

质控品名： 多专业免疫分析非定值质控品

|       |       |       |     |            |     |         |       |         |
|-------|-------|-------|-----|------------|-----|---------|-------|---------|
| REF   | 539-1 | 6×3mL | EXP | 2024-08-01 | LOT | 336A22C | 更新日期： | 2024-04 |
| 1 / 4 |       |       |     |            |     |         |       |         |

| 批号：336A22C                                                                             |        |         |       |          |      |
|----------------------------------------------------------------------------------------|--------|---------|-------|----------|------|
| 项目\仪器\试剂\方法                                                                            | 单位     | 均值 \ CV |       | Lab \ 点数 |      |
| (AFP)甲胎蛋白                                                                              |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | ng/mL  | 7.81    | 12.2% | 9        | 134  |
| chemclin LiCA Series<br>CHIVD \ Chemiluminescence Immunoassay (CLIA )                  | ng/mL  | 7.58    | 7.9%  | 8        | 188  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | ng/mL  | 7.32    | 4.1%  | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | ng/mL  | 7.32    | 10%   | <5       | <100 |
| (ALD)醛固酮                                                                               |        |         |       |          |      |
| Autolumo A2000/A2000 PLUS<br>Autobio \ Chemiluminescence Immunoassay (CLIA )           | pg/mL  | 161     | 11.2% | <5       | <100 |
| (Anti-Tg)抗甲状腺球蛋白抗体                                                                     |        |         |       |          |      |
| Mindray CL-2000i/1000i/6000i series<br>Mindray \ Chemiluminescence Immunoassay (CLIA ) | IU/mL  | 0.75    | 12%   | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | IU/mL  | 11.8    | 10%   | <5       | <100 |
| (Anti-TPO)抗甲状腺过氧化物酶抗体                                                                  |        |         |       |          |      |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | IU/mL  | 12.2    | 10%   | <5       | <100 |
| Mindray CL-2000i/1000i/6000i series<br>Mindray \ Chemiluminescence Immunoassay (CLIA ) | IU/mL  | 9.05    | 12%   | <5       | <100 |
| (CA 125)糖类抗原 125                                                                       |        |         |       |          |      |
| chemclin LiCA Series<br>CHIVD \ Chemiluminescence Immunoassay (CLIA )                  | IU/mL  | 11.3    | 4%    | <5       | <100 |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | IU/mL  | 8.58    | 13%   | 12       | 174  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | IU/mL  | 10.7    | 4.2%  | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | IU/mL  | 9.85    | 10%   | <5       | <100 |
| (CA 15-3)糖类抗原 15-3                                                                     |        |         |       |          |      |
| chemclin LiCA Series<br>CHIVD \ Chemiluminescence Immunoassay (CLIA )                  | IU/mL  | 12.1    | 1.8%  | <5       | <100 |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | IU/mL  | 7.42    | 9.5%  | 12       | 183  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | IU/mL  | 8.46    | 3%    | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | IU/mL  | 11.4    | 10%   | <5       | <100 |
| (CA 19-9)糖类抗原 19-9                                                                     |        |         |       |          |      |
| chemclin LiCA Series<br>CHIVD \ Chemiluminescence Immunoassay (CLIA )                  | IU/mL  | 5.84    | 2.1%  | <5       | <100 |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | IU/mL  | 3.36    | 9.3%  | 12       | 177  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | IU/mL  | 3.37    | 6.8%  | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | IU/mL  | 5.24    | 10%   | <5       | <100 |
| (CEA)癌胚抗原                                                                              |        |         |       |          |      |
| chemclin LiCA Series<br>CHIVD \ Chemiluminescence Immunoassay (CLIA )                  | ng/mL  | 3.28    | 6.2%  | 8        | 190  |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | ng/mL  | 3.26    | 10%   | 10       | 158  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | ng/mL  | 2.84    | 5%    | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | ng/mL  | 3.08    | 10%   | <5       | <100 |
| (Cortisol)皮质醇                                                                          |        |         |       |          |      |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | ng/mL  | 123     | 10%   | <5       | <100 |
| (C-P)C-肽                                                                               |        |         |       |          |      |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | ng/mL  | 1.13    | 12.4% | <5       | <100 |
| (DHEA-S)硫酸脱氢表雄酮                                                                        |        |         |       |          |      |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | ng/mL  | 3130    | 10%   | <5       | <100 |
| (E2)雌二醇                                                                                |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | pmol/L | 342     | 8.6%  | 9        | <100 |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | pmol/L | 327     | 4.9%  | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | pmol/L | 241     | 12%   | <5       | <100 |
| (F-PSA)游离前列腺特异性抗原                                                                      |        |         |       |          |      |
| chemclin LiCA Series<br>CHIVD \ Chemiluminescence Immunoassay (CLIA )                  | ng/mL  | 0.15    | 6.1%  | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | ng/mL  | 0.124   | 10%   | <5       | <100 |

