



浙江东方基因生物制品股份有限公司  
Zhejiang Orient Gene Biotech Co.,LTD

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## STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC in Moldova only. The detailed product list is in the Annex 1 in the following pages.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement letter will be valid from Mar.10th,2025to Mar.09th, 2027.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2025/3/10



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地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号  
Add: 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China  
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浙江东方基因生物制品股份有限公司  
Zhejiang Orient Gene Biotech Co.,LTD

Annex 1

| Numărul de catalog<br>(referință)* | Denumire generică<br>(denumirea dispozitivului) | Denumire comercială<br>(brand)* | Modelul                                     |
|------------------------------------|-------------------------------------------------|---------------------------------|---------------------------------------------|
| GCCOV-702a-H1                      | TEST RAPID                                      | Orient Gene                     | Rapid COVID-19 Antigen Oral Fluid Self-Test |
| GCCOV-702a-H5                      | TEST RAPID                                      | Orient Gene                     | Rapid COVID-19 Antigen Oral Fluid Self-Test |
| GCCOV-702a-H20                     | TEST RAPID                                      | Orient Gene                     | Rapid COVID-19 Antigen Oral Fluid Self-Test |
| GCCOV-502a-H1OGE                   | TEST RAPID                                      | Orient Gene                     | Rapid COVID-19 (Antigen) Self-test          |
| GCCOV-502a-H5OGE                   | TEST RAPID                                      | Orient Gene                     | Rapid COVID-19 (Antigen) Self-test          |
| GCCOV-502a-H20OGE                  | TEST RAPID                                      | Orient Gene                     | Rapid COVID-19 (Antigen) Self-test          |

|                   |            |             |                                                            |
|-------------------|------------|-------------|------------------------------------------------------------|
| GIHSA-102a        | TEST RAPID | Orient Gene | One Step Microalbumin Test Cassette                        |
| GIHSA-101a        | TEST RAPID | Orient Gene | One Step Microalbumin Test Strip (Urine)                   |
| GCROA-602a        | TEST RAPID | Orient Gene | Rotavirus rapid test cassette (feces)                      |
| GCMAL(pf/pv)-402a | TEST RAPID | Orient Gene | Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood)     |
| GCROA/ADE-602a    | TEST RAPID | Orient Gene | Rotavirus and Adenovirus Combo Rapid Test Cassette (Feces) |
| GASPE-902a        | TEST RAPID | Orient Gene | Male Fertility Rapid Test Cassette (Semen)                 |
| GAFSH-101a        | TEST RAPID | Orient Gene | One Step Menopause Test Strip (Urine)                      |
| GAFSH-102a        | TEST RAPID | Orient Gene | One Step Menopause Test Cassette (Urine)                   |
| GAIGF1-502a       | TEST RAPID | Orient Gene | iGFBP-1 Rapid test Cassette (Swab)                         |

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|                    |            |             |                                                                                 |
|--------------------|------------|-------------|---------------------------------------------------------------------------------|
| GAIGF1-501a        | TEST RAPID | Orient Gene | iGFBP-1 Rapid Test Strip (Cervical Secretion)                                   |
| GALH-101a          | TEST RAPID | Orient Gene | One Step Ovulation Test Strip (Urine) (25mlU)                                   |
| GALH-101b          | TEST RAPID | Orient Gene | One Step Ovulation Test Strip (Urine) (40mlU)                                   |
| GALH-102a          | TEST RAPID | Orient Gene | One Step Ovulation Test Cassette (Urine) (25mlU)                                |
| GALH-102b          | TEST RAPID | Orient Gene | One Step Ovulation Test Cassette (Urine) (40mlU)                                |
| GCTYP-302a         | TEST RAPID | Orient Gene | Typhoid IgG/IgM Rapid Test Cassette (serum/plasma)                              |
| GCMAL(pf/pan)-402a | TEST RAPID | Orient Gene | Malaria P.f./Pan Ag Rapid Test Cassette (Whole Blood)                           |
| GCDEN-425a         | TEST RAPID | Orient Gene | Dengue NS1+IgM/IgG Combo Rapid Test Cassette (Whole blood/serum/plasma)         |
| GCDEN(NS)-402c     | TEST RAPID | Orient Gene | Dengue NS1 Antigen Rapid Test Cassette (Whole blood/serum/plasma)               |
| GCDEN(ab)-402c     | TEST RAPID | Orient Gene | Dengue IgM/IgG Rapid Test Cassette (Whole blood/serum/plasma)                   |
| GCVCH(O1/O9)-602a  | TEST RAPID | Orient Gene | V.cholerae O1/O139 Ag Combo Rapid Test Cassette (Feces)                         |
| GCMAL(pf)-402a     | TEST RAPID | Orient Gene | Malaria Pf Ag Rapid Test Cassette (Whole blood)                                 |
| GCSAL(ST)-602a     | TEST RAPID | Orient Gene | S. typhi Ag Rapid Test Cassette (Serum/plasma/Feces)                            |
| GCCHK(IgM)-402a    | TEST RAPID | Orient Gene | Chikungunya IgM Rapid Test Cassette (Whole blood/Serum/Plasma)                  |
| GCCOV-502a-NN      | TEST RAPID | Orient Gene | Coronavirus Ag Rapid Test Cassette (Swab)                                       |
| GCCOV (Nab)-402b   | TEST RAPID | Orient Gene | SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette (Whole blood/Serum/Plasma) |
| GCCOV-502a-NA      | TEST RAPID | Orient Gene | Coronavirus Ag Rapid Tests Cassette (Swab)                                      |

