

# **Product Catalogue**

2019-2020



**Tellgen Corporation** 



Deeper understanding of life

## **PROFILE**

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**HPV GENOTYPING** 

Y-CHROMESOME MICRODELETION

**SERVICE & SUPPORT** 

# Road of Tellgen

#### **2003**

Tellgen was found in Zhangjiang Hi-Tech Park, Pudong and became the first development parter of Luminex Corporation based on xMAP<sup>®</sup> technology in China.

#### · 2007

Tellgen*plex*<sup>™</sup> Tumor Marker Detection Kit won high-tech award of Zhangjiang Hi-Tech Park

#### 2009

Tellgen Tumor Marker Detection Kit and Tellgen*plex*™ HPV DNA Test Kit got clearance from SFDA

#### 2010

Tellgen developed pharmacogenomic panel of EGFR/K-ras/B-raf om Onology area based in Tellgen*plex*™ technology

#### 2011

Tellgen developed EGFR/K-ras/B-raf reagents besed on TEEM™ PCR

#### 2013

Tellgen PGI /II Detection Kit got clearance from NMPA

#### 2014

Tellgen HPV 2+12/5+9 Detection Kit got clearance from NMPA

#### 2015

Tellgen Y-CHROMESOME MICRODELETION, Tumor Marker, EGFR, ToRCH, TESMI 3999 got clearance from NMPA

#### 2016

Teligen NT-proBNP got clearance from NMPA, HPV GENOTYPING, HPV 2+12/5+9, Y-CHROMESOME, EGFR,K-Ras, B-RAF and SHOX2 and RASSF1A DNA methylation got clearance from CE.

#### 2017

Tellgen has been listed on the Growth Enterprise Market of Shenzhen Stock Exchange(stock code: 300642)

#### 2018

Tellgen introduced a total laboratory automation streamline: TESMI Connection Modules (TCM).

#### 2020

SARS-CoV-2 RTPCR kit and SARS-CoV-2 cartridge PCR kit got clearance form CE.

# INTRODUCTION



Tellgen corporation( stock code: 300642) is a public company specializing in the development and manufacture of multiple biomarks and high throughput platform of in vitro diagnostic products. The company was founded in 2003 and headquartered in Shanghai Zhangjiang Hi-Tech Park.

The Tellgen Corporation focuses on tumor markers detection ,provide total solution from screening to prognosis evaluation related products for customers. The methodology platform employed including immunofluorescence, chemiluminescence immunoassay and multiple fluorescent PCR, mass spectrometry, etc.

Tellgen is one of the global strategic partners with Luminex Corp. Meanwhile, Tellgen is the first one to launch an automated high-throughput immunoassay system (TESMI) based on fluorescence flowcytometry technology. In 2019, we have introduced a total laboratory automation streamline: TESMI Connection Modules (TCM).

Tellgen corporation will always adhere to the R & D philosophy of "internalizing technology knowledge globally & ploughing self-innovation locally", Tellgen Coporation strives to become an influential company in the field of international life science and contribute to public health.

# TECHNOLOGY--Tellgen*plex*<sup>TM</sup>

Tellgen*plex*™ is a technical based on xMAP technology combines advanced fluidics, optics, and digital signal processing with proprietary microsphere technology to deliver multiplexed assay capabilities. color-codes tiny beads, called microspheres, class into up to 500 distinct sets. Each bead set can be coated with a reagent specific to a particular bioassay, allowing the capture and detection of specific analytes from a sample. Inside the Luminex analyzer, a light source excites the internal dyes that identify each microsphere particle, and also any reporter dye captured during the assay. Many readings are made on each bead set, which further validates the results.

# Instrument—TESMI F4000

The TESMI F4000 System is a flexible analyzer based on the principles of flow cytometry. The system enables you to multiplex (simultaneously measure) up to 100 analytes in a single microplate well, using very small sample volumes. The system delivers fast and cost-effective bioassay results on many assay formats including nucleic acid assays, receptor-ligand assays, immunoassays and enzymatic assays.



