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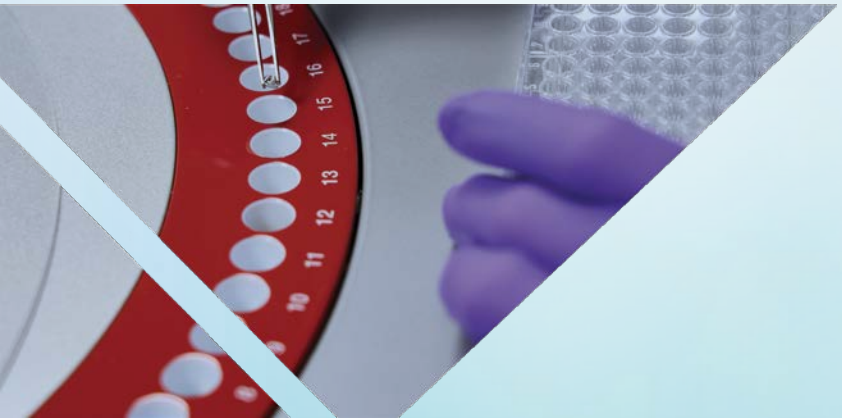
PHARMARON

Bioanalytical Services

For all Molecules and Modalities

Discovery to Development
From Insight to Impact



Your Global Partner in Bioanalysis

End-to-end Services to Accelerate your Pipeline

Pharmaron is a leader in bioanalytical services that delivers high-quality data across small molecules, biologics, biomarkers and integrated study workflows.

With a global footprint of state-of-the-art laboratories and specialist scientific teams, Pharmaron delivers robust, reliable bioanalysis to enable confident decision-making.

Supporting Clinical Confidence

From early discovery screening to regulated toxicokinetic and clinical PK studies, our analytical platforms ensure reliable, reproducible data.

Non-Regulatory Sample Analysis

GxP, TK & PK Sample Analysis

Complete Method Development, Transfer, Qualification, and Validation

IND and NDA-Enabling Animal Studies

Biomarkers

Phase I – III Clinical Sample Analysis

Pharmaron's Experience by the Numbers

20+ years scientific excellence in bioanalysis

Global network of facilities supporting GCP, GLP and non-GLP clients with dedicated bioanalytical teams

Trusted by 18 of top 20 leading pharma, emerging biopharma and biotech partners around the world

17 NMPA, 1 PMDA, 2 EMA, 4 FDA audits in the last **5** years

Expediated turn-around-time 3 – 5 business days from sample receipt

Harmonized platforms and state-of-the-art technology

across all locations including:

- Worldwide ^{14}C and **accelerator mass spectrometry** coverage
- Sciex API 4000/5500/6500+/7500/7500+
- Sciex API 7600/8600 (Q-TOF)
- Sciex 7600 ZenoTOF
- Thermo Q Exative
- MSD S600
- Revvity EnVision 2105
- SpectraMax iD5 & M2e
- Thermo Scientific KingFisher Apex
- Sony ID7000
- Beckman Coulter CytoFLEX
- Luminex 200
- Mabtech ELISpot

