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LifeCell launches ‘Transformational’ Newborn Screening Program

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World's First to launch Integrated DNA testing for more accurate results & reduced false positives

LifeCell International, India’s premier stem cell bank and mother & baby diagnostics company today announced the launch of “RightStart” - the world’s first Integrated DNA testing for Newborn Screening to detect over 50 medical conditions. This technology has been proven to be more accurate than current screening methods and has also been found to drastically reduce the false-positive reporting thereby avoiding unnecessary follow-up tests and anxiety of the parents.

In current process of newborn screening, a few drops of blood are obtained through heel prick from the baby’s heel, usually 48 hours after childbirth, and is analysed by profiling a specific set of metabolites present in the blood. If an abnormal metabolic profile is found further testing is recommended for confirmation.

The confirmatory test would need an additional sample to be taken once again from the child. Since most routine screening labs do not have DNA testing capabilities, the child is referred to specialised labs leading to further delays in diagnosis & treatment apart from causing further agony for the parents. The DNA based test is considered a gold standard and is most reliable for confirmation as it does not get impacted by interferences such as medications, nutrition, temperature, or preterm status.

LifeCell’s “RightStart” Newborn screening, which adopts an integrated DNA testing approach, does not require an additional sample since a portion of the sample collected initially can be used. Also, no additional costs would need to be incurred by the parents. “RightStart” provides more accurate results and also saves time & effort enabling a speedy diagnosis to initiate treatment. More importantly, the parents are alerted to the risk only if the DNA tests are positive thereby reducing parental anxiety.

Ishaan Khanna, CEO of Diagnostic & BioBank Divisions, LifeCell International said “As a leader, we always bring the first and best to the country and “RightStart” is another milestone achievement. For the first time, over 50 conditions can be tested with ‘RightStart’s integrated DNA testing in the country with a faster throughput and higher accuracy of test results”.

Citing an example of a condition called Congenital Adrenal Hyperplasia (CAH) it was observed that less than 10% of alarms

raised with current screening technologies are finally confirmed as being truly being affected by the condition with DNA testing. Hence with DNA testing, the predictive power increases to 100%1, thereby eliminating any false alarms.

Commenting on the launch of RightStart Dr Vrajesh Udani, Consultant in Child Neurology and Epilepsy, Hinduja Hospital & Saifee Hospital, Mumbai said “RightStart is an initiative by LifeCell where a positive report on newborn screening is automatically subjected to a confirmatory test. This will eliminate false positives, which is very welcome. False positive reports in newborn screening cause unwanted concerns and sometimes unwarranted treatments. I’m happy RightStart will help to reduce such false alarms”

Dr Uday Pai, Paediatrician & Neonatologist, Former President, Indian Academy of Paediatrics (IAP) added, “Launch of RightStart is a welcome initiative by LifeCell and I’m sure this will surely help in better accuracy of results with integrated DNA testing and also drastically reduce the parental anxiety and delays arising due to false positives”

With LifeCell launching the new RightStart Newborn Screening program the laboratory facility at Chennai has been upgraded with complete capabilities to perform these specialized DNA testing in-house.

LifeCell anticipates a substantial increase in the adoption of the RightStart Newborn Screening and is collaborating with PerkinElmer, a global market leader in newborn screening. LifeCell will use PerkinElmer’s fully automated and high throughput analyser - the Genetic Screening Processor® (GSP) instrument, a first by a commercial lab in India. Also as another first-in-India, LifeCell will incorporate PerkinElmer’s next generation NeoBase™ 2 non-derivatized MS MS kit, which can screen for all the common amino acid, organic acid and fatty acid oxidation, as well as purine and peroxisomal metabolic disorders – more than any other commercial kit available in the market today.

Further LifeCell had tied up with Dr Mary Seeterlin, who has a decade of experience in newborn screening program at the Department of Public Health in Michigan and is the co-author of several guidelines and publications on the subject, as a consultant to the program.

“LifeCell’s mission is to improve outcomes for newborns in India, giving them the best start at birth. Towards that goal, we’ve made a major step forward by bringing in the world’s best partners, equipment, consumables, advisors, and testing programs. This centre-for-excellence will help bring together the power of metabolomics and genomics platforms to provide a holistic approach towards screening of rare disorders” said Mayur Abhaya, Managing Director, LifeCell International.

India is the world’s largest birthing country with over 25 million births a year and is, unfortunately, having the highest number of infant mortality ratio too. A large number of these deaths can be prevented by screening newborns at birth for a variety of inborn genetic and metabolic disorders, even before the symptoms start showing up so that they can be managed at an early stage to reduce or even eliminate the burden of disease”.

Globally millions of babies are screened through nationwide programs in over 60 countries every year. However, in India, the adoption of newborn screening has been weak largely due to low awareness and also due to the lack of reliability of the test results.