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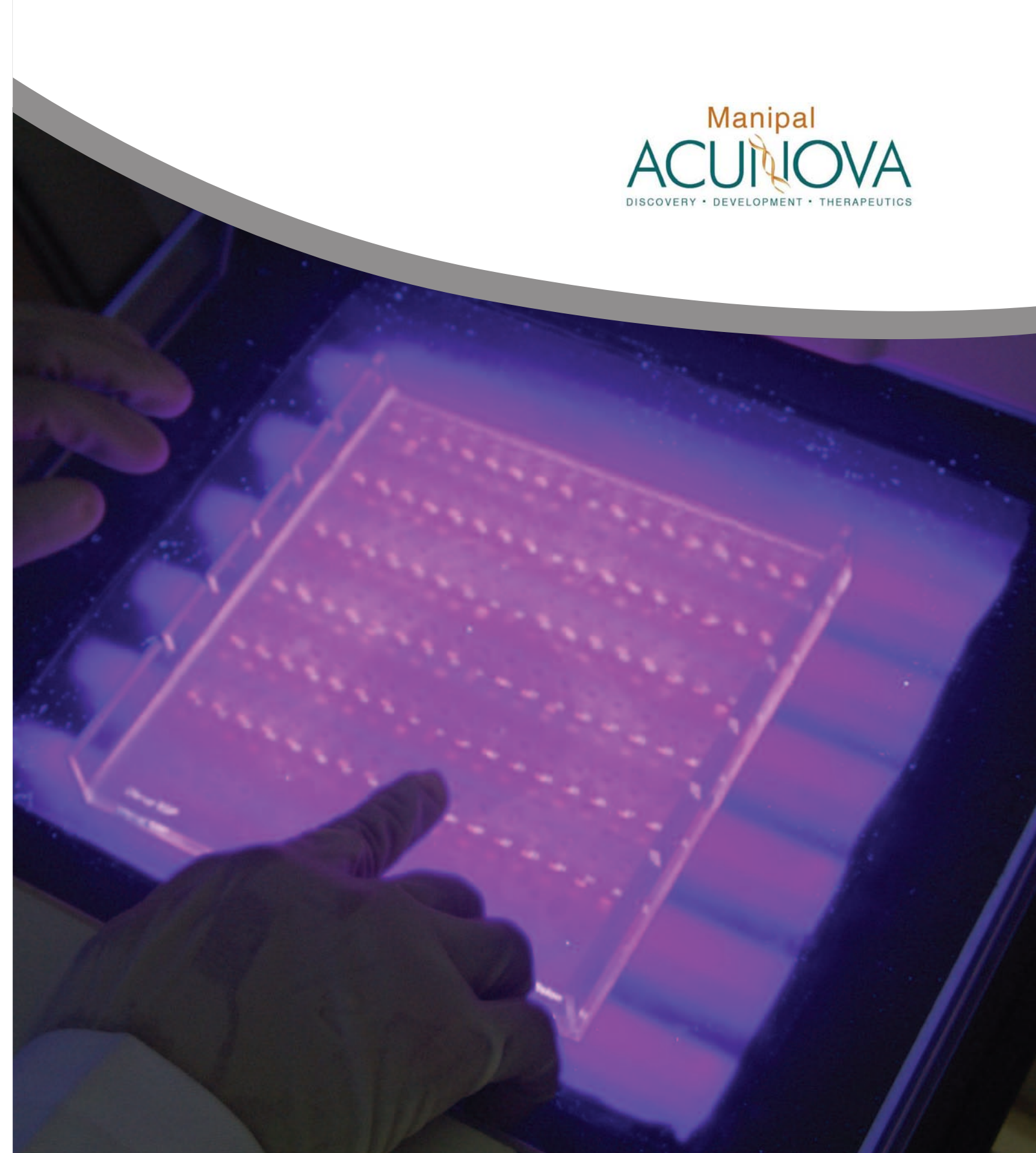
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Manipal AcuNova derives its laboratory expertise from its parent Manipal. Manipal has the largest network of Teaching Hospitals with 11 hospitals, 1300 doctors and 7000 beds. Manipal is engaged in health sciences education and research with campuses in India Nepal and Malaysia. Manipal has a strong record in quality and a successful track record for 53 years. Manipal AcuNova is the research arm of the Manipal Group.

Manipal AcuNova's mission is to bring the India intellectual advantage to drug discovery, bring speed in clinical development, bring new drug therapy devices to market and create an ethical research institution valued by clients, researchers & community.

Our clinical reference lab offers to pharma and biotech clients laboratory services at all stages of clinical development- from pre-clinical to phase IV trials. We conduct pharmacokinetic studies, support clinical trials and provide advanced molecular and esoteric diagnostic services to patients. We offer custom tailored studies using molecular and cellular sciences. We conduct research in diagnostics. These unique capabilities make us a "thinking lab".



Clinical Testing Lab for BA/BE studies

Manipal AcuNova offers drug metabolism, pharmacokinetics and BA/BE studies. The CTL offers safety testing parameters in Clinical chemistry, Hematology, Urinalysis, Serology and also runs tests for drugs of abuse and enables Manipal AcuNova to have a volunteer database screened and ready for studies. Volunteer biometrics, screening data and test records are integrated with study data using a state of the art LIMS Clin-one ®.

