Nephrolyx

KDIGO 2024 CKD Guideline Gold Standard

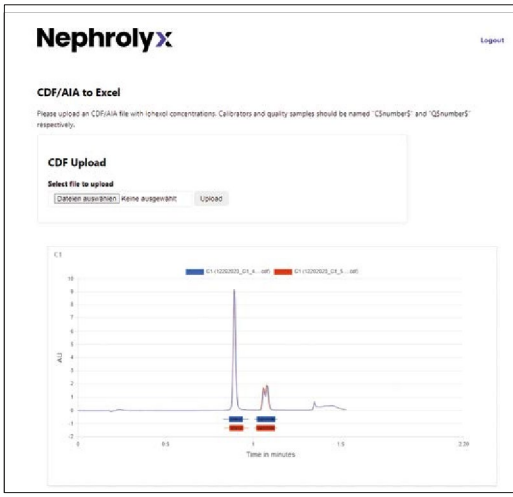
True GFR Measurement by Iohexol Plasma Clearance

The Nephrolyx DNPx software platform enables smooth workflow integration of GFR measurement

Digital Nephrology Platform (DNPx)

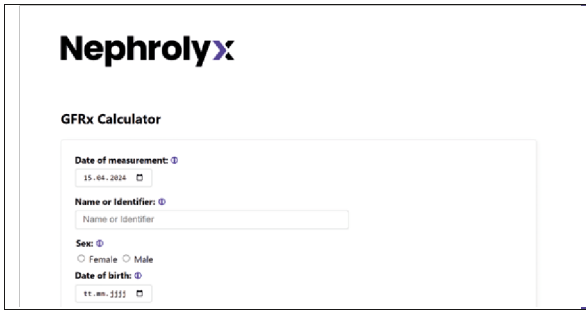
The GFR is determined by tracking the clearance of Iohexol by the patient's kidneys over time. Utilizing data from Iohexol administration, sampling times, and available patient-specific parameters, the mGFR is accurately calculated using a sophisticated algorithmic software application. The Nephrolyx DNPx offers flexible deployment options, including on-premises hosting or as a cloud solution within the facility's private network.

Chromatogram



UHPLC Settings	
Solvent A	UHPLC-grade water with 0.1 % formic acid
Solvent B	UHPLC-grade acetonitrile with 0.1 % formic acid
Autosampler wash solution	UHPLC-grade water with 10.0 % acetonitrile
Flow	1.0 ml/min
Column temp.	50 °C
Inject volume	10 µl
Autosampler temperature	4 °C
Wavelength	250 nm

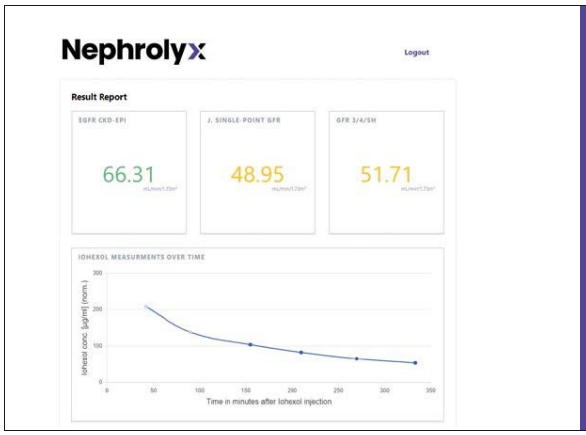
Patient/sample information input



Data transfer from LIMS and UHPLC instrument software can be automated & integrated.

- Manual input possible

Result display



mGFR automatically calculated and reported:

- Area under the curve (AUC)
- Single and multiple-sample protocol GFR results
- Absolut or body surface indexed

The Nephrolyx RUOx is a ready-to-use solution for direct kidney function measurement – mGFR

The test is intended for the in-vitro diagnostic use to quantify the serum iohexol concentration followed by the calculation of the resulting glomerular filtration rate (GFR) as an aid in the diagnosis, monitoring, and treatment of kidney diseases. The principle of the test is based on quantification using UHPLC with UV light detection. The chromatographic separation and elution of iohexol is performed using a linear gradient on a reversed-phase chromatography column.

Nephrolyx RUOx Test kit:
The kit is ready to use and allows up to 152 patient sample measurements in addition to calibration and QC measurements. It has an open-vial (in-use) stability of 14 days. Time to result: less than 3 hours; 90 seconds gradient.

Nephrolyx RUOx test kit contains 6 calibrants and 3 quality control levels for use in the UHPLC analysis. It uses European Pharmacopeia Iohexol Certified Reference Standard as a primary reference material to establish a calibration hierarchy for both the end-user RUO calibrators and the quality control materials according to EN ISO 17511:2021.

Key features and advantages

Providing confidence to physicians & patients

Measuring Glomerular Filtration Rate (mGFR) through plasma clearance of the exogenous marker Iohexol is recognized as the gold standard by the latest Kidney Disease Improving Global Outcomes (KDIGO) 2024 CKD guideline. Consequently, Nephrolyx RUOx delivers the highest accuracy and precision in GFR measurement, enabling physicians to utilize precision medicine to enhance patient clinical outcomes.

Accuracy & ease of use

The Nephrolyx RUOx provides direct GFR measurement with superior accuracy and precision over traditional biomarker-based estimates like serum creatinine, Cystatin C, and others. As a RUO product, it not only meets the highest regulatory standards but is also more user-friendly and easier to perform than lab-developed tests (LDTs) or nuclear medicine solutions. The kit is ready to use and allows up to 152 sample measurements in addition to calibration and QC measurements. It features an open-vial (in-use) stability of 14 days.