# **Tumor Markers**

Base on suspension bead array method, Tellgen developed Tellgen*plex*<sup>TM</sup> Tumor Marker Test which is intended for the simultaneous quantitative determination up to 13 tumor markers in 1 reaction. All these tumor markers were obtained clearance from SFDA. The customers could select these markers by singleplex or multiplex manner according to their needs. The kit could apply in both clinical test and personnel physical test, and became a cutting-end product in oncology biomarker screening area.

# Singleplex markers

- F-PSA, T-PSA
- AFP, CEA, free-β-hCG
- NSE, CYFRA21-1, SCCA
- CA125, CA19-9, CA24-2, CA72-4, CA153, CA50

### Panels recommended

- total-PSA \(\text{free-PSA}\) (CE Marked)
- AFP、CEA
- NSE, CYFRA21-1. CEA
- CA242、CA125、CA19-9、CA15-3、CA50
   NSE、CYFRA21-1、free-β-hCG、SCCA

### **Benifits**

- Trace sample, multiple markers in 1 reaction
- Less sample-to-answer time, ~1 hours/96 samples
- · Multiple combination according to your needs
- · Most robust platform

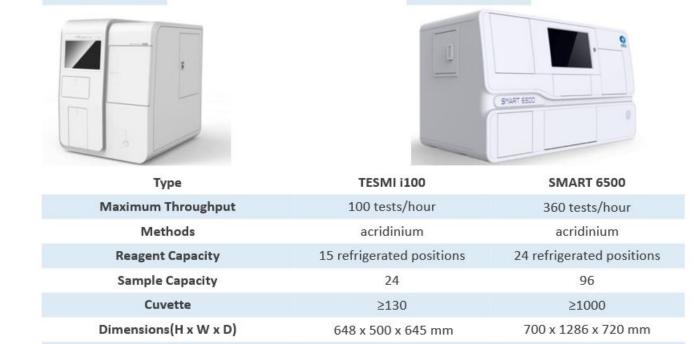
# Panels available

		T	1	
NO.	Tumor Markers	CODE	Cat NO.	Tests
1	CA125	LP111010B	LP111010	96
2	CA153	LP011020A	LP011020	96
3	CYFRA21-1	LP111040A	LP111040	96
4	AFP	LP111050B	LP111050	96
5	CEA	LP111062A	LP111062	480
6	CEA	LP111060A	LP111060	96
7	total PSA	LP111080C	LP111080	96
8	free PSA	LP111090A	LP111090	96
9	free-β-hCG	LP111100B	LP111100	96
10	CA19-9	LP111110C	LP111110	96
11	NSE	LP111070A	LP111070	96
12	SCCA	LP011160	LP011160	96
13	CA50	LP011180B	LP011180	96
14	F-PSA/T-PSA	LP110050C	LP110050	96
15	AFP/CEA	LP110060D	LP110060	96
16	AFP/CEA/CA125/CA19-9	LP110200A	LP110200	96
17	AFP/CEA/CA125/CA19-9/T-PSA	LP110230B	LP110230	96
18	AFP/CEA/CA125/CA19-9/T-PSA	LP110232C	LP110232	480
19	AFP/CA125/CYFRA21-1/CA19-9 /CEA /free-β- hCG/NSE/F-PSA/T-PSA	LP110240A	LP110240	96
20	AFP/CEA/CA125/CYFRA21-1/free-β-hCG/NSE/F- PSA/T-PSA	LP010300	LP010300	96
21	CA125/CA19-9	LP110330C	LP110330	96
22	CA19-9/total PSA	LP110360B	LP110360	96
23	CA125/CA19-9/NSE/T-PSA	LP110370A	LP110370	96
24	AFP/CEA/CA125/CA19-9/CYFRA21-1	LP110380B	LP110380	96
25	AFP/total PSA	LP110390A	LP110390	96
26	AFP/CEA/total PSA	LP110440A	LP110440	96
27	AFP/CEA/CA125	LP110450A	LP110450	96
28	CEA/CYFRA21-1/NSE	LP110460A	LP110460	96
29	CYFRA21-1/NSE	LP110490A	LP110490	96
30	CA19-9/F-PSA/T-PSA	LP110500A	LP110500	96
31	AFP/CEA/F-PSA/T-PSA	LP110510A	LP110510	96

