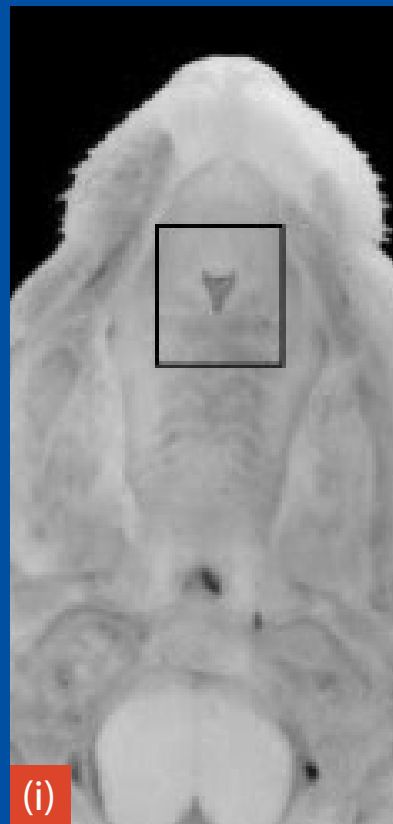


Comprehensive and GLP “Developmental and Reproductive Toxicology (DART)” studies

Focused expertise in conducting DART and specialized toxicology services along with exceptional bioanalytical capabilities for small molecules, large molecules, vaccines and biomarkers.

Developmental and reproductive toxicology studies (DART) are an essential part of the non-clinical dossier for a regulatory submission. Intox, a wholly owned subsidiary of Aragen Life Science, offers an extensive range of services in developmental and reproductive toxicology (DART) to advance pharmaceuticals and biopharmaceuticals. Our expertise encompasses in-depth investigations of the adverse effects of test items on various aspects of fertility and early embryonic development, embryo-fetal development and pre/postnatal development (PPND). In addition, we specialize in conducting various advanced assessments such as neurobehavioral testing and immunologic assays to provide in-depth insights into the functional effects. We conduct tests on a diverse range of rodent and nonrodent species, utilizing various administration such as oral, subcutaneous, intramuscular, intradermal, dietary. Our comprehensive laboratory facilities are equipped to support these studies, and we have a team of regulatory experts who provide guidance and assistance throughout the process.



(i)



(ii)



(iii)

(i): Fissure of Palate (ii): Congenital Twins
(iii): Branched Ribs

Comprehensive GLP DART Studies Conducted at Intox

- Fertility and early embryonic development studies in Rats (Segment I)
- Embryo fetal developmental toxicity (Teratology) studies in Rats/Rabbits. (Segment II)
- Pre and postnatal toxicity studies in Rats (Segment III)
- Combined repeated dose toxicity studies with the reproduction/developmental toxicity screening test
- Extended one generation toxicity studies in Rat
- Multi-generation reproduction toxicity studies

DART for Vaccines

- Pre and postnatal developmental toxicity studies on vaccine candidates, including mRNA/DNA vaccines
- Biodistribution and immunogenicity studies

Start to Finish DART studies on the range of compounds:

Pharmaceutical drugs, Vaccines, Industrial chemicals (REACH), Pesticides, Agrochemicals, Plant Extracts, Medical devices

Testing programs are designed to support product registration as per requirements of

INDIA:

- DCGI (Pharmaceuticals)
- CIB (Agrochemicals)
- DBT (Biotechnology derived)

INTERNATIONAL:

- US – FDA, EPA / OPPTS
- ICH, ISO etc.
- OECD, EFSA, EMA, Redbook 2000
- WHO

Reporting time (including range finding studies, if any) for DART studies:

Fertility and early embryonic development study in Rats (Segment I)

5-6 Months

Embryo fetal developmental toxicity (Teratology) studies in Rats/Rabbits (Segment II)

4-6 Months (Rat) and 10-12 Months (Rabbit)

Pre and postnatal toxicity studies in Rats (Segment III)

15-18 Months

Reproductive/Developmental toxicity screening test (OECD 421/422)

5-6 Months

Extended one generation reproductive toxicity/ Two generation reproductive toxicity studies

15-18 Months

Well Established Standardized Protocols for both Single and Double Staining for Skeletal Evaluation

Examples of Single Staining (Alizarin Red S stain):



Examples of Double Staining (Alizarin Red S and Alcian Blue stain):