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Small Molecule Capabilities

Bioanalytical Expertise for Small Molecule Therapeutics

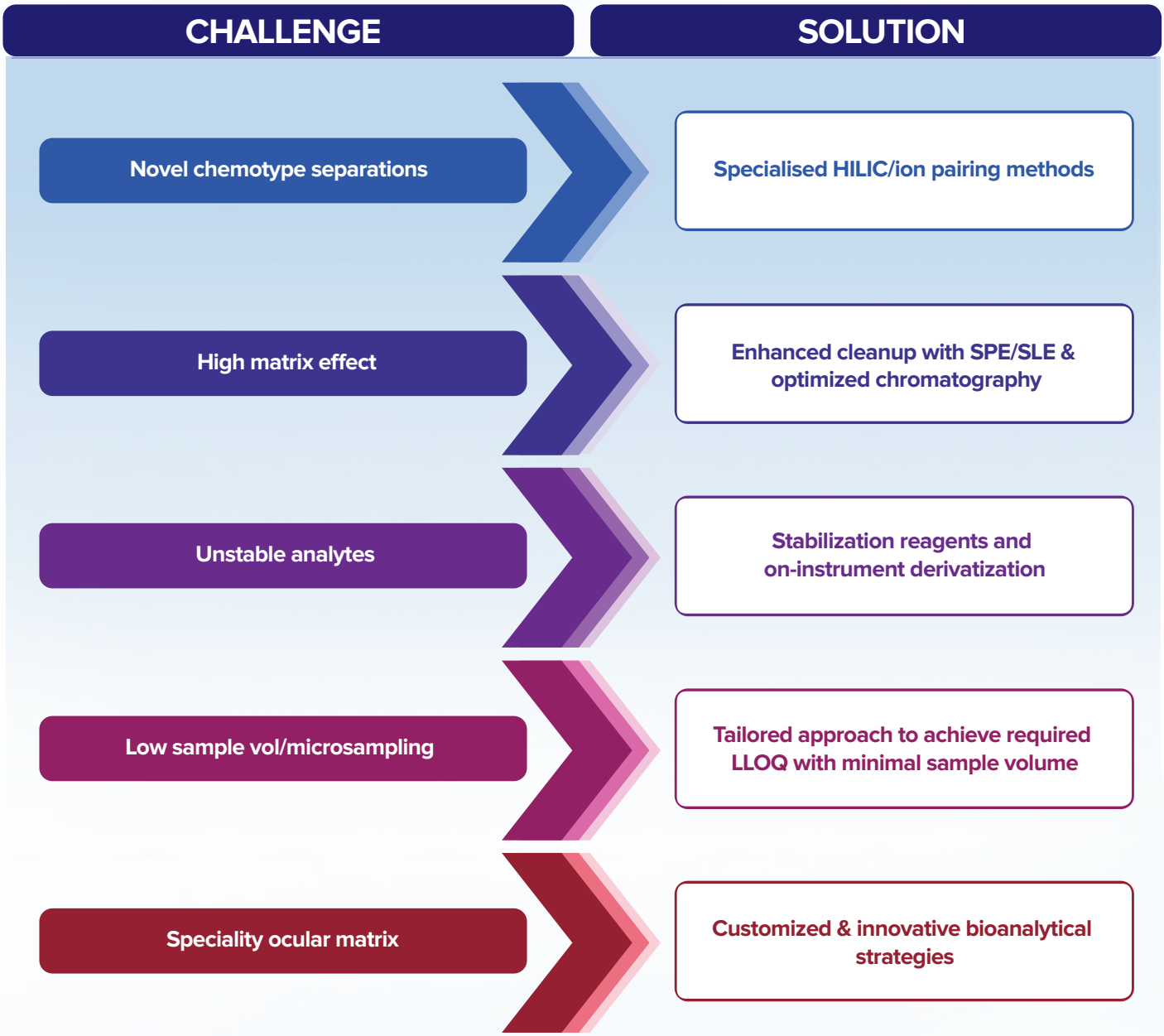
Our small molecule bioanalysis teams deliver high-performance quantification to support pharmacokinetics (PK), toxicokinetics (TK) and ADME studies across multiple matrices relevant to clinical and non-clinical investigations, including plasma, serum, urine, feces, and tissues.

State-of-the-Art Technology and Methodology

Our bioanalytical services combine advanced automation, specialized methodologies, and a range of state-of-the-art analytical platforms to support all phases of development. With automated SPE/SLE workflows, chiral and peptide-focused methods and sophisticated HILIC, ion-pairing, and multidimensional LC solutions, we're equipped to tackle complex modalities with precision.

Solutions-Driven Approaches

We deliver bioanalysis solutions shaped around your science, combining flexibility, speed, and deep technical expertise to solve even the most challenging analytical problems. Our teams have extensive experience across small-molecule therapeutics from 200–5000 Da, including protein degraders, chiral compounds, pathway-targeting agents, peptide analogues, and other beyond-rule-of-five modalities.



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Large Molecule & Complex Modalities

