STATEMENT

We, ACON Laboratories, Inc. having a registered office at *5850 Oberlin Drive #340, San Diego, CA 92121* assign SRL Sanmedico having a registered office at *A. Corobceanu street 7A, apt. 9, Chisinău, MD-2012, Moldova*, as authorized representative in correspondence with the conditions of directive 98/79/EC.

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 authorization will be valid for one year after the date of this statement.

Date: June 1, 2021

Signature: _____

Qiyi Xie, Md, MPH
Sr. Officer, Regulatory & Clinical Affairs
ACON Laboratories, Inc.
Ph: 858-875-8011
Email: qxie@aconlabs.com

Digitally signed by Monastîrschii Viorica
Date: 2022.09.07 15:36:02 EEST
Reason: MoldSign Signature
Location: Moldova

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 01

Manufacturer: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Product Category(ies): **In Vitro diagnostics for the detection of human infections and tumor markers, blood glucose measuring self-testing systems, self-testing devices for clinical chemistry, hematology and pregnancy and ovulation**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report no.: SH1974310

Valid from: 2019-10-24
Valid until: 2022-09-12

Date, 2019-10-24

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZLG-BS-245.10.07

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 01

Model(s): **For Detail Models see attachment**

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate

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(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 01

For the product(s)/product category (ies):

On Call Plus Blood Glucose Monitoring System,
On Call Plus Blood Glucose Test Strips,
On Call EZ II Blood Glucose Monitoring System,
On Call Redi Blood Glucose Monitoring System,
On Call Redi II Blood Glucose Test Strips,
On Call Advanced Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Test Strips,
On Call Platinum Blood Glucose Monitoring System,
On Call Platinum Blood Glucose Test Strips,
On Call Chosen Blood Glucose Monitoring System,
On Call Chosen Blood Glucose Test Strips,
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Blood Glucose Test Strips (OGS-101),
On Call Vivid Pal Blood Glucose Monitoring System (OGM-102),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Plus II Blood Glucose Test Strips (OGS-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call Extra Blood Glucose Test Strips (OGS-191),
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
On Call Blood Ketone Test Strips (OGS-161),
D-ONE Blood Glucose Monitoring System,
D-ONE Blood Glucose Test Strips,
Urinalysis Reagent Strips (Urine),
UTI Urinary Tract Infection Test Strips,
Toxoplasma IgG EIA Test Kit,
Toxoplasma IgM EIA Test Kit,
Rubella IgG EIA Test Kit,
Rubella IgM EIA Test Kit,
CMV IgG EIA Test Kit,

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

Benannt durch/Designated by
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Product Service

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(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 01

CMV IgM EIA Test Kit,

Total PSA EIA Test Kit,

PT Coagulation Monitoring System (CCM-121),

PT Coagulation Test Strips (CCS-121),

Cholesterol Monitoring System (CCM-111),

CHOL Total Cholesterol Test Devices (CCS-111),

TRIG Triglycerides Test Devices (CCS-112),

HDL High Density Lipoprotein Test Devices (CCS-113),

3-1 Lipid Panel Test Devices (CCS-114),

Cholesterol CTRL Control Devices,

Cholesterol Monitoring System (CCM-101),

CHOL Total Cholesterol Test Strips (CCS-101),

PT/INR Monitoring System (CCM-151),

PT/INR Test Strips (CCS-151),

Hemoglobin Testing System (CCM-141),

Hemoglobin Test Strips (CCS-141),

hCG Pregnancy Rapid Test Cassette (Urine),

Pregnancy Rapid Test Midstream,

On Call Extra Mobile Blood Glucose Monitoring System (OGM-281)

On Call Sure Blood Glucose Monitoring System (OGM-211)

On Call Sure Sync Blood Glucose Monitoring System (OGM-212)

On Call Sure Blood Glucose Test Strips (OGS-211)

On Call GU Dual Blood Glucose & Uric Acid Monitoring System (OGM-201)

On Call Blood Uric Acid Test Strips (OGS-201)

LH Ovulation Rapid Test Cassette (Urine)

Ovulation Rapid Test Midstream

Ovulation & Pregnancy Test Combo Pack

On Call Extra Voice Blood Glucose Monitoring System (OGM-291)

Early Detection Pregnancy Test

Digital Pregnancy Test

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight Total T3 EIA Test Kit (1231-3041)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

ACON
5850 Oberlin Drive #340 · San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight TSH EIA Test Kit (I231-3011)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight TSH EIA Test Kit (I231-3011)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD; MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight Total Syphilis Antibody EIA Test Kit (1231-1041)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight Rubella IgM EIA Test Kit (I231-1121)

classified as *Annex II List B* of the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The declaration according to Annex IV of the Directive is based on approval by the notified body TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 MÜNCHEN, Germany, notified under No. 0123 to the EC Commission.