For other combination, please contact with us via email: zhaozhengzhen@tellgen.com

# TECHNOLOGY-Chemiluminescence immunoassay

# Immunoassay: TESMI i100 and SMART 6500



√Tumor markers

TESMI i100

✓ SARS-CoV-2 (IgG&IGM)

Weight

Onboard Maintenance Records

- √ Cardiac markers
- **✓ Thyroid funtion**
- **✓ ToRCH**

✓ Autoimmune markers

**SMART 6500** 

- √ Fertility/ hormones
- √ Vitamin D

89 kg

Yes

√ Hepatitis /infectious disease

150 kg

Yes

√ Bone makers

# Panels available

#### Tumor markers (20)

Tumor markers (20)	
α-fetoprotein	AFP
Carcinoembryonic antigen	CEA
Neuron Specific Enolase	NSE
Cytokeratin fragment 19	CYFRA21-1
Carbohydrate antigen 125	CA125
Carbohydrate antigen 19-9	CA19-9
Squamous cell carcinoma antigen	SCCA
Total prostate specific antigen	tPSA
Free prostate specific antigen	fPSA
Free human chorionic gonadotropin hormone $\beta$ subunit	free-β-hCG
pepsinogenI	PGI
pepsinogen II	PGII
ferritin	ferritin
β2-microglobulin	β2-MG
Carbohydrate antigen 15-3	CA15-3
pro-gastrin-releasing peptide	proGRP
Human epididymis protein 4	HE4
Carbohydrate antigen 72-4	CA72-4
Carbohydrate antigen 24-2	CA24-2
Carbohydrate antigen 50	CA50
Thyroid function indicators (5)	
Thyroid stimulating hormone,	TSH
Total serum thyroxine	TT3
Free triiodothyronine	FT3
The hormone thyroxine T4	TT4
Free Thyroxine, FT4	FT4

For other combination, please contact with us via email: zhaozhengzhen@tellgen.com

# Panels available

## **Myocardial and Inflammatory Markers**

Brain natriuretic peptide	BNP
N-terminal brain natriuretic peptide precursor	NT-ProBNP
high-sensitivity cardiac troponin I	hs-cTnl
CK-MB the MB isoenzyme of creatine kinase	СК-МВ
Myoglobin	MYO
heart-type fatty acid-binding protein	H-FABP
Interleukin 6	IL-6
Procalcitonin	PCT



For other combination, please contact with us via email: zhaozhengzhen@tellgen.com

# TECHNOLOGY— Clinical Chemistry

# **General Clinical chemistry** analyzers





- √ General chemistry
- **✓ Diabetes**
- ✓ Anemia
- √ Cardiology and lipids
- √ specific protein
- ✓ coagulation
- ✓ Broad menu >60 items

# TECHNOLOGY— Molecular tests





- ✓ Sars-CoV-2
- **✓** HPV-27
- **√**HPV2+12
- ✓ Lung-Me methylation for lung cancer
- √ Septin9 colorectal cancer blood screening
- **✓**Y6 chromosome microdeletion
- **✓**EGFR/K-RAS/B-RAF

# SARS-CoV-2 Nucleic acid detection kit based on Real-Time PCR platform

The kit for the in vitro qualitative determination of N gene and S gene for SARS-

CoV-2 in human throat swab and sputum. This kit is used for nucleic acid detection of SARS-CoV-2, and the results can be used for auxiliary diagnosis of patients with SARS-CoV-2 infection or patients suspected of COVID 19, and provide molecular diagnostic bas is for infected patients. The test results of this kit are for clinical



# **Benifits**

- High Specificity: A dual-target assay for the conserved region of spike protein S gene (FAM)
- Stable: Lyophilized form of the reagent can be transport at room temperature
- Multilple Applicable instrument: Any real-time PCR instrument with FAM / ROX / Cy5 detection channel

1	Liquid form	PGA4102P1	48
2	Lyophilized form	PGA4102P2	1414

# SARS-CoV-2 Nucleic acid detection kit Based on Cartridge Real-Time PCR platform

The kit for the in vitro qualitative determination of two different target fragements of N gene for SARS-CoV-2 in human throat swab and sputum. This kit is used for nucleic acid detection of SARS-CoV-2, and the results can be used for auxiliary diagnosis of patients with SARS-CoV-2 infection or patients suspected of COVID 19, and provide molecular diagnostic basis for infected patients.