|       |       |       |     |            |     |         |       |         |
|-------|-------|-------|-----|------------|-----|---------|-------|---------|
| REF   | 539-1 | 6×3mL | EXP | 2024-08-01 | LOT | 336A22C | 更新日期： | 2024-04 |
| 2 / 4 |       |       |     |            |     |         |       |         |

| 批号：336A22C                                                                             |        |         |       |          |      |
|----------------------------------------------------------------------------------------|--------|---------|-------|----------|------|
| 项目\仪器\试剂\方法                                                                            | 单位     | 均值 \ CV |       | Lab \ 点数 |      |
| (FSH)促卵泡刺激素                                                                            |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | IU/L   | 5.16    | 4.7%  | 10       | <100 |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | IU/L   | 6.1     | 2.3%  | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | IU/L   | 5.36    | 10%   | <5       | <100 |
| (FT3)游离T3                                                                              |        |         |       |          |      |
| chemclin LICA Series<br>CHIVD \ Chemiluminescence Immunoassay (CLIA )                  | pmol/L | 4.47    | 3.3%  | <5       | <100 |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | pmol/L | 7.55    | 12.6% | 13       | 206  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | pmol/L | 6.12    | 3.7%  | <5       | <100 |
| Mindray CL-2000i/1000i/6000i series<br>Mindray \ Chemiluminescence Immunoassay (CLIA ) | pmol/L | 5.57    | 12%   | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | pmol/L | 5.88    | 10%   | <5       | <100 |
| (FT4 )游离T4                                                                             |        |         |       |          |      |
| chemclin LICA Series<br>CHIVD \ Chemiluminescence Immunoassay (CLIA )                  | pmol/L | 17.7    | 2.9%  | <5       | <100 |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | pmol/L | 17.8    | 7.4%  | 13       | 237  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | pmol/L | 16.3    | 4.8%  | <5       | <100 |
| Mindray CL-2000i/1000i/6000i series<br>Mindray \ Chemiluminescence Immunoassay (CLIA ) | pmol/L | 15.9    | 12%   | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | pmol/L | 16.5    | 10%   | <5       | <100 |
| (HBcAb)乙肝核心抗体                                                                          |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | IU/mL  | 1.83    | 7.9%  | <5       | <100 |
| (HBsAb)乙肝e抗体                                                                           |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | IU/mL  | 0.553   | 1%    | <5       | <100 |
| (HBsAg)乙肝e抗原                                                                           |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | IU/mL  | 2.21    | 1.9%  | <5       | <100 |
| (HBsAb)乙肝表面抗体                                                                          |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | IU/L   | 46.1    | 3.8%  | <5       | <100 |
| (HBsAg)乙肝表面抗原                                                                          |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | IU/mL  | 1.08    | 1.9%  | <5       | <100 |
| (hCG)人绒毛膜促性腺激素                                                                         |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | IU/L   | 5.17    | 7.3%  | 10       | 121  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | IU/L   | 4.94    | 1.6%  | <5       | <100 |
| (HCY)同型半胱氨酸                                                                            |        |         |       |          |      |
| Roche cobas 4000/6000/8000<br>Roche \ Enzymatic Cycling Assays Method                  | μmol/L | 13.6    | 10%   | <5       | <100 |
| (HGH)人生长激素                                                                             |        |         |       |          |      |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | μg/L   | 2.06    | 10%   | <5       | <100 |
| (IgE)免疫球蛋白 IgE                                                                         |        |         |       |          |      |
| Beckman Image 800<br>Roche \ Immunoturbidimetry (ITA)                                  | IU/mL  | 90.9    | 10%   | <5       | <100 |
| (IGF1)胰岛素生长因子1                                                                         |        |         |       |          |      |
| Autolumo A2000/A2000 PLUS<br>Autobio \ Chemiluminescence Immunoassay (CLIA )           | ng/mL  | 215     | 10%   | <5       | <100 |
| (INS)胰岛素                                                                               |        |         |       |          |      |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | mIU/L  | 8.36    | 10%   | <5       | <100 |
| (LH)促黄体生成素                                                                             |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | IU/L   | 5.06    | 3%    | 8        | <100 |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | IU/L   | 5.24    | 1.7%  | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | IU/L   | 4.74    | 10%   | <5       | <100 |
| (Myo / Mb)肌红蛋白                                                                         |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | μg/L   | 40.8    | 10.3% | 9        | 166  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | μg/L   | 43.4    | 3%    | <5       | <100 |

