3B-NEO Basic Test

For Guardian

Comprehensive Genetic Screening for Your Newborn

NEWBORN DETAILS

Unique ID	[Unique ID]	**Physician**	[Physician]	**Sample type**	DBS
3billion ID	[3billion ID]	**Department**	Obstetrics & Gynecology	**Collected on**	yyyy-mm-dd
DOB* / Sex	yyyy-mm-dd / Male	**Institution**	[Institution]	**Ordered on**	yyyy-mm-dd
Ethnicity	Latino/Admixed American			**Accessioned on**	yyyy-mm-dd

* (YYYY-MM-DD)

RESULT SUMMARY

NOT DETECTED No remarkable findings

No clinically significant genetic variants were identified in your newborn at this time. Please note that this screening covers 704 specific genes and does not rule out all possible genetic conditions.

※ **IMPORTANT:** This report is for parental reference only. For an accurate interpretation of the results, please consult with your attending physician.

WHAT DOES THIS RESULT MEAN?

1. This screening analyzed 704 genes linked to serious childhood conditions where early treatment can make a meaningful difference. Within the scope of this screening, **no concerning genetic changes were detected** — this is an encouraging finding.
2. It is important to note that this result applies specifically to the conditions covered by this test. While no screening can detect every possible genetic variant, this result means that **none of the conditions we looked for appear to pose an elevated risk** for your newborn at this time.

WHAT SHOULD I DO?

1. 

Keep up with Routine Care

Continue all scheduled pediatric check-ups. This screening is a powerful tool, but it complements—rather than replaces—regular medical care.

2. 

Watch for Symptoms

If your child shows any unusual symptoms or developmental delays, consult a specialist. Clinical observation by a doctor is always the most important factor.

3. 

Share with your Doctor

Especially if you have a family history of genetic conditions, discuss this report with your pediatrician to plan long-term health management.

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ABOUT THIS SCREENING

This screening provides a comprehensive analysis of **704 genes** associated with serious, early-onset childhood conditions. It spans all medical specialties, including **Metabolism, Neurology, Immunology, Cardiology**, and more, to ensure a thorough genetic assessment for your newborn.

For the complete list of genes and associated conditions, please click here.

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TEST METHODS

Sample Collection  › Genomic Analysis  › Expert Review  › Result Reporting 

1. **Sample Collection**
   A Dried Blood Spot (DBS) sample was safely collected from your newborn and sent to our laboratory for analysis.
2. **Genomic Analysis**
   Your newborn's DNA was analyzed using Genome Sequencing (GS), a cutting-edge technology that reads through the most critical parts of the genetic code to identify changes that may affect health.
3. **Expert Review**
   The identified genetic changes were reviewed and classified by our specialists using our proprietary software, EVIDENCE, and internationally recognized guidelines from the American College of Medical Genetics and Genomics (ACMG).
4. **Result Reporting**
   This report focuses on genetic variants associated with serious conditions that begin in childhood, where early intervention and immediate medical care can prevent irreversible harm.

TEST LIMITATION

To ensure a correct understanding of your results, please review the following:

1. **Technical Scope**
   This test is highly accurate but focuses on specific genomic regions. Certain complex changes (e.g., mosaic variants or non-coding regions) may not be detectable. Specialized testing may be needed if these are clinically suspected.
2. **Medical Updates**
   Interpretations are based on data available at the time of reporting and not subject to automatic reanalysis. As genomic science evolves, please consult a specialist if new symptoms arise to determine if updated testing or re-interpretation is needed.
3. **Screening Nature**
   This is a screening tool, not a final diagnosis. A "Detected" result requires confirmation, and "Not Detected" does not 100% rule out a condition (potential for false negatives).
4. **Follow-up Care**
   If symptoms or family history are present, consult a specialist regardless of these results. Final diagnosis may require additional clinical evaluation and confirmatory tests (e.g., biochemical assays). Note: For certain genes including SMN1 and CYP21A2, confirmatory testing is especially recommended due to technical limitations inherent to these genomic regions.

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DISCLAIMER

This test was developed by 3billion for the purpose of identifying single nucleotide variants, small insertions and deletions, and structural variants from the [exome/genome] sequence. This laboratory is certified under the College of American Pathologists (CAP#: 8750906) and Clinical Laboratory Improvement Amendments (CLIA#: 99D2274041) as qualified to perform high complexity clinical laboratory testing.Assay validation and clinical validation were performed following the Korea Institute of Genetic Testing Evaluation, the American College of Medical Genetics and Genomics (ACMG) Technical Standards and Guidelines Section G (https://www.acmg.net/PDFLibrary/Standards-Guidelines-Clinical-Molecular-Genetics.pdf) and the CAP Next Generation Sequencing (NGS) Worksheets (Santani A et al. J Mol Diagn. 2019 May;21(3):369-374; https://www. cap.org/member-resources/precision-medicine/next-generation-sequencing-ngs-worksheets). This test is designed for newborn screening purposes only and is not intended as a standalone diagnostic tool. If low-level mosaicism or variants within regions that are incompletely sequenced due to technical difficulties with amplification, sequencing, or alignment are suspected, it is recommended to perform appropriate testing specifically designed to detect such variants. This report may not be copied or reproduced except in its totality.

ACCREDITATIONS AND CERTIFICATIONS

CAP License #	CLIA ID #
8750906, AU-ID# 2052626	99D2274041

This case has been comprehensively reviewed by our clinical team of physicians, geneticists and informaticists.
Report electronically signed by:

Go Hun Seo, M.D, Ph.D.
Chief Medical Officer & Laboratory Director