# **Benifits**

- Applicable for rapid diagnosis of SARS-CoV-2
- Simple: No hands-on process for nucleic acid purification, no restrictions of licensed PCR labortory or qualified PCR technicians
- Safe: The whole process is performed in a closed system.

1	Detection kit Cartridge PCR (N&N)	PGA4101P3	24
2	Detection kit Cartridge PCR (O&N)	PGA4103P3	24
3	Tellgen Life Ready 1000 (AIGS)	PJA0001	

# Swab Transport Medium (Modified Hank's buffer)

The formulation of STM-HB contains Hanks's solution, which is suitable for subsequent molecular experiment (e.g. PCR amplification) after nucleic acid purification as well as virus isolation and cultivation. Contains a variety of antibiotics to inhibit the growth of bacteria and fungi . Suitable for collection and transportation of a variety of specimens including viruses, mycoplasma and chlamydia



Package	Description	Pack
specification		
PFA4X051	Vial with 1.0ml transport medium, regular polyester	48 bottles/kit
	tipped swab	
PFA4X052	Vial with 2.0ml transport medium, regular polyester	48 bottles/kit
	tipped swab	
PFA4X053	Vial with 3.0ml transport medium, regular polyester	48 bottles/kit
	tipped swab	
PFA4X054	Vial with 0.75ml transport medium, regular polyester	100 bottles/kit
	tipped swab	
PFA4X055	Vial with 1.0ml transport medium, regular polyester	100 bottles/kit
	tipped swab	

# Swab Transport Medium(Modified Lysis buffer)

Swab Transport Medium (Modified Lysis buffer) is intended for the collection and transport of clinical samples containing tissue or cellular which used for pathology analysis from the collection site to the testing laboratory.



Package	Description	Pack
specification		
PFA4X042	Vial with 1.8ml transport medium, regular polyester	48 bottles/kit
	tipped swab	
PFA4X043	Vial with 3.0ml transport medium, regular polyester 48 bottles/kit	
	tipped swab	
PFA4X044 Vial with 0.75ml transport medium, regular polyester		100 bottles/kit
	tipped swab	
PFA4X045	Vial with 1.0ml transport medium, regular polyester	100 bottles/kit
	tipped swab	

# Lung Me<sup>TM</sup> methylation test



This kit is a real time PCR assay, used for the detection of methylated human SHOX2 and RASSF1A genes in human bronchoalveolar lavage fluid.

#### Significance of DNA methylation

- 1. Differential diagnosis of benign and malignant lung lesions: In cases where it's impossible to diagnose lung cancer through cytological examination with bronchial bronchoalveolar lavage fluid, conducting the methylation detection of SHOX2 and RASSF1A genes can further improve the detection rate and specificity of lung cancer
- 2. Early screening of lung cancer: Researches have shown that gene methylation can be detected on asymptomatic patients before the emergence of clinical symptoms, thus to assist in early lung cancer diagnosis.

1	SHOX2 and RASSF1A DNA methylation PCR Kit	PG09104F4	20
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# Septin9 colorectal cancer blood screening

This kit is a qualitative assay for the real-time PCR detection of methylated Septin9 DNA in bisulfite converted DNA from human plasma samples. Presence of methylated Septin9 is associated with, and may aid in, the detection of colorectal cancer.

Comprehensive Sensitivity of Screening for Stage I~IV Colorectal Cancer



1	Human methylated Septin9 DNA detection kit based on Real- Time PCR platform (Liquid Form)	PGA9105S4	20
2	Human methylated Septin9 DNA detection kit based on Real- Time PCR platform (Liquid Form)	PGA9105S5	50
3	Human methylated Septin9 DNA detection kit based on Real- Time PCR platform (Liquid Form)	PGA9105S6	100
4	Human methylated Septin9 DNA detection kit based on Real- Time PCR platform (Lyophilized form)	PGA9105D4	20
5	Human methylated Septin9 DNA detection kit based on Real- Time PCR platform (Lyophilized form)	PGA9105D5	50
6	Human methylated Septin9 DNA detection kit based on Real- Time PCR platform (Lyophilized form)	PGA9105D6	100