|       |       |       |     |            |     |         |       |         |
|-------|-------|-------|-----|------------|-----|---------|-------|---------|
| REF   | 539-1 | 6×3mL | EXP | 2024-08-01 | LOT | 336A22C | 更新日期： | 2024-04 |
| 3 / 4 |       |       |     |            |     |         |       |         |

| 批号：336A22C                                                                             |        |         |       |          |      |
|----------------------------------------------------------------------------------------|--------|---------|-------|----------|------|
| 项目\仪器\试剂\方法                                                                            | 单位     | 均值 \ CV |       | Lab \ 点数 |      |
| (NT-proBNP)N-末端脑钠肽前体                                                                   |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | pg/mL  | 114     | 25.4% | 10       | 191  |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | pmol/L | 13.4    | 25.4% | 10       | 191  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | pg/mL  | 93.3    | 3.8%  | <5       | <100 |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | pmol/L | 11      | 3.8%  | <5       | <100 |
| (PCT)降钙素原                                                                              |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | ng/mL  | 1.26    | 3.5%  | 6        | <100 |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | ng/mL  | 1.35    | 5.4%  | <5       | <100 |
| (PRL)催/ 泌乳素                                                                            |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | ng/mL  | 8.48    | 4.5%  | 10       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | ng/mL  | 8.52    | 10%   | <5       | <100 |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | ng/mL  | 8.97    | 1%    | <5       | <100 |
| (PROG)孕酮                                                                               |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | ng/mL  | 0.767   | 11.4% | 5        | <100 |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | ng/mL  | 0.5     | 0%    | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | ng/mL  | 0.759   | 10%   | <5       | <100 |
| (PSA)前列腺特异性抗原                                                                          |        |         |       |          |      |
| chemclin LiCA Series<br>CHIVD \ Chemiluminescence Immunoassay (CLIA )                  | ng/mL  | 0.856   | 2.3%  | 8        | 188  |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | ng/mL  | 0.587   | 8.8%  | 11       | 156  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | ng/mL  | 0.59    | 4.4%  | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | ng/mL  | 0.659   | 10%   | <5       | <100 |
| (PTH)甲状旁腺素                                                                             |        |         |       |          |      |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | pmol/L | 1.13    | 10%   | <5       | <100 |
| (TES)睾酮                                                                                |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | ng/mL  | 8.77    | 9%    | 9        | 126  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | ng/mL  | 8.26    | 1.5%  | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | ng/mL  | 8.09    | 10%   | <5       | <100 |
| (Tg)甲状腺球蛋白                                                                             |        |         |       |          |      |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | ng/mL  | 10.4    | 10%   | <5       | <100 |
