



NEOGEN LABS		
Focus		Singular focus on Newborn Screening. Our competencies lie in this field and our goal is to be on par with the best NBS Labs in the world.
NEWBORN SCREENING TESTING		
Screening Panels		<p>Based on the ACMG Screening Panels that form the basis of population screening efforts across the world. The panels were presented in May 2006 in a paper in the Journal of American Academy of Pediatrics, <i>"Newborn Screening: Toward a Uniform Screening Panel and System"</i></p> <p>Originally, there were 54 disorders in primary and secondary disorders (including Hearing) in the ACMG panels which have been increased to 56 (SCID and CCHD). NeoGen Labs screens for over 50 of these disorders.</p> <p>Additionally, we offer SCID and LSD testing in partnership with PerkinElmer Genetics.</p>
TMS Tandem Mass Spectrometry	Technology	Technology Licensing Agreement with PerkinElmer Genetics, (formerly Pediatrix Screening), Bridgeville, USA, the world's leading company and pioneers in Newborn Screening using Tandem Mass Spectrometry.
	Interpretation	Interpretation of results is based on a proprietary database of over 4 million samples which is not publicly available.
	Backup	The PerkinElmer Genetics Lab, USA executes the same protocol as NeoGen Labs and serves as a backup lab. No NBS facility in India has access to a similar interpretation database, comparable technology or back up services.
	Training	<p>Dr. Cariappa has been trained on interpretation by Dr. Donald Chace, a pioneer in developing TMS interpretation. Dr. Chace has been awarded the Guthrie Award, the highest recognition in the field.</p> <p>He has also had additional training in interpretation at Mayo Clinic, USA, under Dr. Piero Rinaldo, and in New South Wales, Australia, under Dr. Veronica Wiley.</p>
Biochemical Testing	Technology	NeoGen uses Fluorescent Enzyme Immuno Assay (FEIA) technology from Labsystems in Finland. Additionally, as a backup and to confirm results, we also use validated ELISA technology from Bio-Rad.



TAT	TMS	Any TMS sample that meets our acceptance criteria and reaches our lab by 1 PM will be reported by 8 PM the same day. If notified that it is a sick or NICU baby sample, results can be reported even earlier.
	Biochemical	Sample Receipt: Mon/Wed/Fri Reported: Tue/Thurs/Sat Sample Receipt: Tue/Thurs/Sat Reported: Thurs/Sat/Tue
	Sunday Screening	In special circumstances (For example, a sick infant) where time is of essence, we will do a special Sunday (or holiday) run, if required.
Sample Storage		We store DBS samples indefinitely. If in the future the sample is required for further DNA or other testing, these residual samples can be provided with appropriate authorization.
Quality Control	NSQAP	We participate in the Centers for Disease Control and Prevention's (CDC) Newborn Screening Quality Assurance Program. NeoGen Labs have been participating in their Proficiency Testing and Quality Control for the past 8 years, since inception.
Filter Paper		Today, we are the only newborn screening laboratory in India that contracts with the two companies in the world that manufacture the special barcoded filter paper required to collect the sample for NBS. The collection form that is custom manufactured for us meets the CLSI standards, <i>"Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Sixth Edition (NBS01-A6)"</i> These collection forms are barcoded so that samples are correctly identified when detached from the demographic information on the form.
Accreditations	CAP	NeoGen Labs has been certified by The College of American Pathologists (CAP) specifically for its Newborn Screening Services. Accredited until December 31, 2016. CAP meets the ISO 15189 criteria for medical laboratories.
	NABL	NeoGen Labs has been certified by The National Accreditation Board for Testing & Calibration Laboratories specifically for its Newborn Screening Services. All screening tests performed at NeoGen Labs are included in the scope. Certificate No. M-0786. Issue Date: June 8, 2015 Valid Till: June 7, 2017
Collaborative Research	Region 4	We were the only participants from India in the Region 4 Genetics Collaborative , a worldwide effort, led by Dr. Rinaldo,



		Mayo Clinic, USA. The details of the study were published in a paper titled " <i>Clinical validation of cut-off target ranges in newborn screening of metabolic disorders by tandem mass spectrometry: A worldwide collaborative project</i> (PubMed ID 21325949)", which acknowledges our contributions. This effort is ongoing and we continue to participate in it.
Staff Training		Our laboratory team is led by Dr. Rohit Cariappa who has worked in organizations in the US and Australia and holds a PhD. in Biochemistry and Molecular Biology from the University of Florida. All our staff have undergone Quality Training. Some of them have been sent to NBS labs in Australia and USA to train in laboratory operations and interpretations.
Experience	Goa	NeoGen Labs also managed the Goa NBS program (India's first comprehensive newborn screening program), in collaboration with the Goa government from 2008 to 2013, screening every baby born in a Goa state healthcare facility for over 50 disorders. NeoGen Labs managed the program, to international standards, for five years, and screened approximately 48,000 infants.
Confirmatory Testing		We work with our clients to identify the best third party labs for confirmatory testing. For some of the testing we use the PerkinElmer Genetics Lab in the US. For other disorders, we work a mix of local and international labs. We do not provide confirmatory or GCMS testing ourselves to prevent a conflict of interest which may influence reporting of differing screening and confirmatory results, or profit motives present in private labs.
Addressing Errors and Non Compliances		In spite of our best efforts, errors and issues occur. In each of these cases, we do a Root Cause Analysis to determine and address the issues. We also inform the clients the steps we have taken.
Accountability		We are open to audit anytime to our clients.
Technology Evaluations		We are constantly evaluating and investing in the best technologies to improve Newborn Screening.
SERVICE		
Service Response		We respond to queries from doctors or patients as soon as we get them. Our Chief Scientist and CEO are available anytime by cell phone or email and you will usually get an answer to your query immediately or within 24 hours.



Continuous Process Improvements		We continually evaluate our processes against the best in class. Our staff are trained in the best NBS labs in the world and bring back with them that learning and knowledge. We also attend major NBS conferences across the world to keep abreast of new NBS technologies and advances in Newborn Screening.
Notifications		Customers are notified by email or SMS when samples are received. All positive cases are reported by a telephone call to the attending physician, as soon as the results are known and before the final report is generated.
Data	Data for Research	Any customer of ours can request their screening data for research or papers. We archive all our testing results and reports.
CLIENTS		
Hospitals	India	Some of the hospitals we work with are Breach Candy Hospital, Kokilaben Dhirubhai Ambani Hospital, Nanavati Hospital, Hinduja Hospital, JJ Hospital, KEM, Reliance H N Hospital (Mumbai), Manipal Hospital, Fortis La Femme Hospital, Baptist Hospital, St. Johns Hospital (Bangalore), Rainbow Children's Hospital (Hyderabad) and Fortis La Femme (New Delhi). Additionally, we work with more than 300 hospitals and maternity homes across the country which have NBS requirement.