This declaration is valid until expiration of EC Certificate
No. V1 104507 0003 Rev. 01
Expiration Date: 2022-09-12

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight Rubella IgG EIA Test Kit (I231-1111)

classified as *Annex II List B* of the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The declaration according to Annex IV of the Directive is based on approval by the notified body TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 MÜNCHEN, Germany, notified under No. 0123 to the EC Commission.

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Expiration Date: 2022-09-12

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight LH EIA Test Kit (I231-4021)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight HSV 2 IgM EIA Test Kit (1231-1181)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight HSV 2 IgG EIA Test Kit (1231-1171)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight HSV ½ IgM EIA Test Kit (1231-1201)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight HSV ½ IgG EIA Test Kit (1231-1191)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
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Acon Laboratories, Inc.

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E-mail: info@aconlabs.com

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight HSV 1 IgM EIA Test Kit (1231-1161)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight HSV 1 IgG EIA Test Kit (1231-1151)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
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E-mail: info@aconlabs.com

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight HEV IgM EIA Kit (I231-1211)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight hCG EIA Test Kit (I231-4051)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight H. pylori Antigen EIA Test Kit (I231-1231)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
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We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight H. pylori Antigen EIA Test Kit (I231-1231)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
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E-mail: info@aconlabs.com

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight FSH EIA Test Kit (I231-4031)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight Free T4 EIA Test Kit (1231-3031)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
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Qiyi Xie, MD, MPH
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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight Free T3 EIA Test Kit (1231-3051)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
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Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
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E-mail: info@aconlabs.com

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight CMV IgM EIA Test Kit (I231-1141)

classified as *Annex II List B* of the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The declaration according to Annex IV of the Directive is based on approval by the notified body TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 MÜNCHEN, Germany, notified under No. 0123 to the EC Commission.

This declaration is valid until expiration of EC Certificate
No. V1 104507 0003 Rev. 01
Expiration Date: 2022-09-12

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

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Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

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E-mail: info@aconlabs.com

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight CMV IgG EIA Test Kit (I231-1131)

classified as *Annex II List B* of the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

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Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

ACON
5850 Oberlin Drive #340 · San Diego, CA 92121, USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight CEA EIA Kit (I231-2021)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11th day of December, 2019
in San Diego, CA, USA

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Acon Laboratories, Inc.

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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight Allergen Test Kit (I031-1011)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

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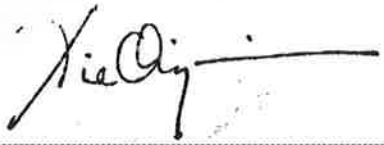

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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Foresight AFP EIA Kit (I231-2011)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 104507 0001 Rev. 01

Holder of Certificate: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development,
Manufacture and distribution of
In Vitro Diagnostic Test Kits and Reagents for
the Determination of Infectious Diseases,
Clinical Chemistry, Drugs of Abuse,
Tumor/Cardiac Marker,
Fertility/Pregnancy and Blood Glucose
Monitoring System,
Lancing Devices and Lancets**

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). See also notes overleaf.

Report No.: SH1974310

Valid from: 2019-10-24
Valid until: 2022-09-06

Date, 2019-10-24

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 104507 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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ACON Laboratories, Inc.
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ACON Laboratories, Inc.
6865 Flanders Dr., Suite B, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Foresight®

AFP EIA Test Kit
Package Insert

REF I231-2011 | English

An enzyme immunoassay (EIA) for the quantitative detection of AFP (Alpha-fetoprotein) in human serum or plasma.

For professional in vitro diagnostic use only.

INTENDED USE

The AFP EIA Test Kit is an enzyme immunoassay for *in vitro* quantitative determination of AFP level in human serum or plasma. It is intended as an aid in the assessment and diagnosis of fetal open neural tube defects and other types of cancers, such as ovarian, liver and testicular cancers.

