Guidelines

4301 Connecticut Ave NW
Suite 404
Washington, DC 20008

Phone: 202.966.5557
www.BabysFirstTest.org
info@BabysFirstTest.org

Plain Language Recommendations for Reporting Newborn Screening Results

By law, lab results must be reported to anyone receiving testing and the individuals they legally represent. People undergoing laboratory testing are encouraged to review their reports, including newborn screening results. With this in mind, **newborn screening lab reports must be understandable to parents and families.** While some aspects of these reports may be difficult to change due to regulatory requirements, when an opportunity comes to make edits, these recommendations serve as a **guidance document** to create clear reports.

1. SUMMARIZE THE RESULTS

Screening results should be concisely and simply summarized

- As more diseases are added to screening panels, reports become more complex - summaries are useful to **highlight key information.**
  - List **key information** and **immediate action items**
  - Include **appropriate contact information** for follow-up questions
  - Be clear when **further follow-up is necessary**
- See below for examples of summary text:
  - This screen showed **high risk** for **[CONDITION NAME]**. Please take this child for immediate further testing. This screen showed a low risk for all other conditions.
  - This screen was **low risk** for **ALL CONDITIONS**. No further action is needed at this time. Should this child develop any health concerns, a healthcare provider may suggest diagnostic testing.

2. LANGUAGE RECOMMENDATIONS

Clearly and concisely state the meaning of results

- Writing should be at or below an **8th grade reading level.**
- Use the Federal Plain Language Guidelines to learn to write in plain language: **https://www.plainlanguage.gov/guidelines/**.
- Alternatively, use **plain language software** such as:
  - Visible Thread Readability
  - Readable.io
- Include a noticeable disclaimer stating that false negatives can happen in newborn screening. Example: "In very rare cases, a child with a condition on the newborn screening panel may not be identified by the screen."

References

1. Claustres, M., Kožich, V., Dequeker, E., Fowler, B., Hehir-Kwa, J. Y., Miller, K., ... Barton, D. E. (2014). Recommendations for reporting results of diagnostic genetic testing (biochemical, cytogenetic and molecular genetic). European Journal of Human Genetics, 22(2), 160–170. http://doi.org/10.1038/ejhg.2013.125
2. Higgins, J. P., & Green, S. (2008). Cochrane handbook for systematic reviews of interventions. Chichester, England: Wiley-Blackwell.

3. RISK TERMINOLOGY IS RECOMMENDED

Move towards risk terminology

- Include specific language about high risk condtions or if all results are low risk:
  - Use **high risk, indeterminate risk (borderline), and low risk.**
  - The terms **"positive" and "negative" can be confusing** and imply diagnostic testing. These terms should only be used if the results are considered diagnostic - **further follow-up is necessary for any result not considered normal.**
- Terminology should always be clearly explained.

4. DESIGN RECOMMENDATIONS

Abnormal results should stand out from other results

- Highlight, change the font color, CAPITALIZE, underline or **bold** important points
- **Place summaries and action steps before any other results** so the eye goes there first. Some parents won't read the whole report.
- If there is a trailer/footnote at the bottom of the results page, make sure any **important information stands out.**
- If analytes are listed, **use a table** and **clearly state the risk profile** of each condition in a column next to the analyte.

Condition	Analyte	Results
Galactosemia	**Gal-1-Phosphate Uridyl Transferase**	**High Risk of Condition**
Cystic Fibrosis	Immunoreactive Trypsinogen	Low Risk of Condition
Hypothyroidism	Thyroid Stimulating Hormone	Indeterminate Risk (Rescreen)

baby's first test

 This project was supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under Cooperative Agreement no. U36MC16509 (Quality Assessment of the Newborn Screening System) as part of an award totaling $3,000,000. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.