

## 质检报告单 (gDNA)

温馨提示: 请在开盖前离心以防产品损耗

| 产品信息                                                                                  |                                       |      |                                       |        |      |
|---------------------------------------------------------------------------------------|---------------------------------------|------|---------------------------------------|--------|------|
| 货号                                                                                    | GW-OYC001                             | 批号   | 2023072801                            |        |      |
| 描述                                                                                    | 髓系血液瘤 gDNA 标准品                        | 生产时间 | 2023-07-28                            |        |      |
| 产品特征                                                                                  |                                       |      |                                       |        |      |
| 规格                                                                                    | 0.5µg/支                               |      |                                       |        |      |
| 参数                                                                                    | 30ng/uL                               |      |                                       |        |      |
| 储存条件                                                                                  | 2-8℃                                  |      |                                       |        |      |
| 有效期                                                                                   | 自生产之日起, 36 个月内有效                      |      |                                       |        |      |
| 产品质控                                                                                  |                                       |      |                                       |        |      |
| 项目                                                                                    | 质控标准                                  |      |                                       | 是否符合要求 |      |
| 突变频率/<br>拷贝数 *                                                                        | 突变频率, 单位: %                           |      | 拷贝数, 单位: Copies                       |        | PASS |
|                                                                                       | Expected Value    Acceptance Criteria |      | Expected Value    Acceptance Criteria |        |      |
|                                                                                       | 0    ≤ 0.1%                           |      | < 5    Expected Value ±30%            |        |      |
|                                                                                       | < 5    Expected Value ±30%            |      | ≥ 5 and < 10    Expected Value ±20%   |        |      |
|                                                                                       | ≥ 5 and < 10    Expected Value ±20%   |      | ≥ 10    Expected Value ±10%           |        |      |
|                                                                                       | ≥ 10    Expected Value ±10%           |      |                                       |        |      |
| 浓度 #                                                                                  | 30 ng/µL ± 15% (25.5~34.5ng/µL)       |      |                                       | PASS   |      |
| 凝胶电泳 ^                                                                                | 15kb 以上有明亮单一不拖尾条带                     |      |                                       | PASS   |      |
| * 突变频率/拷贝数测定使用 QX200 Droplet Digital PCR+ddPCR Supermix for Probes(No dUTP) (BIO-RAD) |                                       |      |                                       |        |      |
| # 浓度测定使用 Qubit 4.0 Fluorometer+ Qubit dsDNA BR Assay Kit (Thermo Fisher Scientific)   |                                       |      |                                       |        |      |
| ^ 凝胶电泳测定使用 1.0%琼脂凝胶(Sangon Biotech)                                                   |                                       |      |                                       |        |      |

| Gene   | Variant (AA)     | Expected AF (%) | Actual AF (%) | Acceptance Criteria (%) |      | Pass/Fail |
|--------|------------------|-----------------|---------------|-------------------------|------|-----------|
|        |                  |                 |               | Low                     | High |           |
| ABL1   | T315I/T334I      | 5.00            | 4.83          | 4                       | 6    | Pass      |
| ASXL1  | G646Wfs*12       | 30.00           | 30.34         | 27                      | 33   | Pass      |
| ASXL1  | W796C            | 5.00            | 4.86          | 4                       | 6    | Pass      |
| BCOR   | Q1208Tfs*8       | 60.00           | 58.32         | 54                      | 66   | Pass      |
| CBL    | S403F            | 5.00            | 4.77          | 4                       | 6    | Pass      |
| DNMT3A | R882C            | 5.00            | 6.00          | 4                       | 6    | Pass      |
| EZH2   | R418Q            | 5.00            | 4.26          | 4                       | 6    | Pass      |
| FLT3   | D835Y            | 5.00            | 5.19          | 4                       | 6    | Pass      |
| FLT3   | ITD300           | 5.00            | 4.86          | 4                       | 6    | Pass      |
| GATA1  | Q119*            | 10.00           | 10.20         | 9                       | 11   | Pass      |
| GATA2  | G200Vfs*18       | 30.00           | 31.03         | 27                      | 33   | Pass      |
| IDH1   | R132C            | 5.00            | 5.44          | 4                       | 6    | Pass      |
| IDH2   | R172K            | 5.00            | 5.06          | 4                       | 6    | Pass      |
| JAK2   | F537_K539delinsL | 5.00            | 5.21          | 4                       | 6    | Pass      |
| JAK2   | V617F            | 5.00            | 5.05          | 4                       | 6    | Pass      |

|       |            |       |       |      |      |      |
|-------|------------|-------|-------|------|------|------|
| KRAS  | G13D       | 35.00 | 36.01 | 31.5 | 38.5 | Pass |
| NPM1  | W288Cfs*12 | 5.00  | 5.95  | 4    | 6    | Pass |
| NRAS  | Q61L       | 10.00 | 10.61 | 9    | 11   | Pass |
| RUNX1 | M267I      | 30.00 | 32.63 | 27   | 33   | Pass |
| SF3B1 | G740E      | 5.00  | 5.22  | 4    | 6    | Pass |
| TET2  | R1261H     | 5.00  | 5.19  | 4    | 6    | Pass |
| TP53  | S241F      | 5.00  | 5.32  | 4    | 6    | Pass |

| Acceptance Criteria | Correct sequence confirmed by Sanger Sequencing | Pass/Fail |
|---------------------|-------------------------------------------------|-----------|
| FLT3 ITD300         | Confirmed                                       | PASS      |



质量授权人：

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