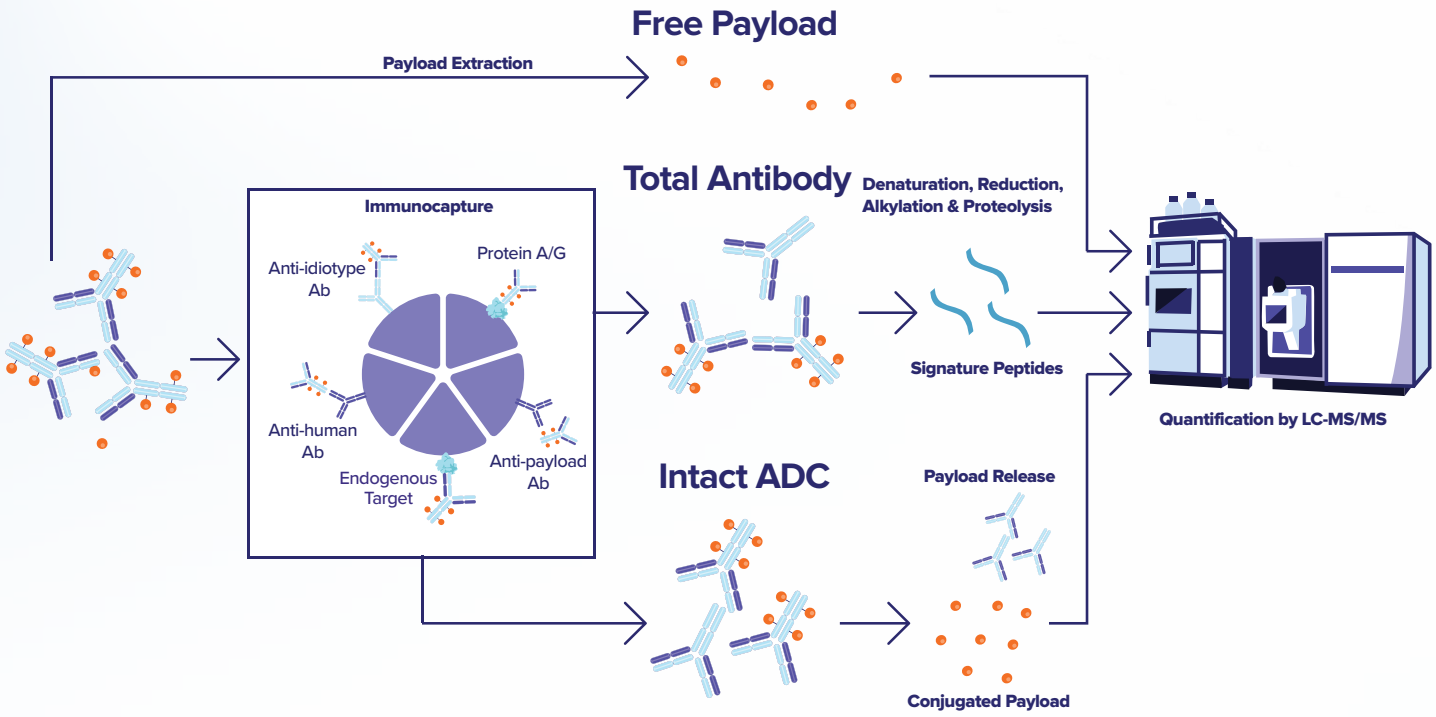
Specialized Solutions

Large molecule modalities continue to shape the future of drug development, with complex modalities such as antibodies, fusion proteins, peptides, cell and gene therapies, and anti-sense oligonucleotides (ASOs), surging to 60% of total projected pipeline value in 2025[1].

Pharmaron combines deep expertise in advanced therapeutic modalities with a full suite of large-molecule bioanalytical capabilities spanning across PK/TK, biodistribution, viral shedding, and immunogenicity assays. We develop tailored assay strategies for complex and emerging constructs, enabling robust, reproducible, and phase-appropriate bioanalysis that addresses the unique structure and behaviour of each therapeutic modality.

[1] Emerging New Drug Modalities in 2025 | BCG

Antibody-drug conjugate (ADC) PK analysis workflow



ADC are a rapidly growing large molecule therapeutic class and we have demonstrated expertise to perform comprehensive PK analysis on discovery, pre-clinical, and clinical samples.

Systemic Exposure & Target Occupancy

Therapeutic modalities differ widely in how they achieve target engagement. Understanding the factors that drive occupancy and influence PK is essential for designing robust, modality-appropriate bioanalysis.

