"Because of newborn screening, we still have hope and life and joy."

-Parent of a child with infantile onset Pompe disease, identified following newborn screening





Newborn Screening Platform Powered by Digital Microfluidics



Newborn screening gives every baby the chance to experience the healthiest possible start in life.

When it comes to some genetic diseases, days matter. Screening babies for these diseases at birth enables early diagnosis and can lead to earlier initiation of treatment – dramatically impacting the outcome for the baby.

SEEKER®

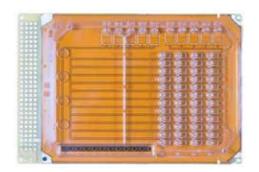
is a flexible throughput laboratory solution performing multiple assays at the same time using just one punch from a newborn dried blood spot (DBS) specimen. SEEKER tests thousands of babies each day around the world.



Advantages of Digital Microfluidics

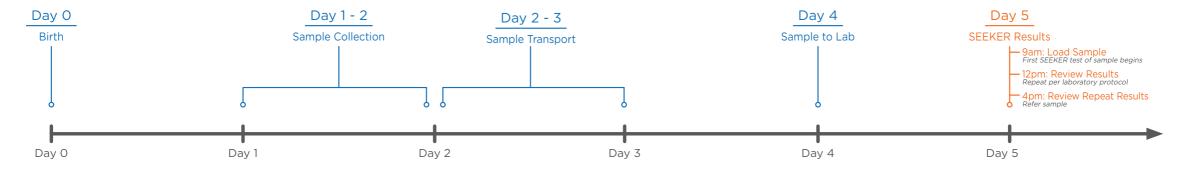
SEEKER utilizes digital microfluidics technology to quickly move separate droplets by electrical control on a cartridge. Advantages include:

- Multiple assays from one DBS punch
- Small, portable instruments with faster time to results
- Flexibility for future assay expansion on same cartridge and instrument



Many of the technology inventors are on the Baebies team. Baebies' technology is protected by more than a hundred patents.

From heel prick to referral, SEEKER accelerates delivery of reported results.



Leverage the Power of Digital Microfluidics to Save Time and Money

Accurate and Reliable

- No reported false negatives
- All electronic workstation so your lab is always up and running

Cost Effective

- Installs easily into your lab workstation fits on a standard lab bench
- No renovations needed just plug it in
- No daily platform maintenance or maintenance contracts

Incredibly Fast

- Screening results in under 3 hours
- Up to 480 samples per day per SEEKER workstation
- Time from punch to referral in as little as one day...days matter

Everything Your Lab Needs for Screening in One Small Workstation



Instruments

Software & Desktop PC

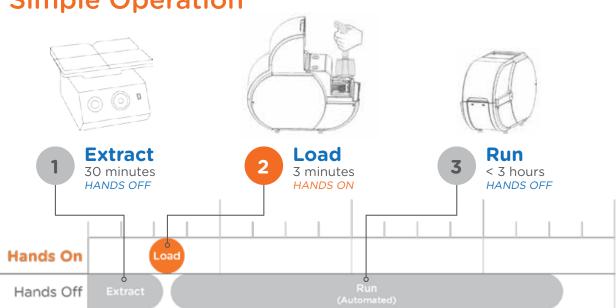
Consumables

Accessories

Designed for Ease of Use and Quick Implementation

- Minimal hands-on time and no advanced training required
- Simple cross training of all staff for flexible staff rotations
- Easily integrated with standard LIMS systems
- Prompt customer service always

Simple Operation





SEEKER LSD Reagent Kit - IDUA|GAA|GBA|GLA

SEEKER is the first FDA-authorized and CE-marked newborn screening platform for lysosomal storage disorders (LSDs).

LSDs are inherited disorders characterized by lack of specific enzymes to break down sugars and fats. The buildup of excess fats and sugars affects different parts of the body, including the skeleton, brain, skin, heart, and central nervous system. While there are currently no cures for LSDs, there are treatments available for some of the disorders that can greatly improve the quality of life for the patient.

Newborn screening for lysosomal storage disorders enables early diagnosis and can lead to earlier initiation of treatment.

SEEKER quantitatively measures the activity of lysosomal enzymes from newborn dried blood spot specimens. Reduced activity of these enzymes may be indicative of:

MPS I • Pompe • Gaucher • Fabry

This kit features:

- Multiple assays performed with just a single punch from a dried blood spot
- Fast screening results in under 3 hours for time-sensitive conditions
- Flexible throughput with up to 480 samples per day per workstation

SEEKER LSD Reagent Kit - IDUA|GAA|GBA|GLA is available in the USA and territories which accept CE Mark. Please check with your local sales representative for local availability/product registration and regulatory status.



Second Tier Sequencing

Baebies offers second tier testing for newborn screening (NBS) programs using the original dried blood spot sample to perform next-generation sequencing. First tier newborn screening tests are designed to maximize sensitivity such that all potential cases are identified. The addition of second tier testing reduces false positives and thereby reduces the burden of referral.

Newborn screening programs have several options when it comes to second tier tests including biochemical testing or next-generation DNA sequencing. Baebies provides second tier sequencing in our CLIA-licensed lab as a comprehensive test which can inform treatment and can substitute for multiple biochemical tests.



The Power of Next-Generation Sequencing

- Reduce false positives. Save follow-up programs time and money.
- Second tier sequencing reduces false positive results through identification of 'normals' such as carriers and pseudodeficiencies thereby allowing the lab to 'rule out' unaffected babies before the follow-up program and family get involved.
- Prevent unnecessary family anxiety while awaiting results.
- False positive referrals often put the newborn through additional invasive tests and cause stress for the family awaiting follow-up results.
- Reduce healthcare access disparities for families.
- By enabling equal access to second tier sequencing, newborn screening programs avoid healthcare disparity moving insurance-based DNA sequencing follow-up to NBS-based universal screening.
- Inform treatment faster with precise genetic characterization.
- Second tier sequencing provides genotype differentiated data to help promptly inform treatment decisions.



Baebies can offer molecular characterization of these genes that are screened for in NBS:

GAA (Pompe disease)GBA (Gaucher)GLA (Fabry)IDUA (MPS I)IDS (MPS II)SGSH (MPS IIIA)NAGLU (MPS IIIB)ARSB (MPS VI)GUSB (MPS VII)DMD (Duchenne muscular dystrophy)TPP1 (CLN2. Batten)+ more under development

Test Description

Baebies second tier sequencing analysis covers clinically-relevant regions of the gene, including coding exons, +/- 25 base pairs of adjacent intronic sequence in the transcript at >95% coverage (99.5% at current specs). In addition, analysis covers the select non-coding variants specifically defined in databases (e.g. ClinVar). Any variants that fall outside of these regions are not analyzed. Our analysis detects most deletions and duplication events at single exon resolution (window size 20-60 bp).



Reporting to Newborn Screening Programs

Baebies creates a customized report for each customer based on the requested information, including date and gene, variants identified, interpretation, classification, etc.

Integrate Primary Newborn Screening on Baebies SEEKER with Rapid, Cost-Effective Second Tier Sequencing in our CLIA Lab.

Contact Us Today for More Information and to Discuss Your Customized Lab Needs:

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Our mission is to save lives and make lives better for all children by bringing new technologies, new tests and new hope to parents and healthcare professionals worldwide.

