA (18S).

Supplementary Table 3. Brief overview of current imaging techniques for kidney disease diagnosis and their main limitations.

Diagnostic imaging	Target disease*	Sensitivity	Specificity	Ref.	Main Limitations
Ultrasound	**AKI**	Obstructive acute nephropathy (value NA)	Obstructive acute nephropathy (value NA)	63	Operator-dependent Influenced by body habitus of the patient Presence of gas may affect the image
	CKD	Correlation with chronic, irreversible renal disease (value NA)	Correlation with chronic, irreversible renal disease (value NA)	64	
	Allograft disease	Rejection: limited utility (value NA)	Rejection: limited utility (value NA)	65	
Doppler ultrasound	**AKI**	32%	72%	66	
	CKD	80% (CKD stages ≥4-5)	88% (CKD stages ≥4-5)	67	
	Allograft disease	47% 43-82% (Acute rejection)	67% 33-100% (Acute rejection)	68 69	
CEUS	**AKI**	60% (AKI stage 3)	70% (AKI stage 3)	70	
	CKD	28% (CKD progression)	33% (CKD progression)	70	
	Allograft disease	Rejection-related perfusion abnormalities: not defined	Rejection-related perfusion abnormalities: not defined	71	
CT	**AKI**	Obstructive acute nephropathy (value NA)	Obstructive acute nephropathy (value NA)	72	Irradiation Iodine-containing contrast medium
	CKD	CKD progression by assessing kidney volume (value NA)	CKD progression by assessing kidney volume (value NA)	73	
	Allograft disease	Urinary leaks and urinoma Peri-operative or iatrogenic complications (value NA)	Urinary leaks and urinoma Peri-operative or iatrogenic complications (value NA)	74	
MRI	**AKI**	Evidence growing due to new techniques (value NA)	Evidence growing due to new techniques (value NA)	75	Contraindicated if electrically,

		Acute bilateral renal cortical necrosis (value NA)	Acute bilateral renal cortical necrosis (value NA)	76	magnetically or mechanically implanted devices (i.e., cardiac pacemaker)
	CKD	MRI imaging biomarkers under development (values NA)	MRI imaging biomarkers under development (values NA)	77	Prolonged images acquisition
	Allograft disease	Not established in routine follow up (value NA)	Not established in routine follow-up (value NA)	78	
***Other specific diseases affecting the kidneys that could be significantly detected by radiologic tools:** congenital anomalies of kidney and urinary tract, renal masses, renal artery stenosis, renal vein thrombosis, renal infarction.					

Abbreviations: References (Ref.), Not Available (NA), Acute Kidney Injury (AKI), Chronic Kidney Disease (CKD), Contrast-enhanced Ultrasound (CEUS), Computed Tomography (CT), Magnetic Resonance Imaging (MRI).

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