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|                      |            |             |                                                                     |
|----------------------|------------|-------------|---------------------------------------------------------------------|
| GCCOV (Ag)-PN10      | TEST RAPID | Orient Gene | COVID-19 Antigen Control Kit                                        |
| GCCOV (Ag)-PN20      | TEST RAPID | Orient Gene | COVID-19 Antigen Control Kit                                        |
| GCFERA-545a          | TEST RAPID | Orient Gene | Flu, COVID-19,RSV&Adeno Ag Combo Tests Cassette (Swab)              |
| GCTV-502a            | TEST RAPID | Orient Gene | Trichomonas Ag Rapid Test Cassette (Swab)                           |
| GCVCH(O1)-602a       | TEST RAPID | Orient Gene | V.cholerae O1 Ag Rapid Test Cassette (Feces)                        |
| GCCHA-402a           | TEST RAPID | Orient Gene | Chagas Ab Rapid Test Cassette (Whole blood/serum/plasma)            |
| GCMAL(pf/pv Ab)-302a | TEST RAPID | Orient Gene | Malaria Pf/Pv Ab Rapid Test Cassette (Serum/plasma)                 |
| GCMAL(pf/pv Ab)-402a | TEST RAPID | Orient Gene | Malaria Pf/Pv Ab Rapid Test Cassette (Whole blood/Serum/plasma)     |
| GCMKP-502b           | TEST RAPID | Orient Gene | Monkeypox Ag Rapid Test Cassette (Swab)                             |
| GCCOV(Del)-T502a     | TEST RAPID | Orient Gene | SARS-CoV-2 Delta-series Mutant Strain Ag Rapid Test cassette (Swab) |
| GCCOV-PN10           | TEST RAPID | Orient Gene | COVID-19 IgG/IgM Control kit                                        |
| GCCOV-PN20           | TEST RAPID | Orient Gene | COVID-19 IgG/IgM Control kit                                        |
| GCFER-T525a          | TEST RAPID | Orient Gene | COVID-19/Flu A&B/ RSV Ag Combo Rapid Test Cassette (Swab)           |
| GCCOV(B117)-525a     | TEST RAPID | Orient Gene | COVID-19 Ag&B.1.1.7 Mutant Strain Combo Test Cassette (Swab)        |
| GCFERA-T525a         | TEST RAPID | Orient Gene | COVID-19/Flu A&B/ RSV/Adeno Ag Combo Rapid Test Cassette (Swab)     |
| GCCOV-702a           | TEST RAPID | Orient Gene | COVID-19 Ag Rapid Test Cassette (Oral fluid)                        |
| GCFE-T502a           | TEST RAPID | Orient Gene | COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab)                |

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| GCMKP-402a        | TEST RAPID | Orient Gene | Monkeypox IgG/IgM Rapid Test Cassette (Whole blood/serum/plasma)     |
| GCKa1-401a        | TEST RAPID | Orient Gene | Leishmania Ab Rapid Test strip (Whole blood/serum/plasma)            |
| GCKa1-T402a       | TEST RAPID | Orient Gene | Leishmania IgG/IgM Rapid test cassette (whole blood/serum/plasma)    |
| GCCOV-503a        | TEST RAPID | Orient Gene | Smart Rapid COVID-19 Ag Test Device                                  |
| GCBRU-402a        | TEST RAPID | Orient Gene | Brucella Antibody Rapid Test Cassette (Whole blood/serum/plasma)     |
| GCCHA-302a        | TEST RAPID | Orient Gene | Chagas Ab Rapid Test Cassette (Serum/plasma)                         |
| GCCHK(IgM)-302a   | TEST RAPID | Orient Gene | Chikungunya IgM Rapid Test Cassette (Serum/Plasma)                   |
| GCCOV-501a        | TEST RAPID | Orient Gene | Rapid COVID-19 Antigen Test Strip                                    |
| GCMON-352a        | TEST RAPID | Orient Gene | Mononucleosis IgG/IgM Rapid Test Cassette (Serum/plasma)             |
| GCMON-402a        | TEST RAPID | Orient Gene | Mononucleosis Rapid Test Cassette (Whole blood/Serum/plasma)         |
| GCMON-425a        | TEST RAPID | Orient Gene | Mononucleosis IgG/IgM Rapid Test Cassette (Whole blood/Serum/plasma) |
| GCEV71 (IgM)-302a | TEST RAPID | Orient Gene | EV71 IgM Rapid Test Cassette (Serum/plasma)                          |
| GCEV71 (IgM)-402a | TEST RAPID | Orient Gene | EV71 IgM Rapid Test Cassette (Whole blood/Serum/plasma)              |
| GENMP22-102a      | TEST RAPID | Orient Gene | One Step Nuclear Matrix Protein 22 Test Cassette (Urine)             |
| GEFOB/TF-602a     | TEST RAPID | Orient Gene | Fecal Occult Blood and Transferrin Combo Rapid Test Cassette (Feces) |
| GCHEV-302a        | TEST RAPID | Orient Gene | HEV IgM Rapid Test Cassette (Serum/Plasma)                           |
| GCMP (IgM)-302a   | TEST RAPID | Orient Gene | M.pneumonia IgM Rapid Test Cassette (Serum/plasma)                   |

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|-------------|------------|-------------|-----------------------------------------------------------------|
| FCCOV-502a  | TEST RAPID | Orient Gene | SARS-CoV-2 Ag Fluorescence Rapid Test Cassette (Swab)           |
| GCCOV-402Ba | TEST RAPID | Orient Gene | COVID-19 IgG/IgM Rapid test cassette (whole blood/serum/plasma) |
| GCCOV-402a  | TEST RAPID | Orient Gene | COVID-19 IgG/IgM Rapid test cassette (whole blood/serum/plasma) |
| GCCOV-502a  | TEST RAPID | Orient Gene | Coronavirus Ag Rapid Test Cassette (Swab)                       |
| GCFC-T503a  | TEST RAPID | Orient Gene | Smart Rapid COVID-19 &Flu A/B Ag Test Device                    |
| GAHCG-101a  | TEST RAPID | Orient Gene | One step pregnancy test strip (urine)                           |
| GAHCG-101d  | TEST RAPID | Orient Gene | One step pregnancy test strip (urine)                           |
| GAHCG-101b  | TEST RAPID | Orient Gene | One step pregnancy test strip (urine)                           |
| GAHCG-102a  | TEST RAPID | Orient Gene | One step pregnancy test cassette (urine)                        |
| GAHCG-102d  | TEST RAPID | Orient Gene | One step pregnancy test cassette (urine)                        |
| GAHCG-102b  | TEST RAPID | Orient Gene | One step pregnancy test cassette (urine)                        |

|            |            |             |                                                                         |
|------------|------------|-------------|-------------------------------------------------------------------------|
| GEFOB-602c | TEST RAPID | Orient Gene | Fecal Occult Blood Rapid Test Cassette (Feces)                          |
| GEFOB-602b | TEST RAPID | Orient Gene | Fecal Occult Blood Rapid Test Cassette (Feces)                          |
| GEFOB-601c | TEST RAPID | Orient Gene | Fecal Occult Blood Rapid Test Strip (Feces)                             |
| GEFOB-601b | TEST RAPID | Orient Gene | Fecal Occult Blood Rapid Test Strip (Feces)                             |
| GECEA-402a | TEST RAPID | Orient Gene | Carcinoembryonic Antigen Rapid Test Cassette (Whole blood/serum/plasma) |