	Primary Driver of Occupancy	Key PK Nuance	Exposure-Occupancy Relationship
Peptides	Peak concentration (C_{max})	Rapid renal clearance	Short-lived
Monoclonal Antibodies (mAb)	Trough concentration (C_{min})	TMDD at low doses	Sustained
Fusion Proteins	Trough concentration (C_{min})	TMDD with slow distribution	Sustained but sensitive to turnover
Bi-specific Antibodies	Ternary complex formation	Proximity-dependent	Hook effect
ADCs	Receptor density & turnover	Payload release rate	Intracellular

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Biosimilars & Biomarkers

Non-clinical Evidence Informing Clinical Outcomes

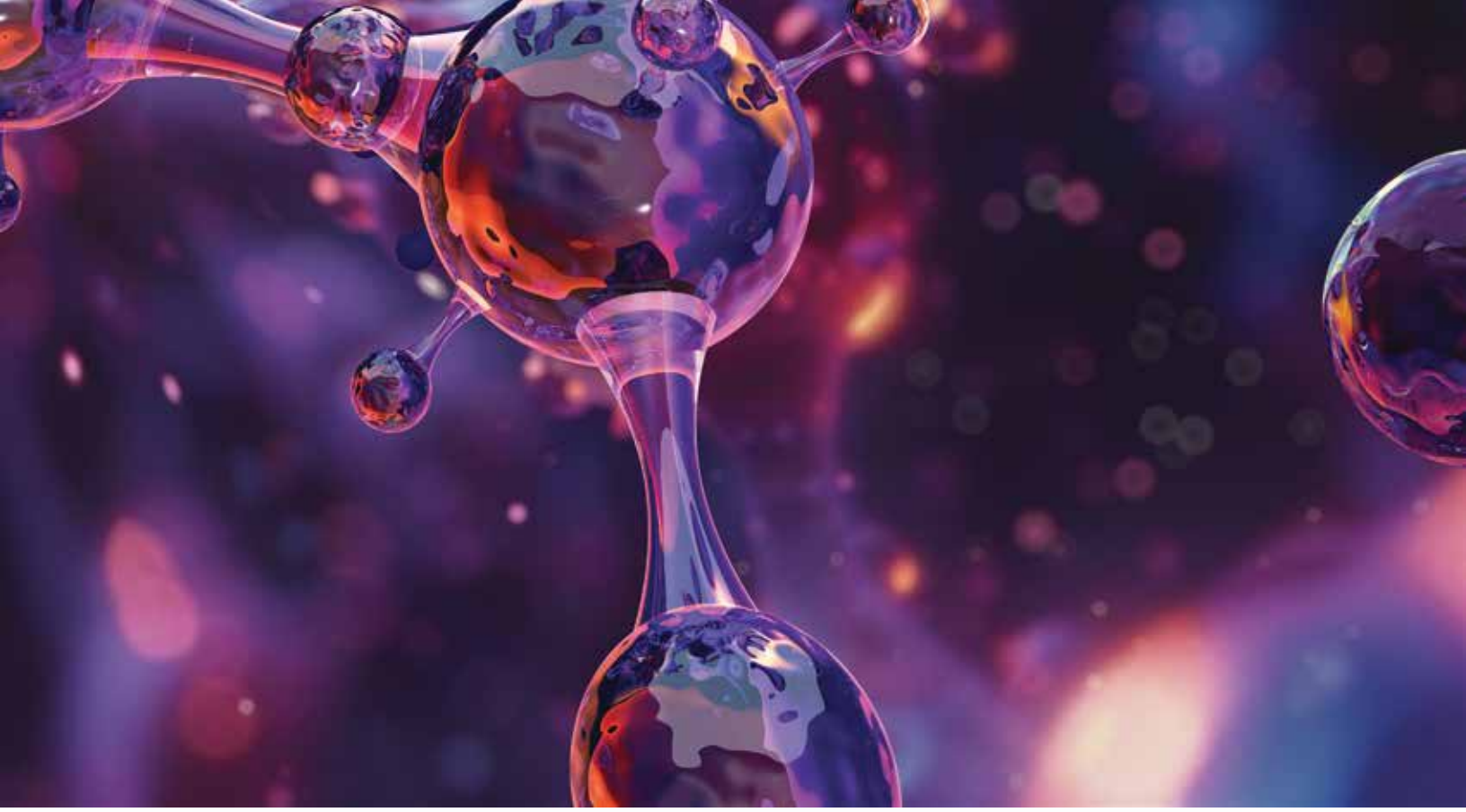
Biosimilar and biomarker development is increasingly supported by New Approach Methodologies (NAMs); human-relevant *in vitro, in chemico* and *in silico* tools that strengthen predictivity while reducing reliance on animal testing in line with the 3Rs (Reduce, Refine, Replace).

Regulators now actively endorse these approaches. The FDA confirms that non-animal data may be sufficient for INDs and biosimilar BLAs when scientifically justified[1], and the EMA supports the regulatory acceptance of validated NAMs and provides structured pathways to integrate them into EU submissions while minimising animal use[2].