# **HPV Genotyping**

Cervical Cancer turn into the second killers of female Cancer all of the world and HPV DNA test become a very effective method to prevent Cervical Cancer. Tellgen*plex*<sup>TM</sup> HPV DNA Test is the unique kit which could show digital results of 14 high-risk HPV subtypes or 26 HPV subtypes with most solid consideration. The kit possesses lots of advantages, including all-round typing in 1 reaction, high sensitive and flexibility, liquid phase and 15 minutes fast hybridization. It was praised as cutting-end HPV genotyping product and applied in cervical cancer screening, female physical, cervical carcinoma assistant diagnose and therapeutic evaluation.

#### Panel 1: 14 high-risk HPV types (CE Marked)

16、18、31、33、35、39、45、51、52、56、58、59、66、68

#### Panel 2: 27 HPV types (SFDA cleared)

**High-risk type:** 16、18、26、31、33、35、39、45、52、58、26、51、55、

56、59、53、66、68、82、83

**Low-risk type:** 6、11、40、42、44、61、73

### **Benifits**

- Trace sample, multiple markers in 1 reaction
- · Only 15 minutes hybridization
- · High sensitive and flexibility

1	High-risk HPV DNA Test (14 Subtypes)	LG010021	48
2	27 HPV DNA Test (27 Subtypes)	LG010011	20202

# EGFR mutation analysis

Nonsmall-cell lung cancer (NSCLC) patients with a mutation in the epidermal growth-factor receptor (*EGFR*) gene appear to be more likely to benefit from gefitinib (*Iressa*) than from conventional chemotherapy.

The Epidermal Growth Factor Receptor (EGFR) activates an important pathway that leads to cell proliferation, differentiation, migration/motility, adhesion, protection from apoptosis, enhanced survival and gene transcription. A large body of experimental and clinical work supports the view that EGFR is a relevant target for cancer therapy. The development of selective tyrosine kinase inhibitors has become an important area of drug discovery for the treatment of a variety of solid tumors such as breast, ovarian and colorectal cancers, NSCLC, and carcinoma of the head and neck.

EGFR mutations can be seen in about 10-15% of patients. Patients with EGFR mutations have been reported to respond to selective anti-EGFR tyrosine kinase inhibitors. The EGFR mutation test offered by Tellgen will be able to detect these mutations and identify all those patients that may respond to these targeted therapies.

# Methodology

Multiplex real-time PCR

# **Specimen Requirements**

Formalin-fixed, paraffin-embedded tissue

unstained slides

Fresh snap frozen biopsy

FNA materials.

## Tests available

29 mutations in 8 tubes

- ■T790M
- **■**L858R
- **■**L861Q
- ■S768IG719S, G719A and G719C
- ■3 insert mutation in exon 20
- ■19 deletion mutation in exon 19

# EGFR mutation analysis

# Methodology

xMAP technology

# **Specimen Requirements**

Formalin-fixed paraffin-embedded tissue unstained slides.

Fresh snap frozen biopsy

FNA materials.

# Tests available

8 most common mutations in 1 tube

Mutation	Exon	Base change
G719C	18	2155G>T
E746-A750del(1)	19	2235_2249del15
E746-A750del(2)	19	2236_2250del15
L747_T751>S	19	2240_2251del12
L747_P753>S	19	2240_2257del18
L858R	21	2573T>G
L861Q	21	2582T>A
T790M	20	2369C>T

# KRAS mutation analysis

KRAS has been extensively studied in a wide array of human malignancies, including mCRC. Mutant KRAS can be detected in approximately 30-50% of colorectal cancers. The Ras-Raf-MAPK pathway lies just downstream of EGFR. The hypothesis suggests that a mutation in KRAS could render cells independent of upstream EGFR activation or inhibition of the receptor through anti-EGFR therapies. Several recent studies now show strong correlation of KRAS mutation with response to Erbitux® (cetuximab) and Vectibix<sup>™</sup> (panitumumab). These studies show compelling evidence that KRAS mutations are a biomarker of non-responsiveness to either of these drugs in mCRC patients. In addition to being a predictive marker in mCRC, KRAS mutations are a sign of poor prognosis in many other clinical indications.