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|------------|------------|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| GECEA-401a | TEST RAPID | Orient Gene | Carcinoembryonic Antigen Rapid Test Strip (Whole blood/serum/plasma)                                                                                                                           |
| GETF-602a  | TEST RAPID | Orient Gene | Transferrin Rapid Test Cassette (Feces)                                                                                                                                                        |
| GETF-601a  | TEST RAPID | Orient Gene | Transferrin Rapid Test Strip (Feces)                                                                                                                                                           |
| GEAFP-401a | TEST RAPID | Orient Gene | Alpha-Fetoprotein Rapid Test Strip (Whole blood/serum/plasma)                                                                                                                                  |
| GEAFP-402a | TEST RAPID | Orient Gene | Alpha-Fetoprotein Rapid Test Cassette (Whole blood/serum/plasma)                                                                                                                               |
| GIHSA-101a | TEST RAPID | Orient Gene | One step microalbumin test strip (urine)                                                                                                                                                       |
| GIHSA-102a | TEST RAPID | Orient Gene | One step microalbumin test cassette (urine)                                                                                                                                                    |
| GDCAR-335a | TEST RAPID | Orient Gene | Myoglobin/CK-MB/Troponin I Combo Test Cassette (Serum/plasma)                                                                                                                                  |
| GDCKM-302a | TEST RAPID | Orient Gene | One step CK-MB Test Cassette (Serum/Plasma)                                                                                                                                                    |
| GDCKM-402a | TEST RAPID | Orient Gene | CK-MB Rapid Test Cassette (Whole blood/serum/plasma)                                                                                                                                           |
| GDCRP-402a | TEST RAPID | Orient Gene | C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/serum/plasma)                                                                                                            |
| GDTRO-302a | TEST RAPID | Orient Gene | Troponin I Rapid Test Cassette (Serum/Plasma)                                                                                                                                                  |
| GDTRO-402a | TEST RAPID | Orient Gene | Troponin I Rapid Test Cassette (Whole blood/Serum/Plasma)<br>(Except the tender No. ocds-b3wdp1-MD-1722410248839<br>din 05.09.2024, limited to the quantity 28060 pcs only, as per the tender) |
| GDTRO-402b | TEST RAPID | Orient Gene | Troponin I Rapid Test Cassette (Whole blood/Serum/Plasma)                                                                                                                                      |

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|------------------|------------|-------------|---------------------------------------------------------------------------------|
| GDMYO-402a       | TEST RAPID | Orient Gene | Myoglobin Rapid Test Cassette (Whole blood/serum/plasma)                        |
| GDCAR-W435a      | TEST RAPID | Orient Gene | Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (whole blood/Serum/plasma) |
| GDPCT-402a       | TEST RAPID | Orient Gene | Procalcitonin Rapid Test Cassette (Whole blood/serum/plasma)                    |
| GDPCT-T402a      | TEST RAPID | Orient Gene | Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole blood/serum/plasma)  |
| GDPCT-T401a      | TEST RAPID | Orient Gene | Procalcitonin Semi-Quantitative Rapid Test Strip (Whole blood/serum/plasma)     |
| FDPCT -302a      | TEST RAPID | Orient Gene | Procalcitonin Rapid Test Kit (serum/plasma)                                     |
| GDDDI-402b       | TEST RAPID | Orient Gene | D-Dimer Rapid Test Cassette (Whole blood/plasma)                                |
| FDCAR-T302a      | TEST RAPID | Orient Gene | Troponin I/CK-MB/Myoglobin Fluorescence Combo Test Kit (Serum/plasma)           |
| FDTRO-302a       | TEST RAPID | Orient Gene | Troponin I Fluorescence Rapid Test Kit (Serum/plasma)                           |
| FDBNP-302a       | TEST RAPID | Orient Gene | NT-ProBNP Fluorescence Rapid Test Kit (Serum/plasma)                            |
| FDCRP-402a       | TEST RAPID | Orient Gene | C-Reactive Protein Rapid Test Kit (Whole blood/serum/plasma)                    |
| GDCKM-402a       | TEST RAPID | Orient Gene | CK-MB Rapid Test Cassette (whole blood/serum/plasma)                            |
| GAHCG-201a       | TEST RAPID | Orient Gene | One step pregnancy test strip (Urine/serum)                                     |
| GAHCG-202a       | TEST RAPID | Orient Gene | One step pregnancy test cassette (Urine/serum)                                  |
| GAHCG-201b       | TEST RAPID | Orient Gene | One step pregnancy test strip (Urine/serum)                                     |
| GAHCG-202b       | TEST RAPID | Orient Gene | One step pregnancy test cassette (Urine/serum)                                  |
| GCHAV(IgM)-302Ba | TEST RAPID | Orient Gene | HAV IgM Rapid Test Cassette (Serum/plasma)                                      |
| GCHAV-602a       | TEST RAPID | Orient Gene | HAV Ag Rapid Test Cassette (Feces)                                              |

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| GCHAV(IgG/IgM) -302a | TEST RAPID | Orient Gene | HAV IgG/IgM Rapid Test Cassette (Serum/plasma)                      |
| GCHSV(IgG)-402a      | TEST RAPID | Orient Gene | HSV IgG Rapid Test Cassette (Whole blood/serum/plasma)              |
| GCHSV(IgM)-302a      | TEST RAPID | Orient Gene | HSV IgM Rapid test Cassette (serum/plasma)                          |
| GCHP-601a            | TEST RAPID | Orient Gene | H.pylori Ag Rapid Test Strip (feces)                                |
| GCHP-602a            | TEST RAPID | Orient Gene | H.pylori Ag Rapid Test Cassette(feces)                              |
| GCTB-302a            | TEST RAPID | Orient Gene | Tuberculosis IgG/IgM Rapid Test Cassette (serum/plasma)             |
| GCTB-402a            | TEST RAPID | Orient Gene | Tuberculosis IgG/IgM Rapid Test Cassette (whole blood/serum/plasma) |
| GCFLU(A/B)-501a      | TEST RAPID | Orient Gene | Influenza A&B Ag Rapid Test Strip (Swab)                            |
| GCFLU(A/B)-502a      | TEST RAPID | Orient Gene | Influenza A&B Ag Rapid Test Cassette (Swab)                         |
| GCFLU(A/B)-502Ca     | TEST RAPID | Orient Gene | Influenza A&B Ag Rapid Test Cassette (Swab)                         |
| GCFLU(A)-501a        | TEST RAPID | Orient Gene | Influenza A Ag Rapid Test Strip (Swab)                              |
| GCFLU(A)-502a        | TEST RAPID | Orient Gene | Influenza A Ag Rapid Test Cassette (Swab)                           |
| GCHP-301a            | TEST RAPID | Orient Gene | H.Pylori Ab Rapid Test Strip (serum/plasma)                         |
| GCHP-302a            | TEST RAPID | Orient Gene | H.pylori Ab Rapid Test Cassette (serum/plasma)                      |
| GCHP-401a            | TEST RAPID | Orient Gene | H.pylori Ab Rapid Test Strip (Whole blood/serum/plasma)             |
| GCHP-402a            | TEST RAPID | Orient Gene | H.pylori Ab Rapid Test Cassette (Whole blood/serum/plasma)          |
| GCCA-502a            | TEST RAPID | Orient Gene | Candida albicans Antigen rapid test cassette (swab)                 |
| GCGON-502b           | TEST RAPID | Orient Gene | Gonorrhea Rapid Test Cassette (Swab)                                |
| GCGIA-602a           | TEST RAPID | Orient Gene | Giardia lamblia Antigen Rapid tests cassette (feces)                |

