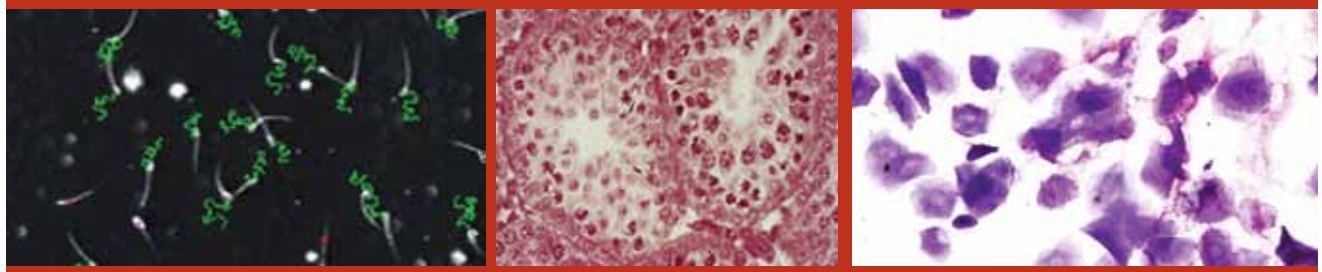


Developmental and Reproductive Toxicology (DART) Services



RTI International has specialized in reproductive and developmental toxicity studies for more than 30 years. Under the guidance of Shelley Tyl, PhD, DABT, we have achieved a reputation for designing, executing, and reporting the findings of complex and comprehensive reproductive and developmental toxicology studies of the highest scientific caliber.

Testing Services

RTI offers extensive drug, pesticide, and commodity chemical testing and reproductive toxicology services, such as the following:

- ICH/FDA Segments I, II, and III reproductive/developmental toxicity studies for Investigational New Drug and New Drug Application submissions
- OECD 414 prenatal developmental toxicity studies
- Standard and extended OECD 421/422 reproductive/developmental toxicity screens
- Multigenerational studies under the testing guidelines of the U.S. Food and Drug Administration (FDA), U.S. Environmental Protection Agency (EPA), and the Organisation for Economic Cooperation and Development (OECD)
- Adult and developmental neurotoxicity in compliance with FDA/EPA guidelines
- Endocrine screening assays, including both in vivo and in vitro designs:
 - Uterotrophic assay
 - Hershberger assays
 - One-generation and in utero/lactational studies
 - Adult male assay

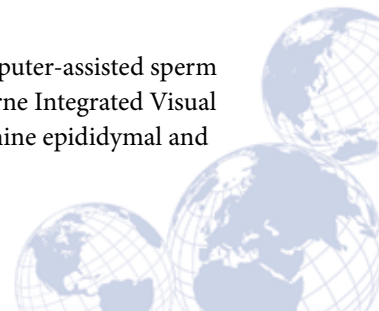
- Pubertal male and female assay
- Aromatase inhibition assay
- Estrogen and androgen binding assays
- Steroidogenesis assay using H295R cells

- Hormone challenge testing
- Validated assays for free and total testosterone, dihydrotestosterone (DHT), androstenedione, estradiol, estrone, progesterone, growth hormone, prolactin, follicle-stimulating hormone (FSH), luteinizing hormone (LH), thyroid-stimulating hormone (TSH), triiodothyronine (T3), thyroxine (T4), cortisol, corticosterone, aldosterone, adrenocorticotropic hormone (ACTH), and inhibin

Capabilities

Our services cover a broad spectrum of assessments, including the following:

- Routine and specialized treatment routes—oral, continuous infusion, intravenous, percutaneous, nose-only inhalation, dermal, intramuscular, transcervical, and rectal
- Andrology assessments with computer-assisted sperm analysis, using the Hamilton Thorne Integrated Visual Optical System (IVOS), to determine epididymal and



- ejaculated sperm number, motility, and morphology in all species, and spermatid head counts to calculate daily sperm production (DSP) and DSP efficiency in rodent species
- Spermatogenic potency evaluation using the spermatogenic index
- Testicular staging and estrous cycle staging
- Fetal evaluations (rat, mouse, and rabbit)
 - External examination
 - Fresh tissue dissection for visceral anomalies
 - Double-stained skeletal evaluation for anomalies in both cartilaginous and ossified bones
- Neurobehavioral assessments (juvenile and adult), including learning and memory
- Direct gavage dosing of neonates
- Acquisition of developmental landmarks
- Clinical chemistry and hematology
- Customized longitudinal endocrine studies using intra-atrial cannulation
- Whole organ cultures or cell culture studies using Sertoli cells, Leydig cells, or granulosa cells
- Real-time data access using the Provantis® Electronic Data Collection System

Support Services

- Custom SAS® statistical analyses
- PK/TK analyses
- Dose formulation and analysis

Working Closely with Our Clients

RTI's technical, research, and development services meet the highest standards of professional performance to satisfy the unique requirements of our clients. We work closely with our clients to identify their requirements and clarify their expectations, including cost and time constraints.

RTI extends its excellence in research and technical services to its business systems and processes, making it easy for clients, subcontractors, and vendors to partner with us. We have the contractual, legal, and business structures to serve any client with projects of all sizes. RTI is a 501(c)(3) nonprofit corporation.

More Information

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