# Methodology

Multiplex real-time PCR

# **Specimen Requirements**

Formalin-fixed paraffin-embedded tissue unstained slides.

Fresh snap frozen biopsy

FNA materials.

# **Tests available**

Mutation	Base Change
Gly12Asp	GGT>GAT
Gly12Val	GGT>GTT
Gly12Ser	GGT>AGT
Gly12Cys	GGT>TGT
Gly12Ala	GGT>GCT
Gly12Arg	GGT>CGT
Gly13Asp	GGC>GAC

### **Benefits**

Hands on time: <30 min

Sample to answer time: <90 min

Sensitivity: ~1%

# **KRAS-BRAF** mutation analysis

# Methodology

xMAP technology

# **Specimen Requirements**

Formalin-fixed
paraffin-embedded tissue
unstained slides
Fresh snap frozen biopsy
FNA materials.

# **Benefits**

>95% mutation in 1 well

Sample to answer time: <3 hr

Sensitivity: ~1%

# Tests available

Gene	Mutation	Base Change	
KRAS	Gly12Asp	GGT>GAT	
	Gly12Val	GGT>GTT	
	Gly12Ser	GGT>AGT	
	Gly12Cys	GGT>TGT	
	Gly12Ala	GGT>GCT	
	Gly12Arg	GGT>CGT	
	Gly13Asp	GGC>GAC	
	Gly13Cys	GGC>TGC	
BRAF	V600E	T>A	

# BRAF V600E mutation analysis

The BRAF (V600E) mutation analysis is predictive for anti-EGFR therapies (i.e., cetuximab and panitumumab). BRAF mutations account for approximately 12-15% of colorectal cancer patients

# Methodology

real-time PCR

# **Specimen Requirements**

Formalin-fixed
paraffin-embedded tissue
unstained slides
Fresh snap frozen biopsy

FNA materials.

# Y-chromosome Micro-deletions

Micro-deletions of the Y chromosome are the second most frequent genetic cause of male infertility after the Klinefelter syndrome. The portion of the male-specific region of the Y chromosome (MSY), comprising 95% of the Y chromosome and flanked by pseudoautosomal regions, which is affected by deletions has been classically subdivided into three regions called AZFa, AZFb and AZFc, respectively. Deletions of the three AZF areas will lead to spermatogenetic failure resulting in male infertility. According to EAA/EMQN best practice guideline for molecular diagnosis of Y-chromosome micro-deletions, Tellgen developed Y chromosome Micro-deletions Diagnostic Kit to detect 6 STS micro-deletions based on multiplex PCR. Set A primer includes sY254, sY127 and sY86, set B primer includes sY134, sY84 and sY255. SRY gene acts as PCR internal control for the testis-determining factor on the short arm of the Y chromosome and for the presence of Y-specific sequences when the ZFY gene is absent.

# Methodology

multiplex PCR

# **Specimen Requirements**

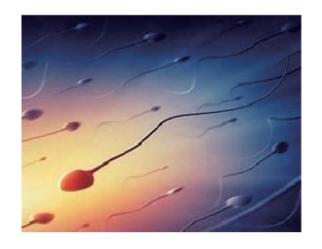
Peripheral blood

# **Benefits**

Hands-on time: <30 min

Sample to answer time: <2 hr

High specificity and low cost



Products	loci	Cat. No.	Tests
TellgenplexTM Y-chromosome microdeletion kit	sY84 、sY86 、sY127 、 sY134、sY254、sY255	PG020012	20

# Service & Support

### **Research Service**

We provide comprehensive research service in

Probe label

Antibody label

Antibody-bead conjugation

Probe-bead conjugation

# **After-sale Support**

Further support is provided in the form of continued technology transfer through regular updates on equipment and processing methods, and the company is always available to provide assistance, guidance and advice.

- Applications and Technical support
- strong customer focus
- development for usability &serviceability
- •minimal after-sale costs.

### **Contact Information**

#### **Products Counseling & Order Management**

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