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|-----------------------|------------|-------------|-------------------------------------------------------------------|
| GCSTR-501a            | TEST RAPID | Orient Gene | Strep A Rapid Test Strip (Throat swab)                            |
| GCSTR-502a            | TEST RAPID | Orient Gene | Strep A Rapid Test Cassette (Throat swab)                         |
| GCFC-525a             | TEST RAPID | Orient Gene | Rapid COVID-19 + Influenza Antigen Test                           |
| GCRSV-502a            | TEST RAPID | Orient Gene | RSV Antigen Rapid Test Cassette (swab)                            |
| GCADE-502a            | TEST RAPID | Orient Gene | Adenovirus antigen rapid test cassette (swab)                     |
| GCADE-602a            | TEST RAPID | Orient Gene | Adenovirus Rapid test cassette (feces)                            |
| GCCD(GDH)-602a        | TEST RAPID | Orient Gene | Clostridium difficile Antigen GDH Rapid Test cassette (feces)     |
| GCCD (Toxin A/B)-602a | TEST RAPID | Orient Gene | Clostridium difficile Toxin A&B rapid test cassette (feces)       |
| GCCD-602a             | TEST RAPID | Orient Gene | Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) |
| GCHSV (IgM)-402a      | TEST RAPID | Orient Gene | HSV IgM Rapid test Cassette (whole blood/serum/plasma)            |
| GCHSV(IgG)-302a       | TEST RAPID | Orient Gene | HSV IgG Rapid Test Cassette (serum/plasma)                        |
| GCSYP-301a            | TEST RAPID | Orient Gene | Syphilis Ab Rapid Test Strip (serum/plasma)                       |
| GCSYP-302a            | TEST RAPID | Orient Gene | Syphilis Ab Rapid Test Cassette (serum/plasma)                    |
| GCSYP-401a            | TEST RAPID | Orient Gene | Syphilis Ab Rapid test strip (whole blood/serum/plasma)           |
| GCSYP-402a            | TEST RAPID | Orient Gene | Syphilis Ab Rapid test cassette (whole blood/serum/plasma)        |
| GBBAR-101a            | TEST RAPID | Orient Gene | One Step Barbiturates Test Strip (Urine)                          |
| GBBAR-102a            | TEST RAPID | Orient Gene | One Step Barbiturates Test Cassette (Urine)                       |
| GBAMP-101a            | TEST RAPID | Orient Gene | One Step Amphetamine Test Strip (Urine)                           |
| GBAMP-102a            | TEST RAPID | Orient Gene | One Step Amphetamine Test Cassette (Urine)                        |
| GBAMP-105a            | TEST RAPID | Orient Gene | One Step Amphetamine Dip Card (Urine)                             |

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|---------------|------------|-------------|--------------------------------------------------|
| GBPPX-101a    | TEST RAPID | Orient Gene | One Step Propoxyphene Test Strip (Urine)         |
| GBPPX-102a    | TEST RAPID | Orient Gene | One Step Propoxyphene Test Cassette (Urine)      |
| GBDSA-XXXXFX  | TEST RAPID | Orient Gene | Oral Fluid Drug test Cube                        |
| GBDSA-XXXXEX  | TEST RAPID | Orient Gene | Oral Fluid Drug test                             |
| GBDSA-XXXXFSI | TEST RAPID | Orient Gene | Oral Fluid Drug test Cube                        |
| GBDSA-XXXXCX  | TEST RAPID | Orient Gene | Oral Fluid Drug test cylinder                    |
| GBOPI-102a    | TEST RAPID | Orient Gene | One Step Opiate Test Cassette (Urine)            |
| GBOPI-101a    | TEST RAPID | Orient Gene | One Step Opiate Test Strip (Urine)               |
| GBETG-101b    | TEST RAPID | Orient Gene | One Step Ethyl Glucoronide Test Strip (urine)    |
| GBETG-102b    | TEST RAPID | Orient Gene | One Step Ethyl Glucoronide Test Cassette (urine) |
| GBMOP-101a    | TEST RAPID | Orient Gene | One step Morphine Test strip (urine)             |
| GBMOP-102a    | TEST RAPID | Orient Gene | One step Morphine Test Cassette (urine)          |
| GBMOP-105a    | TEST RAPID | Orient Gene | One step Morphine Test dip card (urine)          |
| GBTHC-101a    | TEST RAPID | Orient Gene | One Step Marijuana Test Strip (Urine)            |
| GBTHC-102a    | TEST RAPID | Orient Gene | One Step Marijuana Test Cassette (Urine)         |
| GBTHC-105a    | TEST RAPID | Orient Gene | One Step Marijuana Test Dip Card (Urine)         |
| GBMTD-101a    | TEST RAPID | Orient Gene | One step Methadone Test strip (urine)            |
| GBMTD-102a    | TEST RAPID | Orient Gene | One step Methadone Test cassette (urine)         |
| GBXXX-101     | TEST RAPID | Orient Gene | One Step Drugs of Abuse Test Strip (Urine)       |
| GBXXX-102     | TEST RAPID | Orient Gene | One Step Drugs of Abuse Test Cassette (Urine)    |
| GBXXX-105     | TEST RAPID | Orient Gene | One Step Drugs of Abuse Test Dip Card (Urine)    |