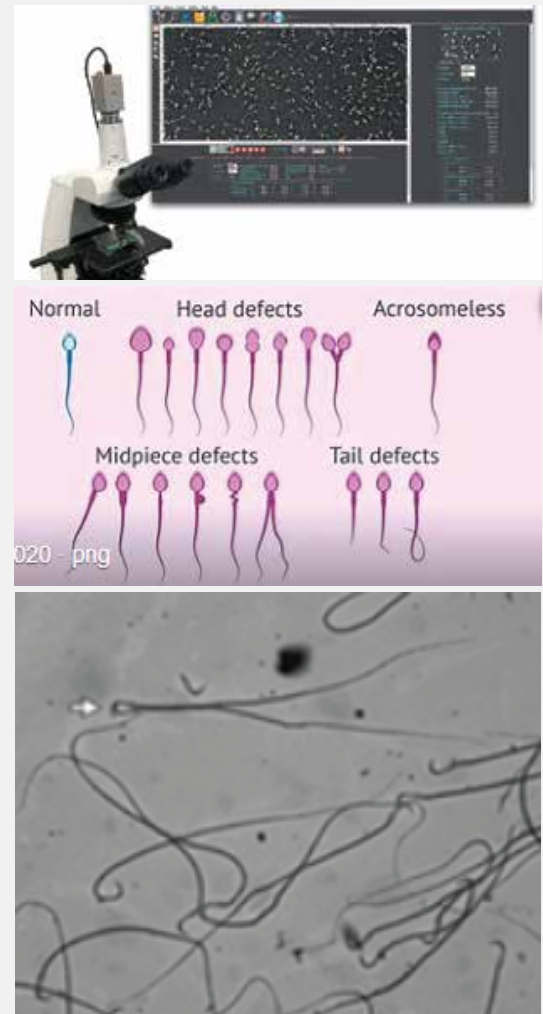


Enhanced Capabilities: High-Resolution Sperm Motility and Morphology Analysis through SMAS system

Sperm motility and Morphology Analysis (SMAS) System is an advanced Japanese CASA System for Precise Evaluation of Sperm Quality. With its user-friendly interface, high-resolution analysis, and an innovative sperm identification algorithm, SMAS accurately measures motility, morphology, and concentration of human and animal sperm. Equipped with a 5-megapixel camera, it eliminates measurement errors during semen examination, offering a remarkable edge in assessing spermatozoa.

Key Highlights:

- Easily Confirm Motile and Immotile Sperm with Visual Results from the Captured Images.
- Experience Unmatched Clarity: Digital Camera Enhances Resolution Fourfold, Outperforming Traditional Alternatives.
- About up to 5,000 motile sperms (a semen sample of about 400,000,000/ml concentration) can be measured in one field of view.
- Cost-less operation is possible by using a MAKLER counting chamber.
- The analysis result can be displayed according to WHO measurement standard (1999/2010) ABCD.
- Traces are color-coded according to sperm velocity to facilitate visualization.
- Custom category classification / cut off filter available.
- Analysed results and traced images are automatically saved for convenient record-keeping.



Track record of performing DART studies on vaccines and other molecules:

| Study Title | Guideline Followed |
|--|--|
| Prenatal and Postnatal Developmental Toxicity Study in Rats with Assessment of Immunogenicity and Bio-distribution (Covid DNA Vaccine) | WHO Technical Report Series, No. 927, 2005 |
| Prenatal and Postnatal Developmental Toxicity Study in Rat (TdaP2 Vaccine) | WHO Technical Report Series, No. 927, 2005 |
| Prenatal Developmental Toxicity Rabies Vaccine (inactivated) and H1N1 inactivated / attenuated Vaccine | OECD/ICH/WHO |
| Prenatal Developmental Toxicity of EX-Vivo cultured human mesenchymal stem cell in Rat | OECD/ICH/WHO |
| Reproduction / Developmental Toxicity Screening Test of Implant mammaire monobloc® Silicone SoftOne®-HP (Haut Profil) 265 MT (micro texture) in Wistar Rat | OECD No. 421, ISO10993-Part 3 and ISO10993 Part 12 |



About Intox:

Intox Pvt Ltd. is a wholly owned subsidiary of Aragen Life Sciences, a leading R&D and manufacturing solutions provider, for the global life sciences industries offering integrated or standalone solutions for small and large molecules. Its OECD GLP-certified and AAALAC-accredited test facility has conducted over 15000 GLP studies and has a successful track record of data submission to global regulatory authorities in USA, Canada, EU, UK, Brazil, Argentina, Japan, India, Australia, and China.

Let's begin the
Conversation

E: bd@aragen.com
W: aragen.com / Intoxlab.com
[in](https://www.linkedin.com/company/aragen-life-sciences) /company/aragen-life-sciences
[f](https://www.facebook.com/AragenLifeSciences) /AragenLifeSciences



India • USA • Netherlands • Japan • Italy • S Korea