MSDS of Fetal Aneuploidies (Trisomy 21, Trisomy18, and Trisomy13) Detection Kit

1. Product Information

Product Name: Fetal Aneuploidies (Trisomy 21, Trisomy18, and Trisomy13) Detection Kit

Packaging: 160 tests/kit

China NMPA Registration No.: GUO XIE ZHU ZHUN 20203400708

Production License NO.: Guangdong Food and Drug Administration Medical Device Production License No. 20203944

Manufacturer: CapitalBio Genomics Co., Ltd

Production Address: Building 11, No. 1 Taoyuan Road, Songshan Lake Park, Dongguan City, Guangdong Province, China

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2. Intended Use

◆ This kit is used for qualitative detection of cell-free fetal DNA in the peripheral blood plasma of pregnant women at 12+0 weeks of gestation or later. By analyzing the differences in the quantities of chromosomes 21, 18 and 13, it facilitates prenatal screening for fetal chromosomal aneuploidy diseases, namely trisomy 21 syndrome, trisomy 18 syndrome and trisomy 13 syndrome. This kit is only used for library construction.

3. Main Components

Kit composition	Components Name	Main Ingredients	Notes
Kit A	End Repair Buffer	Tris-HCl, $MgCl_2$, KCl, dNTP	Common molecular biology reagents and chemical reagents, posing no biosafety threats to human body or environment
	End Repair Enzyme	PNK, DNA polymerase, Glycerin	
	DNA Ligase Enzyme	DNA polymerase, Glycerin	
	Ligase Buffer	Tris-HCl, $MgSO_4$, PEG	
	PCR Buffer	Tris-HCl, $MgCl_2$, KCl, dNTP, DNA polymerase	
	Primer Mix	Nucleotide Sequence	
	Qpcr buffer	Fluorescent dyes, dNTP, $MgCl_2$, DNA polymerase	
	Qpcr Primer	Nucleotide	
	Standard S1~Standard S4	Nucleotide	
	Positive Control sample	Positive genomic nucleotide sequence of trisomy 21, trisomy 18 and trisomy 13, Plasma	
	Negative Control sample	Plasma	
	Adapter	Nucleotide Sequence	
	BarcodeA01-A48	Nucleotide Sequence	
Kit B	Beads 1	Beads	
	Beads 2	Beads	
	TE buffer	Tris-HCl, EDTA	

4. Hazard Overview

- GHS Classification: Not applicable (This product is not a hazardous chemical)
- Hazard Symbols: None
- Warning Word: None
- Hazard Statements: This product poses no significant hazards under normal usage conditions. However, the following potential risks

should be noted:

- Certain chemical substances contained in the product may cause mild irritation to sensitive individuals.

- The negative and positive controls contain plasma, which is of human origin and may be potentially infectious.

- Improper use (not in accordance with instructions) may cause certain hazards to operators and the environment.

5. First Aid Measures

- Inhalation: This product is non-volatile and generally not accessible via inhalation. In case of accidental inhalation, immediately move the affected person to a well-ventilated area with fresh air. If symptoms such as difficulty breathing or coughing occur, seek medical attention immediately.
- Skin Contact: Rinse the contacted area with plenty of water for at least 15 minutes. If discomfort (e.g., redness, pain) occurs, seek medical attention immediately.
- Eye Contact: Immediately rinse the eyes with plenty of water or normal saline for at least 15 minutes. During rinsing, pull up the upper eyelid and pull down the lower eyelid to ensure thorough rinsing. If symptoms such as eye pain or blurred vision occur, seek medical attention immediately.
- Ingestion: There are no specific first aid measures. If discomfort (e.g.,

nausea, vomiting) occurs, seek medical attention immediately.

6. Fire-Fighting Measures

- Hazardous Properties: This product is non-flammable and non-explosive.
- Extinguishing Methods: Use dry powder fire extinguishers, carbon dioxide fire extinguishers, or water mist for extinguishing. During fire fighting, avoid direct contact with the fire source to prevent burns.
- Special Hazards: None.

7. Emergency Handling for Leakage

- Personal Protection: Wear appropriate personal protective equipment (such as protective clothing, gloves, masks, etc.).
- Leakage Handling: Collect the leaked material using adsorbent materials (such as paper towels, rags, sand, or diatomaceous earth) and place it in a dedicated container for disposal; dispose of the collected leaked material in accordance with the handling requirements for medical waste.

8. Handling and Storage

- Precautions for Handling: Read the product manual carefully before use and follow the instructions strictly to ensure correct operation. Avoid contact with eyes, skin, or inhalation of aerosols.
- Maintain a clean laboratory environment during use to prevent reagents from spilling or overflowing. If spilling or overflowing

occurs, handle it immediately.