| (TnI)肌钙蛋白I                                                                             |        |         |       |          |      |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | ng/mL  | 0.046   | 34%   | 10       | 192  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | ng/mL  | 0.054   | 13.9% | <5       | <100 |
| (TSH)促甲状腺素                                                                             |        |         |       |          |      |
| chemclin LiCA Series<br>CHIVD \ Chemiluminescence Immunoassay (CLIA )                  | mIU/L  | 1.89    | 2.7%  | <5       | <100 |
| Maccura i3000<br>MAKER \ Chemiluminescence Immunoassay (CLIA )                         | mIU/L  | 2.36    | 22.9% | 13       | 245  |
| Maccura i3000<br>MAKER \ Electro-Chemiluminescence Immunoassay (ECLIA)                 | mIU/L  | 1.93    | 6.6%  | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | mIU/L  | 2       | 10%   | <5       | <100 |
| Mindray CL-2000i/1000i/6000i series<br>Mindray \ Chemiluminescence Immunoassay (CLIA ) | mIU/L  | 2.25    | 12%   | <5       | <100 |
| (TT3)总三碘甲状原氨酸                                                                          |        |         |       |          |      |
| chemclin LiCA Series<br>CHIVD \ Chemiluminescence Immunoassay (CLIA )                  | ng/mL  | 1.28    | 2%    | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | ng/mL  | 1.21    | 10%   | <5       | <100 |
| Mindray CL-2000i/1000i/6000i series<br>Mindray \ Chemiluminescence Immunoassay (CLIA ) | ng/mL  | 0.97    | 12%   | <5       | <100 |
| (TT4)总T4                                                                               |        |         |       |          |      |
| chemclin LiCA Series<br>CHIVD \ Chemiluminescence Immunoassay (CLIA )                  | ng/mL  | 50      | 2.3%  | <5       | <100 |
| Mindray CL-2000i/1000i/6000i series<br>Mindray \ Chemiluminescence Immunoassay (CLIA ) | ng/mL  | 63.5    | 12%   | <5       | <100 |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA)          | ng/mL  | 68.5    | 10%   | <5       | <100 |

|                |       |       |                |            |                |         |       |         |
|----------------|-------|-------|----------------|------------|----------------|---------|-------|---------|
| <div>REF</div> | 539-1 | 6×3mL | <div>EXP</div> | 2024-08-01 | <div>LOT</div> | 336A22C | 更新日期： | 2024-04 |
| 4 / 4          |       |       |                |            |                |         |       |         |

|                                                                               |       |             |     |          |      |
|-------------------------------------------------------------------------------|-------|-------------|-----|----------|------|
|                                                                               |       | 批号: 336A22C |     |          |      |
| 项目\仪器\试剂\方法                                                                   | 单位    | 均值 \ CV     |     | Lab \ 点数 |      |
| (VB12)维生素B12                                                                  |       |             |     |          |      |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA) | pg/mL | 451         | 10% | <5       | <100 |
| (β2M)β-2-微球蛋白                                                                 |       |             |     |          |      |
| Roche cobas 4000/6000/8000<br>Roche \ Immunoturbidimetry (ITA)                | ng/mL | 855         | 10% | <5       | <100 |
| (β-hCG)人绒毛膜促性腺激素β亚基                                                           |       |             |     |          |      |
| Roche cobas E601/602<br>Roche \ Electro-Chemiluminescence Immunoassay (ECLIA) | IU/mL | 0.004       | 10% | <5       | <100 |

注：此报告所提供的数据均基于检测相同批号质控品的若干实验室的数据汇总统计而来，仅供学习、参考之用。因所用技术、仪器和试剂的不同，或因制造商检测方法的改变，均可导致实验室实际测得的数据偏离此报告所提供的数据。根据良好实验室规范的要求，实验室须遵循相关技术规范确立自己的均值和可接受范围。