SUMMARY

Alpha-Fetoproteine (AFP) is a glycoprotein with a molecular weight of approximately 70,000 daltons that shares sequence homology with albumin.[1,2] AFP is normally produced during fetal and neonatal development by the liver, yolk sac, and small concentrations by the gastrointestinal tract.[3] Fetal plasma AFP diffuses into the fetal urine and is excreted into the amniotic fluid from where it diffuses into the maternal circulation. The concentration of AFP in the fetal plasma peaks at 12-14 weeks and then rapidly falls.[4] At birth, normal infants have AFP levels of above the normal range, but decreasing to within it over the first 1-2 years of life.[5] By the second year of life, AFP concentrations decrease rapidly, and thereafter only trace amounts are normally detected in serum.[6] In general, normal adults have serum AFP concentrations of less than 10 ng/mL.[7] Elevated AFP levels occur in several malignant diseases including hepatocellular carcinoma, testicular nonseminomatous origin, and occasionally of other endodermal origin.[8] Detection of elevated AFP levels can also be used in the detection of fetal open neural tube defects.[9]

The AFP EIA Test Kit is an immunoassay for the quantitative detection of the presence of Alpha-fetoprotein (AFP) in serum or plasma specimen. The test utilizes monoclonal antibodies to selectively detect AFP in serum or plasma.

PRINCIPLE

The AFP EIA Test Kit is a solid phase enzyme immunoassay based on a sandwich principle for the quantitative detection of AFP in human serum or plasma. The microwell plate is coated with monoclonal antibodies specific to AFP. During testing, the specimen and the enzyme-conjugated AFP antibodies are added to the antibody coated microwell plate and then incubated. If the specimen contains AFP, it will bind to the antibodies coated on the microwell plate and simultaneously bind to the conjugate to form immobilized antibody-AFP-conjugate complexes. If the specimen does not contain AFP, the complexes will not be formed. After initial incubation, the microwell plate is washed to remove unbound materials. Substrate A and substrate B are added and then incubated to produce a blue color, indicating the amount of AFP present in the specimen. Sulfuric acid solution is added to the microwell plate to stop the reaction which produces a color change from blue to yellow. The color intensity, which corresponds to the amount of AFP present in the specimen, is measured with a microplate reader at 450/630-700 nm or 450 nm. The absorbance of the specimen is then compared to a calibration curve to obtain the amount of AFP present in the specimen.

PRECAUTIONS

- This kit is NOT intended to be used for the risk evaluation of trisomy 21.
- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not mix reagents from other kits with different lot numbers.
- Avoid cross contamination between reagents to ensure valid test results.
- Add all the calibrators, controls, and specimens into the wells within 15 minutes to minimize the change in absorbance which may affect the results.
- Follow the wash procedure to ensure optimum assay performance.
- Use Plate Sealer to cover microwell plate during incubation to minimize evaporation.
- Use a new pipet tip for each specimen assayed.
- Ensure that the bottom of the plate is clean and dry and that no bubbles are present on the surface of the liquid before reading the plate. Do not allow wells to dry out during the assay procedure.
- Do not touch the bottom of the wells with pipette tips. Do not touch the bottom of the microwell plate with fingertips.
- Do not allow sodium hypochlorite fumes from chlorine bleach or other sources to contact the microwell plate during the assay as the color reaction may be inhibited.
- All equipment should be used with care, calibrated regularly and maintained following the equipment manufacturer's instructions.