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Zhejiang Orient Gene Biotech Co.,LTD

|                     |            |             |                                                            |
|---------------------|------------|-------------|------------------------------------------------------------|
| GBDSA-XXXXJSI       | TEST RAPID | Orient Gene | Oral fluid drug test cylinder                              |
| GBDSA-XXXXJX        | TEST RAPID | Orient Gene | Oral fluid drug test cylinder                              |
| GBDSA-XXXXKX        | TEST RAPID | Orient Gene | Oral fluid drug test cylinder                              |
| GBDSA-XXXXMX        | TEST RAPID | Orient Gene | Oral fluid drug test device                                |
| GBDSA-XXXXA/B/G/H/I | TEST RAPID | Orient Gene | Multi-drug rapid screen test cassette (oral fluid)         |
| GBMTC-101a          | TEST RAPID | Orient Gene | One Step Methcathinone Test Strip (Urine)                  |
| GBMTC-102a          | TEST RAPID | Orient Gene | One Step Methcathinone Test Cassette (Urine)               |
| GBKRA-101a          | TEST RAPID | Orient Gene | One step kratom test strip (urine)                         |
| GBKRA-102a          | TEST RAPID | Orient Gene | One step kratom test cassette (urine)                      |
| GBLSD-101a          | TEST RAPID | Orient Gene | One Step Lysergic Acid Diethylamide Test Strip (Urine)     |
| GBLSD-102a          | TEST RAPID | Orient Gene | One Step Lysergic Acid Diethylamide Test Cassette (Urine)  |
| FBXXX-1102          | TEST RAPID | Orient Gene | Hair Multi-drug rapid test kit                             |
| GBETG-105a          | TEST RAPID | Orient Gene | One step ethyl glucuronide test dip card (urine)           |
| GBPGB-102b          | TEST RAPID | Orient Gene | One step pregabalin test cassette (urine)                  |
| GBTRA-101a          | TEST RAPID | Orient Gene | One step tramadol test strip (urine)                       |
| GBTRA-102a          | TEST RAPID | Orient Gene | One step tramadol test cassette (urine)                    |
| GBOXY-101a          | TEST RAPID | Orient Gene | One step oxycodone Test strip (urine)                      |
| GBOXY-102a          | TEST RAPID | Orient Gene | One step oxycodone Test cassette (urine)                   |
| GBMDP-101a          | TEST RAPID | Orient Gene | One step 3,4-Methylenedioxypyrovalerone Test strip (urine) |

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|            |            |             |                                                                    |
|------------|------------|-------------|--------------------------------------------------------------------|
| GBMDP-101a | TEST RAPID | Orient Gene | One step<br>3,4-Methylenedioxypropylvalerone Test cassette (urine) |
| GBMQL-102a | TEST RAPID | Orient Gene | One step Methaqualone Test cassette (urine)                        |
| GBMQL-101a | TEST RAPID | Orient Gene | One step Methaqualone Test strip (urine)                           |
| GBMPD-101a | TEST RAPID | Orient Gene | One step Methylphenidate Test strip (urine)                        |
| GBMPD-102a | TEST RAPID | Orient Gene | One step Methylphenidate Test cassette (urine)                     |
| GBUR-101a  | TEST RAPID | Orient Gene | One step UR-144 test strip (urine)                                 |
| GBUR-102a  | TEST RAPID | Orient Gene | One step UR-144 test cassette (urine)                              |
| GBBUP-101a | TEST RAPID | Orient Gene | One step buprenorphine test strip (urine)                          |
| GBBUP-102a | TEST RAPID | Orient Gene | One step buprenorphine test cassette (urine)                       |
| GBPCP-101a | TEST RAPID | Orient Gene | One step Phencyclidine Test strip (urine)                          |
| GBPCP-102a | TEST RAPID | Orient Gene | One step Phencyclidine Test cassette (urine)                       |
| GBTCA-101a | TEST RAPID | Orient Gene | One step Tricyclic Antidepressants test strip (urine)              |
| GBTCA-102a | TEST RAPID | Orient Gene | One step Tricyclic Antidepressants test cassette (urine)           |
| GBEDD-101a | TEST RAPID | Orient Gene | One step EDDP test strip (urine)                                   |
| GBEDD-102a | TEST RAPID | Orient Gene | One step EDDP test cassette (urine)                                |
| GBFEN-101b | TEST RAPID | Orient Gene | One step Fentanyl Test strip (urine)                               |
| GBFEN-102b | TEST RAPID | Orient Gene | One step Fentanyl Test cassette (urine)                            |
| GBALC-101a | TEST RAPID | Orient Gene | Urine Alcohol Test Strip                                           |
| GBMAM-S102 | TEST RAPID | Orient Gene | One step 6-MAM Test cassette (urine)                               |

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|              |            |             |                                                  |
|--------------|------------|-------------|--------------------------------------------------|
| GBMAM-S101   | TEST RAPID | Orient Gene | One step 6-MAM Test cassette (urine)             |
| GBHCD-101a   | TEST RAPID | Orient Gene | One step Hydrocodone test strip (urine)          |
| GBHCD-102a   | TEST RAPID | Orient Gene | One step Hydrocodone test cassette (urine)       |
| GBNFT-101c   | TEST RAPID | Orient Gene | One step Norfentanyl test strip (urine)          |
| GBNFT-102c   | TEST RAPID | Orient Gene | One step Norfentanyl test cassette (urine)       |
| GBXXX-1102   | TEST RAPID | Orient Gene | Hair Multi-Drug Rapid Test Kit (ICA)             |
| GBDSA-XXXXLX | TEST RAPID | Orient Gene | Oral Fluid Drug Test Mini Cube                   |
| GBDUA-1X4    | TEST RAPID | Orient Gene | One Step Multi-Drug Screen Test Dip Card (urine) |
| GBDOA-1X5    | TEST RAPID | Orient Gene | One Step Multi-Drug Screen Test Cassette (urine) |
| GBDUA-1X6    | TEST RAPID | Orient Gene | One Step Multi-Drug Screen Test Cup (urine)      |
| GBCOT-102a   | TEST RAPID | Orient Gene | One step cotinine test cassette (urine)          |
| GBK2-101a    | TEST RAPID | Orient Gene | One step K2 Test strip (urine)                   |
| GBK2-102a    | TEST RAPID | Orient Gene | One step K2 Test cassette (urine)                |
| GBKET-101a   | TEST RAPID | Orient Gene | One step Ketamine Test strip (urine)             |
| GBKET-102a   | TEST RAPID | Orient Gene | One step Ketamine Test cassette (urine)          |
| GBBZO-101a   | TEST RAPID | Orient Gene | One step Benzodiazepines Test Strip (urine)      |
| GBBZO-102a   | TEST RAPID | Orient Gene | One step Benzodiazepines Test Cassette (urine)   |
| GBCOC-101a   | TEST RAPID | Orient Gene | One step Cocaine Test strip (urine)              |
| GBCOC-102a   | TEST RAPID | Orient Gene | One step Cocaine Test cassette (urine)           |
| GBCOC-105a   | TEST RAPID | Orient Gene | One step Cocaine Test dip card (urine)           |
| GBMDM-101a   | TEST RAPID | Orient Gene | One step ecstasy Test strip (urine)              |