Clinical Trials Lab Service

Manipal AcuNova CRL supports every stage of clinical trials. We provide expert scientific advice and medical consultancy in selecting tests required to monitor a specific study plan. A dedicated project coordinator studies the requirements specific to a trial, designs lab kits, prepares them in a visit wise shipping container, labels sample collection tubes along with pre-approved shipping labels and documents. A specific client code as well as pass word is provided to the study sites and the sponsors.

Visit wise test menu schedules are pre-entered for the sponsor's convenience. After collecting the sample, dispatch airway bill number is entered in the fields of the LIMS web accesses to pre-register the sample. This helps us to track the sample. Once

the samples are received we report within a specific turn around time. The site as well as the sponsors using the password enabled web accesses will be able to peruse results on the net.

As a standby measure we will also send the generated report by fax and email. We offer lab services to suit our sponsor's needs. We manage trials where clinical samples may need testing at an accredited lab or be sent to a central lab, to integrated services, including providing of central lab service, regulatory consultation, to import kits, reagents, samples, required for clinical research. The systems laid out are at par with the best in the world.



Central Lab facilities

We have set up a Central lab at Bangalore with world class instrument platforms like Olympus for Biochemistry analysis and Beckman Coulter haematology analyser. Our SOP's are designed to comply with ISO/CAP requirements. The temperature and humidity of our labs is climatically controlled with efficient round the clock monitoring. This environment ensures equipment functionality at its peak and delivers consistent performance day in and day out. We deploy a contemporary LIMS-STARLIMS functioning on an Oracle database.

Quality Assurance

At Manipal AcuNova implementation of strict quality systems is a norm and it by far enhances the quality of the work carried out. By implementing standards and systems which comply with CAP and NABL standards from sample transport to reporting (method validation & IATA regulations of sample transport to CFR and HIPAA compliance in reporting). We ensure that we have a world class system capable of withstanding the most rigorous audit requirements.

Our documentation is designed as per ISO:IEC 15189. Daily QC check with a world wide peer and method group evaluation is carried out. We have applied for CAP and NABL accreditation. We participate in EQAS programs for CAP, NABL and NEQAS; Biochemistry programmes from CMC Vellore, Biorad; Hematology programs with AIIMS and Excel Surveys; Molecular Biology with NSRL and DGKC; and for Histopathology and cytogenetics, interlab comparisons and peer reviews are followed.

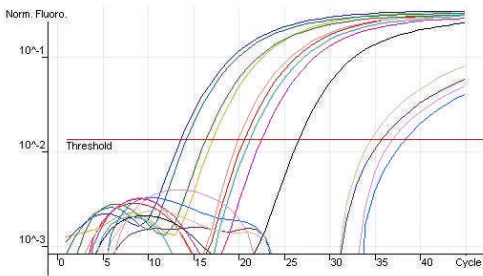
Validated LIMS system

StarLIMS helps in electronic logging and tracking of samples, logistics supplies ensuring that first in first out (FIFO) is followed. All laboratory activities from training record to SOP's are available on the web. All analytical equipment are web integrated passing data directly to the web, which is then released after Quality Assurance. Our LIMS enables scheduling laboratory activities, and ensures flexible reporting procedures. We also provide rapid data access by fax and e-mail. We use Infosys as consultants to establish CFR 21 part 11 compliant systems. The IT Infrastructure is from IBM and is interface able with systems of CDM



Advanced Molecular Diagnostic lab for disease diagnosis

The AMD is of innovative design and is located at Bangalore. We have PCR machines from Biorad TM, a Real time PCR machine from Artus, state of the art gel documentation and electrophoresis systems. The lab offers viral loads for HIV, HBV, HCV using real time PCR, genotyping HCV and HBV using sequencing and nested PCRs. We use a DNA sequencer for detecting congenital genetic defects, SNP's and mutation analysis. Other tests to be done would be immuno-fluorescence assays, cytogenetics and Flourescent In Situ Hyridisation (FISH).



Real Time PCR Graph

The AcuNova Team Advantage

We have undergone audits by national and international clients. We successfully support pharmaceutical industry in custom specific research. We have been able to lay down highly process and quality oriented design for all lab operations. The systems and processes are well laid out and adaptable. Being a part of a CRO we understand rigors of clinical trial testing. We have a range of test menus and would incorporate any new test as required. State of art specialty equipment, LIMS, an Oracle based database help implement our quality systems. Project specific staff will be allotted to enable one point contact. A CDM team is available to help with data mining and processing.

Manipal AcuNova Central Lab has been set up to international quality standards and has been designed as a one stop shop for providing solutions to Pharmaceutical and Biotech industry. We provide quality at an affordable cost and are committed to ethical research. We aim to be a CRL with a difference our USP is to be a thinking lab providing intellectual insights into our projects. We look at our customers as long term partners and are keen to help bring accuracy and innovation into drug discovery.

