

Transdermal, Continuous, **Measurement of Renal Function**

Transdermal measurement of Glomerular Filtration Rate (tGFR) is used extensively in preclinical nephrology research. MediBeacon's system allows calculation and tracking of an animal's kidney function over time without requiring the animal to be restrained during monitoring.

Determination and monitoring of tGFR is essential for various preclinical studies, e.g. characterization of renal function, assessment of new and existing kidney therapeutics, evaluation of nephrotoxicity, screening of novel chemical or medical agents, and fundamental understanding of kidney function.

Historically, the research standard for measuring renal function has required several blood draws as a function of time and subsequent sophisticated laboratory analysis to measure tracer agent concentrations in each blood sample. This methodology using blood and/or urine sampling is labor-intensive, and multiple blood draws put a strain on the animal.

Utilization of the MediBeacon Preclinical MX and a fluorescent tracer agent is independent of blood sampling, urine collection, and laboratory assays and thus enables streamlined preclinical trial design and execution.

To obtain a quote for the Preclinical MX contact sales@medibeacon.com.

Successful Use in **Nephrology Research**

MediBeacon technology is used by leading medical schools, academic centers, research institutes, contract research organizations and pharmaceutical companies worldwide to enhance preclinical assessment of kidney therapeutics, evaluate nephrotoxicity, and gain fundamental understanding of kidney function in animals.

Research using the MediBeacon preclinical product has been featured at scientific meetings worldwide. There are

>450 peer-reviewed publications and conference abstracts in which this tGFR technique has been used.

For the latest research references see www.medibeacon.com/publications/.



Key Advantages*

- · Longitudinal GFR measurements in the same animal are possible.
- System can be used in conscious, freely-moving mice, rats, and larger animals for up to 24 hours.
- Changes in GFR can be observed earlier compared to endogenous markers.
- Streamlined specimen-free trial design and execution are the result.

*Similar to the system currently in human clinical studies.

System

- Device and patch are affixed to animal.
- Fluorescent tracer agent is administered. (a)(b)
- Software analyzes data from the device.

(a) NOT FOR HUMAN USE (b) The Fluorescent tracer agent is administered IV into the animal.



Optimized Handling(c)

- Higher resolution
- Works on a variety of skin types including dark skin
- Measurements for up to 24 hours
- Improved MB Lab Software user interface
- Status LEDs enhance user experience by indicating:
 - Correct attachment
 - Minimum background measurement time
 - Low battery
 - Memory capacity



(c) Comparison is to previous version of the Transdermal GFR Monitor.

Preclinical MX -**Technical Specifications**

The instrument contains light emitting diodes which excite the fluorescent tracer agent and a photodiode that collects the light emission.

After amplification and digitization, the data sets are subsequently stored in the internal memory of the device. The data is transferred to a PC or Mac via USB connection. The Lab 3 software package is provided with the device. For each transfer, an additional MediBeacon Measurement Code must be used. Measurement Codes are acquired together with each order of consumables. An advanced evaluation software product (Studio 3) is sold separately.

Kits including consumables and measurement codes required for use of the Preclinical MX are sold separately. (d)(e)

(d) NOT FOR HUMAN USE

(e) For information regarding compatible fluorescent tracer agents contact us at sales@medibeacon.com.



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About MediBeacon

MediBeacon is a medical technology company focused on advancing fluorescent tracer agents and transdermal detection technology to provide vital and actionable measurement of organ function.

Measurements of organ function in real-time at the point of care have the potential to provide information that will help healthcare providers to fundamentally change the standard of care in numerous clinical situations. It is our mission to provide doctors with information that empowers them to make better decisions faster. Use of the technology in a clinical research setting offers the possibility to help researchers reduce time to market for life-saving pharmaceuticals by giving them data that may help determine whether and how fast therapies are working.

The U.S. Food and Drug Administration has granted Breakthrough Device designation to the MediBeacon® Transdermal GFR Measurement System (TGFR). Clinical studies in subjects with normal and impaired kidney function are ongoing. The MediBeacon® TGFR is engineered to allow non-invasive detection of the change in patient levels of proprietary fluorescent GFR tracer agent, Lumitrace® (relmapirazin) injection, over time via a sensor placed on the patient's skin. The rate of decrease in the emitted fluorescence from the Lumitrace injection is automatically calculated and displayed on the monitor yielding a measured GFR or kidney function.



MediBeacon Clinical **Study Transdermal GFR Measurement System**

MediBeacon products are in various stages of clinical development and are not yet approved for human use.



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