- Pay attention to safety protection during operation. The extraction of positive and negative controls and samples should be conducted in designated laboratory areas. Wear protective clothing, disposable gloves, and masks; all items that have directly contacted samples should be disinfected before being discarded or reused.
- Storage conditions: Kit A should be stored at -30℃～-10℃, and Kit B at 2℃～8℃. Ensure the packaging remains intact during storage to prevent reagent leakage or contamination.

9. Exposure Control/Personal Protection

- Engineering Controls: Laboratory ventilation systems, Biosafety cabinets, and clean benches.
- Respiratory Protection: No special requirements, but it is recommended to wear medical masks when handling reagents to prevent inhalation.
- Eye Protection: Wear goggles to prevent eye contact with reagents.
- Skin and Body Protection: Wear lab coats and gloves to prevent skin contact with reagents.
- Hand Protection: Wear latex gloves or nitrile gloves to prevent hand contact with reagents.

10. Physical and Chemical Properties

- Appearance: All liquid components (except magnetic beads, negative

controls, and positive controls) are clear and transparent, with no precipitates or floccules; the magnetic bead suspension should be uniform, without visible agglomeration or clumping to the naked eye; the negative controls and positive controls are yellow in color.

◆ pH Value

Component Name	pH Value
End Repair Buffer	7.0~8.5
Ligase Buffer	7.5~8.5
PCR Buffer	8.0~9.0
TE Buffer	7.9-8.2
End Repair Enzyme	No specific pH value, usually neutral
DNA Ligase Enzyme	No specific pH value, usually neutral
Primer Mix	No specific pH value, usually neutral
Qpcr buffer	No specific pH value, usually neutral
Qpcr Primer	No specific pH value, usually neutral
Standard S1~Standard S4	No specific pH value, usually neutral
Positive Control sample	No specific pH value, usually neutral
Negative Control sample	No specific pH value, usually neutral
Adapter	No specific pH value, usually neutral
BarcodeA01-A48	No specific pH value, usually neutral
Beads 1	No specific pH value, usually neutral
Beads 2	No specific pH value, usually neutral

- Melting point: No data available.
- Flash point: No data available.
- Boiling point: No data available.
- Solubility: Water-soluble.

11. Stability and Reactivity

- Stability: Unopened reagents are valid for 9 months under the above storage conditions. It is recommended that opened kits be used up within 3 months. Under normal usage conditions, 10 freeze-thaw cycles will not affect the performance.
- Incompatible Substances: Substances to avoid contact with (such as high temperatures, strong acids, strong alkalis, and strong oxidants). Contact with these substances may cause chemical reactions, resulting in reagent inactivation.
- Hazardous Reactions: None.
- Hazardous Decomposition Products: None.
- Conditions to Avoid: High temperatures and light, which may affect the stability of the reagents.

12. Toxicological Information

- Acute toxicity: No data available.
- Skin irritation or corrosion: No data available.
- Eye irritation or corrosion: No data available.

- Respiratory or skin sensitization: No data available.
- Germ cell mutagenicity: No data available.
- Carcinogenicity: No data available.
- Reproductive toxicity: No data available.
- Specific target organ system toxicity (single exposure): No data available.
- Specific target organ system toxicity (repeated exposure): No data available.
- Inhalation hazard: No data available.

13. Ecological Information

- Ecotoxicity: No data available.
- Persistence and degradability: No data available.
- Bioaccumulation: No data available.
- Mobility in soil: No data available.

14. Waste Disposal

- Waste disposal method: In accordance with local laws and regulations, collect waste reagents by category and hand them over to a qualified hazardous waste treatment institution for disposal. Ensure that waste reagents are disposed of safely and effectively to prevent environmental pollution.
- Precautions for waste disposal: Avoid random dumping or discarding to prevent harm to the environment and non-target organisms.

15. Transport Information

- Packaging category: Complies with transportation regulations.
- Special markings: Cold chain transportation.
- Transport precautions: Avoid exposure to high temperatures and light; maintain the integrity of the packaging to prevent reagent leakage or inactivation. During transportation, handle with care, and avoid severe vibration and collision.

16. Regulatory Information

- Applicable regulations complied with: the *Regulations on the Safety Administration of Hazardous Chemicals* and the *Regulations on the Supervision and Administration of Medical Devices*.
- Biosafety regulations: the *Regulations on the Biosafety Administration of Pathogenic Microorganism Laboratories*.

17. Other Information

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Version No.: 1.0

Release date: November 6, 2025

Additional notes: The above content is for reference only. Before using this product, users must carefully read the product manual and operate in strict accordance with the requirements of the manual. If you have any questions or encounter abnormal conditions during product use, please contact the manufacturer or after-sales service unit timely.