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|                      |            |             |                                                                    |
|----------------------|------------|-------------|--------------------------------------------------------------------|
| GBMDM-102a           | TEST RAPID | Orient Gene | One step ecstasy Test cassette (urine)                             |
| GBMET-101a           | TEST RAPID | Orient Gene | One step Methamphetamine test strip (urine)                        |
| GBMET-102a           | TEST RAPID | Orient Gene | One step Methamphetamine test cassette (urine)                     |
| GBMET-105a           | TEST RAPID | Orient Gene | One step Methamphetamine test dip card (urine)                     |
| GCTOXI(IgG/IgM)-302a | TEST RAPID | Orient Gene | Toxoplasma gondii test cassette (serum/plasma)                     |
| GCTOXI(IgG)-302a     | TEST RAPID | Orient Gene | Toxoplasma gondii IgG test cassette (serum/plasma)                 |
| GCTOXI(IgM)-302a     | TEST RAPID | Orient Gene | Toxoplasma gondii IgM test cassette (serum/plasma)                 |
| GCCHL-502a           | TEST RAPID | Orient Gene | Chlamydia Trachomatis Antigen test cassette (swab/urine)           |
| GEPSA-402a           | TEST RAPID | Orient Gene | Prostate specific antigen test cassette (whole blood/serum/plasma) |
| GEPSA-401a           | TEST RAPID | Orient Gene | Prostate specific antigen test strip (whole blood/serum/plasma)    |
| GEPSA-302a           | TEST RAPID | Orient Gene | Prostate specific antigen test cassette (serum/plasma)             |
| GEPSA-301a           | TEST RAPID | Orient Gene | Prostate specific antigen test strip (serum/plasma)                |
| GALH-101a-1T         | TEST RAPID | Orient Gene | LH Ovulation Test Strip                                            |
| GALH-101a-5T         | TEST RAPID | Orient Gene | LH Ovulation Test Strip                                            |
| GALH-101a-7T         | TEST RAPID | Orient Gene | LH Ovulation Test Strip                                            |
| GALH-101b-1T         | TEST RAPID | Orient Gene | LH Ovulation Test Strip                                            |
| GALH-101b-5T         | TEST RAPID | Orient Gene | LH Ovulation Test Strip                                            |
| GALH-101b-7T         | TEST RAPID | Orient Gene | LH Ovulation Test Strip                                            |
| GALH-102a-1T         | TEST RAPID | Orient Gene | LH Ovulation Test Cassette                                         |
| GALH-102a-5T         | TEST RAPID | Orient Gene | LH Ovulation Test Cassette                                         |
| GALH-102a-7T         | TEST RAPID | Orient Gene | LH Ovulation Test Cassette                                         |
| GALH-102b-5T         | TEST RAPID | Orient Gene | LH Ovulation Test Cassette                                         |
| GALH-102b-1T         | TEST RAPID | Orient Gene | LH Ovulation Test Cassette                                         |

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|              |            |             |                            |
|--------------|------------|-------------|----------------------------|
| GALH-102b-7T | TEST RAPID | Orient Gene | LH Ovulation Test Cassette |
|--------------|------------|-------------|----------------------------|

|          |            |             |                                               |
|----------|------------|-------------|-----------------------------------------------|
| VPH-502a | TEST RAPID | Orient Gene | Vaginal pH test cassette (Vaginal secretions) |
|----------|------------|-------------|-----------------------------------------------|

|                                        |                   |             |                                                                         |
|----------------------------------------|-------------------|-------------|-------------------------------------------------------------------------|
| URS-1T to 14T with various combination | STRIPURI DE URINA | Orient Gene | LEU/NIT/URO/MA/PRO/PH/BLO/S<br>G/ASC/CRE/KET/BIL/GLU/CA                 |
| GCHCV-302a                             | TEST RAPID        | Orient Gene | HCV Hepatitis C Virus Rapid Test (serum/plasma) cassette                |
| GCHCV-402a                             | TEST RAPID        | Orient Gene | HCV Hepatitis C Virus Rapid Test (whole blood/serum/plasma) cassette    |
| GCHIV-302a                             | TEST RAPID        | Orient gene | HIV 1/2 Human Immunodeficiency Virus (Serum/Plasma) cassette            |
| GCHIV-402a                             | TEST RAPID        | Orient gene | HIV 1/2 Human Immunodeficiency Virus (Whole blood/serum/plasma)cassette |
| GCHBsg-302a                            | TEST RAPID        | Orient gene | HBsAg Hepatitis B Surface Antigen Rapid Test (Serum/Plasma)             |
| GCHBsg-402a                            | TEST RAPID        | Orient gene | HBsAg Hepatitis B Surface Antigen Rapid Test(Whole Blood/Serum/Plasma)  |

The end.



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# Certificate

No. Q5 092305 0001 Rev. 02

**Holder of Certificate:** **Zhejiang Orient Gene Biotech Co., Ltd.**  
3787#, East Yangguang Avenue, Dipu Street Anji  
313300 Huzhou, Zhejiang  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 02)

**Report No.:** SH2398804

**Valid from:** 2024-03-17

**Valid until:** 2027-03-16

**Date,** 2024-03-01

Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q5 092305 0001 Rev. 02

**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **Zhejiang Orient Gene Biotech Co., Ltd.**  
3787#, East Yangguang Avenue, Dipu Street Anji, 313300  
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate



浙江东方基因生物制品股份有限公司  
Zhejiang Orient Gene Biotech Co., LTD



CE-DOC-OG038  
Version 2.0

# EC Declaration of Conformity

In accordance with Directive 98/79/EC

**Legal Manufacturer:** *Zhejiang Orient Gene Biotech Co., Ltd*

**Legal Manufacturer Address:** *3787#, East Yangguang Avenue, Dipu Street,  
Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products  
Product Name and Model(s)

|                                                           |            |
|-----------------------------------------------------------|------------|
| Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) | GDTRO-402a |
| Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) | GDTRO-402b |

Classification: *Other*

Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

**EC Representative's Name:** *Shanghai International Holding Corp. GmbH (Europe)*

**EC Representative's Address:** *Eiffestrasse 80, 20537 Hamburg, Germany*

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: August 11, 2020

Name of authorized signatory: *Joyce Pang*  
Position held in the company: *Vice-President*



