



Biosensor for Therapeutic Drug Monitoring (TDM) in Point-of-Care Testing (POCT)

a proven technology

Roche Diagnostics is making its highly successful personal blood glucose monitoring technology, as well as some advancements involving immunological detection methods, available for therapeutic drug monitoring (TDM) applications. Designed as a plug-in for handheld personal digital assistants (PDAs), this proven technology can be used bedside to obtain results in 30 minutes or less. POCT provides a fast, cost-efficient alternative to laboratory testing and enables better dosing of drugs, better patient outcomes, and less wasted-drug expense.

Consisting of an immunosensor that uses antibodies to detect drug concentrations in a biological sample, the technology is a valuable aid in ensuring therapeutic efficacy and minimizing drug toxicity. It is particularly useful in cases where drug concentrations are needed to initiate and guide therapy, eliminating the many steps and waiting associated with laboratory-based blood testing.

Based on FDA-approved technology, the prototype device performed well in proof-of-concept tests. And Roche Diagnostics can provide support as your company prepares the new product to make a dramatic entrance into the emerging TDM market.

This technology is available for licensing in all TDM applications except diabetes-related testing, drugs-of-abuse testing, and coagulation. More information is presented below. If you are interested in this licensing opportunity, please contact:

[Nannette Stangle-Castor](#)

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Benefits



- **Versatile:** Can be used for in-patient or out-patient testing, with various types of biological samples (e.g., blood, serum, plasma, urine, saliva), and for a wide variety of drugs.
- **Proven:** Not only has the base technology been used in personal blood glucose monitoring for years, but feasibility studies for TDM using the immunological enhancements already have been completed.
- **Cost-efficient patient protection:** The technology allows immunosuppressants to be administered to transplant patients at the lowest end of the therapeutic range, reducing medication costs and maintaining some patient immune function while still effectively minimizing the risk of organ rejection.
- **High-quality performance:** The technology's low-complexity approach provides laboratory-quality results. Assay accuracy and detection limits are comparable to clinical laboratory analyzers.
- **Portable:** Unlike traditional blood testing, which is performed in a laboratory and often suffers from delays, this technology enables bedside TDM.
- **Fast:** TDM results are available in 30 minutes or less, allowing drug dosages to be adjusted while the physician is bedside—either reduced before toxic levels are reached or increased to avoid transplant failures.
- **Safe:** Because only a finger-stick is needed to obtain blood samples, the technology reduces the risk of venipuncture associated with traditional blood testing.
- **Lower cost:** The technology's innovative and simple design eliminates the need for highly trained technicians to perform the assessment, resulting in an overall cost savings.
- **Easy to use:** The electronic, PDA-like interface is easy to use. Also, wireless connectivity allows for easy printing and automated data management.
- **Easy to manufacture:** The technology uses established, cost-effective manufacturing processes.

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Applications



This technology is particularly useful in any (or all) of the following situations:



- When a drug needs to be monitored closely to provide the appropriate therapeutic range and to avoid toxic overdoses, detrimental side effects, and interactions
- When a drug suffers from extensive pharmacokinetic variability (e.g., busulfan)
- When therapeutic failure leads to serious consequences (e.g., rejection of transplanted organ, deadly infection)
- When the target drug concentration is known but variability may be seen in certain populations (e.g., pediatric or heavily medicated patients)

Additionally, the technology can be used in TDM for a wide range of therapeutic classes:

- **Immunosuppressives** (cyclosporine, mycophenolate mofetil [MMF], sirolimus, tacrolimus)
- **Cancer chemotherapeutics** (methotrexate)
- **Anti-epileptics** (dilatant, phenobarbitol, carbamazepine) Note: This technology enables TDM monitoring during seizures.
- **Aminoglycoside antibiotics** (gentamicin, tobramycin, netilmicin, andamikacin)
- **Bronchodilators** (theophylline)

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Technology Details

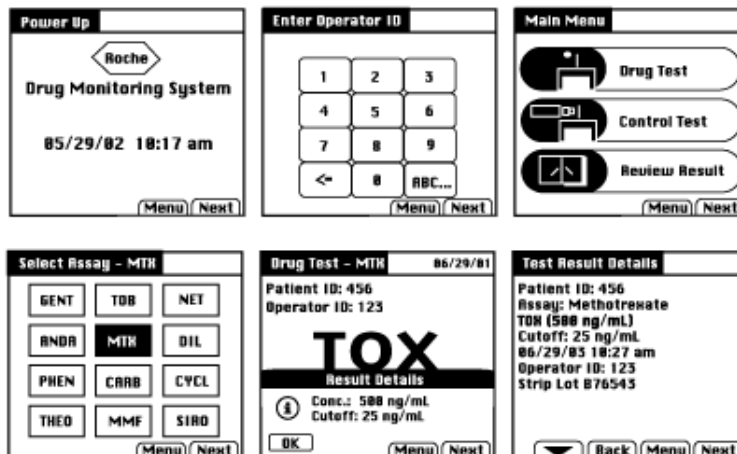
How It Works || Testing || Patents



How It Works

The technology available for [licensing](#) is an electrochemical monitoring concept designed to measure a specific drug in a biological sample (e.g., blood, serum, urine, saliva). The handheld PDA-type device consists of an immunosensor that uses electrodes under bipotentiostatic control to electrochemically test for analytes in samples on disposable strips or cartridges. Immunosuppressive targets as small as 10^{-6} molar can be detected. Results are delivered on the electronic display in 30 minutes or less. Figure 1 presents the six-screen user interface.

Figure 1: User Interface for Electrochemical Biosensor System



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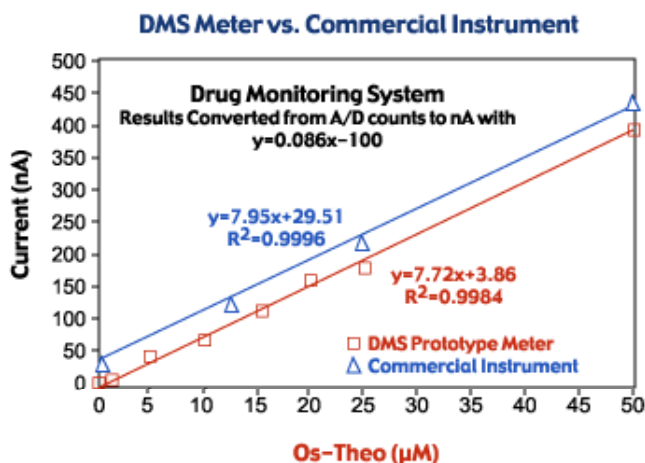
Testing

Feasibility testing already has been completed for two key agents:

- Methotrexate
- Theophylline

Results of this testing were favorable. Figure 2 presents the technology's performance against a commercially available instrument.

Figure 2: Comparison of Roche's TDM System to Standard Laboratory Testing Instrumentation



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Licensing Opportunity



Roche Diagnostics is offering its electrochemical immunosensor for license by qualified companies. As indicated [above](#), these inventions are protected by issued and pending U.S. and world patents and are 100% owned by Roche Diagnostics.

Roche Diagnostics will entertain offers for any field of use **except** diabetes-related testing, drugs-of-abuse testing, and coagulation. As one of the true leaders in diagnostic devices, the company can provide valuable support as the licensee develops the technology into a commercial product.

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