Development Feature	Previous Guidance (2015 - 2024)	Current Guidance (Late 2025+)
Comparative Efficacy Studies (CES)	Generally expected (Phase III) to resolve residual uncertainty	Exception, not the rule; generally not required if analytical data is robust
Interchangeability	Required separate 'switching studies'; multiple crosses between drug and reference product	Switching studies eliminated. FDA now considers most biosimilars interchangeable by default
Development Timeline	5 – 8 years on average	Target of 2 – 4 years via streamlined clinical paths
Statistical Rigor	Focused on clinical equivalence margins in large patient populations	Focused on Comparative Analytical Assessment (CAA) and PK/PD equivalence
Evidence Based	Totality of Evidence (ToE) heavily weighted toward clinical outcomes	ToE heavily weighted toward structure-function relationships

Analytical First Paradigm

[1] General Considerations for the Use of New Approach Methodologies in Drug Development (Draft Guidance, March 2026)
[2] Regulatory acceptance of new approach methodologies (NAMs) to reduce animal use testing



Pharmaron helps you determine whether your biomarker strategy meets the standard for context-of-use.

Case studies for biomarker qualification

Exploratory Research	Preclinical Studies	Early Clinical Trials	Lack of Reference Standards	Limited Time and Resource
Early-stage biomarker discovery, mechanism-of-actions studies, or proof-of-concept experiments for hypothesis generation	Target engagement, PD, go-no-go decisions in animal models or *in vitro* systems	Safety, dose-finding or PD endpoints where biomarker data are not used for regulatory decision-making or efficacy claims	When fully characterized reference standards are unavailable, making full validation impractical or impossible	When rapid data generation is needed to inform further development steps and associated risk with less stringent assay performance is deemed acceptable

Case studies for biomarker validation

Late-Stage Clinical Trials (Phase III)	Clinical Diagnostics	Regulatory Submissions	Routine Clinical Use
When biomarker data are used to support pivotal efficacy or safety endpoints, regulatory submissions or clinical decision-making	Where the assay informs patient management, diagnosis, or treatment decisions, necessitating high reliability and reproducibility	When biomarker data are included in filings for drug approval, labeling claims, or as surrogate endpoints	Ongoing patient monitoring or batch-to-batch quality control in a clinical laboratory setting

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Pharmaron Integrated Services

An End-to-End Integrated Solution

Pharmaron delivers fully integrated ADME/DMPK support across the complete R&D lifecycle, combining synthetic chemistry, advanced bioanalysis, ADME/PK studies and clinical pharmacology into a seamless, end-to-end workflow for both small molecules and biologics.

With in-house capabilities and worldwide coverage, we ensure every study is scientifically robust and operationally aligned. Our dedicated sample-collection and handling processes, coupled with unified project management and metabolism strategy, enable confident decision-making and accelerate development through each of the four pillars of modern ADME/DMPK science.

Synthetic Chemistry

- Radiosynthesis $^{14}C/^{3}H$
- Metabolite synthesis
- Cold API synthesis
- Small & large molecules

CHEMISTRY

BIOLOGY

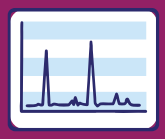
ADME/PK

- Non-clinical/clinical ADME
- Radioactive *in vitro* drug metabolism
- Bioanalysis/discovery PK
- Biomarkers
- Imaging (QWBA/mARG)
- Metabolite profiling & identification

Advanced Bioanalysis

- Clinical ADME/PK/Bioanalysis
- Accelerator mass spectrometry (AMS)
- LSC
- uHPLC/HRMS
- LC-MS/MS (small molecule)
- Immunoassay (large molecule)
- Flow cytometry
- PCR

ANALYTICAL



CLINICAL

Clinical Pharmacology

- Phase I clinical development
- FIH (SAD/MAD/FE)
- TQT, DDI, ethnobridging
- ^{14}C microtracer/macrotracer
- Phase I human ADME & human aBA
- Phase 0 microdosing
- Biometrics (data management, biostatistics)

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Founded in 2004, Pharmaron is a global life science service provider that offers a broad spectrum of research, development and manufacturing service capabilities throughout the entire drug discovery, preclinical and clinical development process across multiple therapeutic modalities, including small molecules, biologics and CGT products.

Driven by Science to Help Our Partners Succeed

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Laboratory Services

Chemistry, Manufacturing & Control

Clinical Development

Biologics & CGT

LabBioBro0426v1

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