Rapid

The Nephrolyx RUOx offers a streamlined workflow that delivers reliable results in less than three hours, making it faster than other mGFR methods.

Reliable data

Operating Nephrolyx RUOx with a compatible UHPLC system enables excellent analytical performance in a fully regulatory compliant workflow (EU only).

Lab perspective:
From requirements to analytical workflow

Required UHPLC specifications
• UPLC class system > 500 bar binary pump system (e.g., Shimadzu, Hitachi, Waters, Agilent, Thermo Scientific) • Autosampler with 4C colling function • UV or DAD/PDA detector • Column heater 50C • 40-100 uL sample loop

Required equipment	
Analytical column	PN 001310 “Nephrolyx UHPLC Column”
Guard column	PN 001320 “Nephrolyx UHPLC Guard Column”
Platform shaker	>= 1,000 rpm
Plate centrifuge	= 1,500 G
Pipette for 20 µl	Systematic error <= 1.0 %, random error <= 0.3 % With reverse pipetting support
Pipette for 180 µl	Systematic error <= 0.8 %, random error <= 0.45 % With reverse pipetting support

The proprietary Nephrolyx guard and analytical columns are used to perform the test with UHPLC; they are not parts of the kit and need to be ordered additionally.

Laboratory workflow

Sample arrival	• Primarily serum tube(s) sent to the lab • Accompanied by sample information
Sample preparation	• 20 µl serum + 180 µl internal standard provided to the filter plate • Mixed and centrifuged prior transferring the collection plate to the autosampler
Sample measurement	• Iohexol quantification by UHPLC technology with UV or DAD/PDA detection • Analytical method operated by UHPLC software
Result reporting	• Quantitative Iohexol result(s) are used to calculate mGFR values by DNPx platform • Result reporting via LIMS integration possible

Analytical specifications

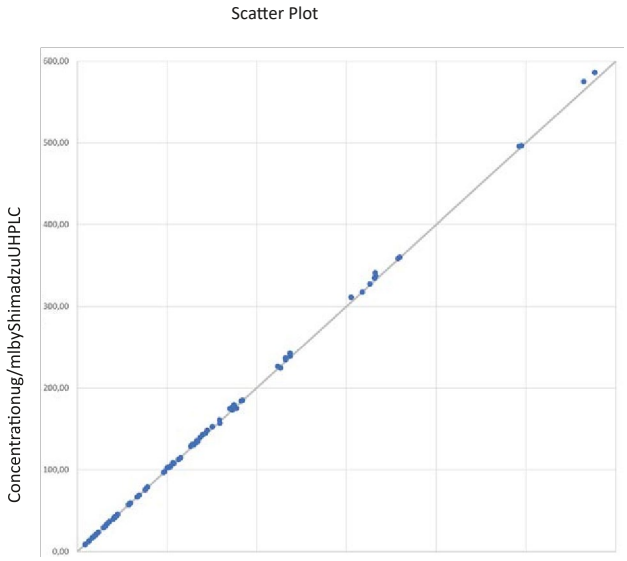


Figure 1 : Correlation between reference and Shimadzu Nexera X3

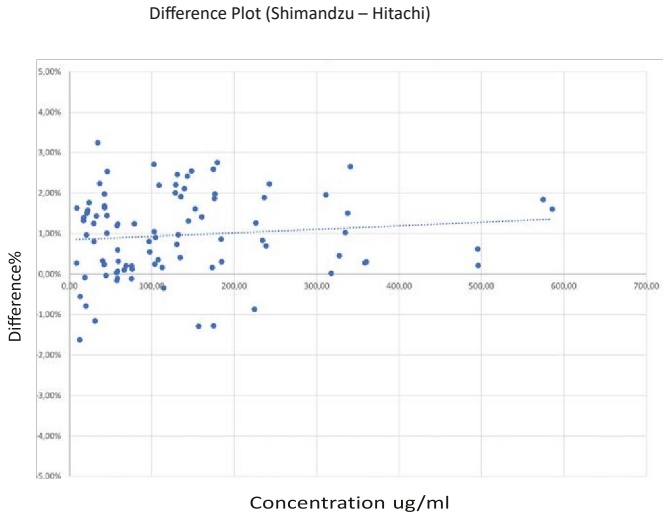


Figure 2 : Difference plot between reference and Shimadzu Nexera X3

Analyte: Iohexol

Measurand: Iohexol in human serum

Characteristics	Value/Description
Measuring range	8.0 to 500 µg/ml
Limit of detection	<= 1.0 µg/ml
Limit of quantification	LLoQ <= 4 µg/ml with CV <= 15 % ULoQ >= 600 µg/ml with CV <= 15 %
Linearity	R >= 0.995 inside the measuring range No hook effect (evaluated up to 4,000 µg/ml)
Accuracy	5 % CV
Repeatability/Reproducibility	Inter-assay: <= 5 % (CI = 95 %) 20-day intra-assay: <= 3 % (CI = 95 %)

Order information

Product No. (PN)	Product name
PN 001100	Nephrolyx IVDx Test Kit
PN 001200	Nephrolyx DNPx Digital Nephrology Basic Platform (1 year license)
PN 001310	Nephrolyx GFRx UHPLC Column
PN 001320	Nephrolyx GFRx UHPLC Guard Column

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