浙江东方基因生物制品股份有限公司  
Zhejiang Orient Gene Biotech Co., LTD



CE-DOC-OG266  
Version 1.0

# EC Declaration of Conformity

In accordance with Directive 98/79/EC

**Legal Manufacturer:** *Zhejiang Orient Gene Biotech Co., Ltd*

**Legal Manufacturer Address:** *3787#, East Yangguang Avenue, Dipu Street,  
Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products  
Product Name and Model(s)

|                                           |            |
|-------------------------------------------|------------|
| Strep A Rapid Test Strip (Throat Swab)    | GCSTR-501a |
| Strep A Rapid Test Cassette (Throat Swab) | GCSTR-502a |

Classification: Other  
Conformity assessment route: Annex III (EC DECLARATION OF CONFORMITY)

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

**EC Representative's Name:** CMC Medical Devices & Drugs S.L

**EC Representative's Address:** C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: May 20, 2022

Name of authorized signatory: Joyce Pang  
Position held in the company: Vice-President

# Strep A Rapid Test Cassette (Throat Swab)



## INTENDED USE

The Strep A Rapid Test Cassette (Throat Swab) is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

## INTRODUCTION

*Streptococcus pyogenes* is non-motile gram-positive cocci, which contains the Lancefield group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.<sup>1</sup> Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.<sup>2</sup> Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.<sup>3,4</sup> The Strep A Rapid Test Cassette (Throat Swab) is a rapid test to qualitatively detect the presence of Strep A antigen in throat swab specimens, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigen in a throat swab specimen.

## PRINCIPLE

The Strep A Rapid Test Cassette (Throat Swab) is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

## MATERIALS SUPPLIED

1. 20 Test cassettes
2. 20 Sterile swabs
3. 20 Extraction tubes and tips
4. 1 Workstation and 1 package insert
5. 1 Reagent B (0.2M acetic acid): 10.0 mL

6. 1 Reagent A (2M sodium nitrite): 10.0 mL



Harmful if swallowed.  
Wash thoroughly after handling.

## MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or timer

## WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Humidity and temperature can adversely affect results.
6. Do not use test if pouch is damaged.
7. Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
8. Do not interchange reagent bottle caps.
9. Do not interchange external control solution bottle caps.

## STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

## SPECIMEN COLLECTION AND STORAGE

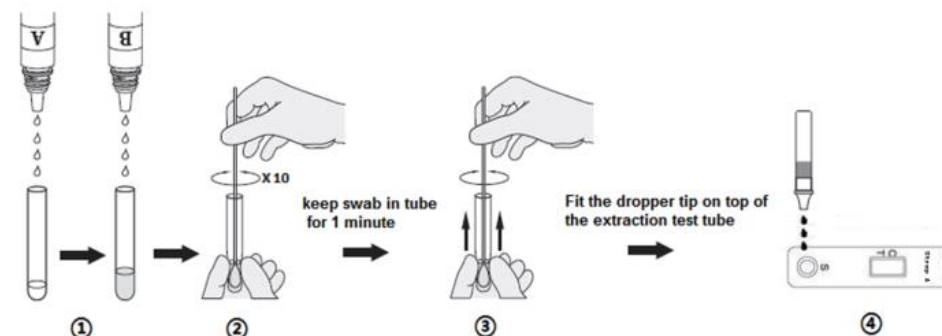
1. Only use reagents and sterile swabs provided in the kit.
2. Collect the throat swab specimen with the sterile swab that is provided in the kit. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.<sup>5</sup>

3. Testing should be performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8°C. Transport swabs containing modified Stuart's or Amies medium can also be used with this product.
4. If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Strep A Rapid Test Cassette (Throat Swab).

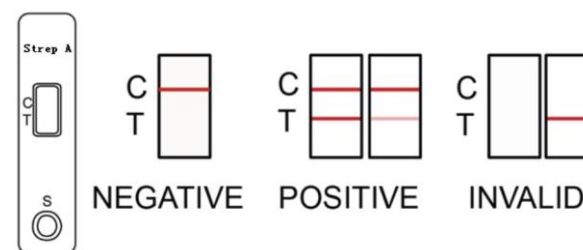
## TEST PROCEDURE

Allow the test device, reagents, throat swab specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Hold the Reagent A bottle vertically and add 4 full drops of Reagent A to an extraction tube. Reagent A is red in color. Hold the Reagent B bottle vertically and add 4 full drops to the tube. Reagent B is colorless. Mix the solution by gently swirling the extraction tube. The addition of Reagent B to Reagent A changes the color of the solution from red to yellow.
3. Immediately add the throat swab to the extraction tube of yellow solution. Agitate the swab 10 times in the tube. Leave the swab in the tube for 1 minute. Then press the swab against the side of the tube and squeeze the bottom of the tube as the swab is withdrawn. Discard the swab.
4. Fit the dropper tip on top of the extraction tube. Place the test device on a clean and level surface. Add 3 full drops of solution to the specimen well (S) and then start the timer.
5. Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not read the result after 10 minutes.



## INTERPRETATION OF RESULTS



**Positive:** Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

**Negative:** One coloured line appears in the control line region (C). No line appears in the test line region (T).

**Invalid:** Control line fails to appear.

**NOTE:** Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

## QUALITY CONTROL

### Internal Quality Control

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

## LIMITATIONS

1. The Strep A Rapid Test Cassette (Throat Swab) is for *in vitro* diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A streptococcus bacteria.
3. A negative result must be confirmed by culture. A negative result may be obtained if the concentration of the Strep A antigen present in the throat swab is not adequate or is below the detectable level of the test.
4. The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth<sup>5</sup> and any bleeding areas of the mouth with the swab when collecting specimens. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

## PERFORMANCE CHARACTERISTICS

### Clinical Sensitivity and Specificity

The Strep A Rapid Test Cassette (Throat Swab) was used to evaluate 368 throat swab specimens collected from three physician offices patients presenting with pharyngitis. The test result compared to the culture method. The below table summarizes the data.

Clinical Performance: Strep A Rapid Test vs. Culture

| Strep A Rapid Test Cassette (Throat Swab) Results | Reference Culture Results |          | Total |
|---------------------------------------------------|---------------------------|----------|-------|
|                                                   | Positive                  | Negative |       |
| Positive                                          | 200                       | 1        | 201   |
| Negative                                          | 6                         | 161      | 167   |
| Total                                             | 206                       | 162      | 368   |

Sensitivity: 97.1% (200/206); 95%CI = 93.7% - 98.8%

Specificity: 99.4% (161/162); 95%CI = 96.2% - 100.0%

Clinical Performance Stratified by Age

| Age     | Sensitivity     | Sensitivity(95%CI) | Specificity     | Specificity(95%CI) |
|---------|-----------------|--------------------|-----------------|--------------------|
| 0 ~ 5   | 97.4% (74/76)   | 90.4% - 99.8%      | 98.1% (52/53)   | 89.1% - 100.0%     |
| 5+ ~ 21 | 96.7% (119/123) | 91.7% - 99.0%      | 100% (88/88)    | 95.0% - 100.0%     |
| 21+     | 100% (7/7)      | 59.6% - 100.0%     | 100% (21/21)    | 81.8% - 100.0%     |
| All     | 97.1% (200/206) | 93.7% - 98.8%      | 99.4% (161/162) | 96.2% - 100.0%     |

### Cross-Reactivity

The following organisms were tested at  $1.0 \times 10^7$  organisms per test and were all found to be negative when tested with the Strep A Rapid Test Cassette (Throat Swab). No mucoid-producing strains were tested.

|                            |                            |                       |
|----------------------------|----------------------------|-----------------------|
| Group B Streptococcus      | Neisseria meningitidis     | Serratia marcescens   |
| Group F Streptococcus      | Neisseria sicca            | Klebsiella pneumoniae |
| Streptococcus pneumoniae   | Branhamella catarrhalis    | Bordetella pertussis  |
| Streptococcus mutans       | Group C Streptococcus      | Neisseria gonorrhea   |
| Staphylococcus aureus      | Group G Streptococcus      | Neisseria subflava    |
| Corynebacterium diphtheria | Streptococcus sanguis      | Hemophilus influenza  |
| Candida albicans           | Enterococcus faecalis      |                       |
| Pseudomonas aeruginosa     | Staphylococcus epidermidis |                       |

### Physician's Office Laboratory (POL) Studies

Three physicians' offices were used to conduct an evaluation of the Strep A Rapid Test Cassette (Throat Swab). Personnel with various educational backgrounds performed the testing. Each physician's office tested a randomly coded panel of samples consisting of negative (20), low positive (20), and medium positive (20) for three days. The results obtained had a 96% correlation with the expected results.

## REFERENCE

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## INDEX OF SYMBOLS

|  |                                         |  |               |  |                           |
|--|-----------------------------------------|--|---------------|--|---------------------------|
|  | Consult instructions for use            |  | Tests per kit |  | Authorized Representative |
|  | For <i>in vitro</i> diagnostic use only |  | Use by        |  | Do not reuse              |
|  | Store between 2~30°C                    |  | Lot Number    |  | Catalog#                  |

Zhejiang Orient Gene Biotech Co.,Ltd  
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Website: www.orientgene.com

CMC Medical Devices & Drugs S.L  
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Tel: +34951214054 Fax: +34952330100  
Email-info@cmcmmedicaldevices.com

GCSTR-502a

**Swab information**

Jiangsu ChangFeng Medical Industry Co., LTD  
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Revision Date: 2022-04-12  
B20402-04

Troponin I

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)

Package Insert

A rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. For professional *in vitro* diagnostic use only.

INTENDED USE

The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. This kit is intended to be used as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa.<sup>1</sup> Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.<sup>2</sup> After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma.<sup>3</sup> cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery.<sup>4</sup> Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.<sup>5</sup>

PRINCIPLE

The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) has been designed to detect cardiac Troponin I through visual interpretation of color development in the strip. The membrane was immobilized with anti-cTnI antibodies on the test region. During the test, the specimen is allowed to react with colored anti-cTnI antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough cTnI in specimens, a colored band will form at the test region of the membrane.

Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- Do not use it if the tube/pouch is damaged or broken.
- Test is for single use only. Do not re- use under any circumstances.
- Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test cassette unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test cassette is brought to room temperature before opening. The test is not stable out of the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND PREPARATION

- The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is intended only for use with human whole blood, serum, or plasma specimens.
- Only clear, non-hemolyzed specimens are recommended for use with this test.
- Serum or plasma should be separated with soonest possible opportunity to avoid hemolysis.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.
- There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test cassette. Repeat the test with a serum or plasma specimen from the same patient using a new test cassette.

Materials Provided

- Test cassettes
- Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for plasma only)
- Clock or Timer

DIRECTIONS FOR USE

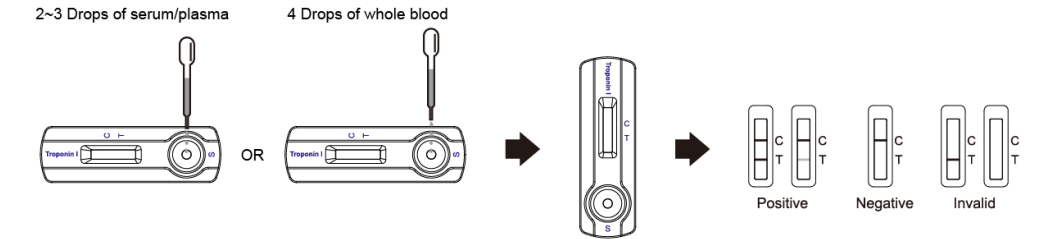
Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- Remove the test from its sealed pouch, and place it on a clean, level surface. Label the cassette with patient or control identification. To obtain a best result, the assay should be performed within one hour.
- Transfer 2-3 drops of serum or plasma to the specimen well(S) of the cassette with a disposable pipette provided in the kit, and then start the timer.

OR

Transfer 4 drops of whole blood specimen to the specimen well(S) of the cassette with a disposable pipette provided in the kit, and then start the timer.

- Wait for the colored band(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**POSITIVE:** Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

**NEGATIVE:** Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

**INVALID:** Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

**NOTE:** Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should be used for the qualitative detection of cardiac Troponin I only. There is no meaning attributed to line color intensity or width.
- The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of Troponin I in the specimen and should not be used as the sole criteria for the diagnosis.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.25 ng/mL of cTnI in specimens. Thus, a negative result does not at any time rule out the existence of Troponin I in blood, because the antibodies may be absent or below the minimum detection level of the test.
- Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Table: Troponin I Rapid Test vs. EIA

| Method        | Troponin I Rapid Test Cassette |          | Total Results |
|---------------|--------------------------------|----------|---------------|
|               | Positive                       | Negative |               |
| EIA           | Positive                       | 138      | 2             |
|               | Negative                       | 1        | 315           |
| Total Results |                                | 139      | 317           |
|               |                                | 317      | 456           |

Relative Sensitivity: 98.6% (94.9%-99.8%)\* Relative Specificity: 99.7% (98.3%-99.9%)\*

Overall Agreement: 99.3% (98.1%-99.9%)\* \*95% Confidence Interval

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