HEALTH AND SAFETY INFORMATION

- Some components of this kit contain human blood derivatives. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. Therefore, all blood derivatives should be considered potentially infectious. It is recommended that these reagents and human specimens be handled using established good laboratory working practices.
- Wear disposable gloves and other protective clothing such as laboratory coats and eye protection while handling kit reagents and specimens. Wash hands thoroughly when finished.
- ProClin™ 300 is included as a preservative in the Conjugate, Concentrated Wash Buffer, Substrate and Calibrators. Avoid any contact with skin or eyes.
- Do not eat, drink or smoke in the area where the specimens or kits are handled. Do not pipette by mouth.
- Avoid any contact of the Substrate and Stop Solution with skin or mucosa. The Stop Solution contains 0.5M sulfuric acid which is a strong acid. If spills occur, wipe immediately with large amounts of water. If the acid contacts the skin or eyes, flush with large amounts of water and seek medical attention.
- Non-disposable apparatus should be sterilized after use. The preferred method is to autoclave for one hour at 121°C. Disposables should be autoclaved or incinerated. Do not autoclave materials containing sodium hypochlorite.
- Handle and dispose all specimens and materials used to perform the test as if they contained infectious agents. Observe established precautions against microbiological hazards throughout all the procedures and follow the standard procedures for proper disposal of specimens.
- Observe Good Laboratory Practices when handling chemicals and potentially infectious material. Discard all contaminated material, specimens and reagents of human origin after proper decontamination and by following local, state and federal regulations.
- Neutralized acids and other liquids should be decontaminated by adding sufficient volume of sodium hypochlorite to obtain a final concentration of at least 1.0%. A 30 minute exposure to a 1.0% sodium hypochlorite may be necessary to ensure effective decontamination.

STORAGE AND STABILITY

- Unopened test kits should be stored at 2-8°C upon receipt. All unopened reagents are stable through the expiration date printed on the box if stored between 2-8°C. Once opened, all reagents are stable for up to 3 months after the first opening date if stored between 2-8°C. Return reagents to 2-8°C immediately after use.
- Allow the sealed pouch to reach room temperature before opening the pouch and remove the required number of strips to prevent condensation of the microwell plate. The remaining unused strips should be stored in the original resealable pouch with desiccant supplied at 2-8°C and can be used within 3 months of the opening date. Return the remaining unused strips and supplied desiccant to the original resealable pouch, firmly press the seal closure to seal the pouch completely and immediately store at 2-8°C.
- Concentrated Wash Buffer may be stored at room temperature to avoid crystallization. If crystals are present, warm up the solution at 37°C. Working Wash Buffer is stable for 2 weeks at room temperature.
- Do not expose reagents especially the Substrate to strong light or hypochlorite fumes during storage or incubation steps.
- Do not store Stop Solution in a shallow dish or return it to the original bottle after use.

SPECIMEN COLLECTION AND PREPARATION

- The AFP EIA Test Kit can be performed using only human serum or plasma collected from venipuncture whole blood.
- EDTA, sodium heparin, and ACD collection tubes may be used to collect venipuncture whole blood and plasma specimens. The preservative sodium azide inactivates horseradish peroxide and may lead to erroneous results.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Grossly hemolytic, lipidic or turbid samples should not be used. Specimen with extensive particulate should be clarified by centrifugation prior to use. Do not use specimens with fibrin particles or contaminated with microbial growth.
- Serum and plasma specimens may be stored at 2-8°C for up to 7 days prior to assaying. For long term storage, specimens should be kept frozen below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

REAGENTS AND COMPONENTS

Materials Provided

No.	Reagent	Component Description	Quantity	
			96 wells/kit	480 wells/kit
	AFP Microwell Plate	Microwell plate coated with monoclonal Anti-AFP	1 plate (96 wells/plate)	5 plates (96 wells/plate)
1	AFP Conjugate	Anti-AFP bound to peroxidase; Preservative: 0.1% ProClin™ 300	1 x 12 mL	5 x 12 mL
2	Concentrated Wash Buffer (25x)	Tris-HCl buffer containing 0.1% Tween 20; Preservative: 0.1% ProClin™ 300	1 x 40 mL	5 x 40 mL
2A	Specimen Diluent	0.02M Phosphate buffered saline (PBS) buffer Preservative: 0.1% ProClin™ 300	1 x 12 mL	5 x 12 mL
3	Substrate A	Citrate-phosphate buffer containing hydrogen peroxide; Preservative: 0.1% ProClin™ 300	1 x 8 mL	5 x 8 mL
4	Substrate B	Buffer containing tetramethylbenzidine (TMB); Preservative: 0.1% ProClin™ 300	1 x 8 mL	5 x 8 mL
5	Stop Solution	0.5M Sulfuric acid	1 x 8 mL	5 x 8 mL
6	AFP Calibrator 1	Diluted human serum non-reactive for AFP; Preservative: 0.1% ProClin™ 300	1 x 0.5 mL	5 x 0.5 mL
7	AFP Calibrator 2	Diluted human serum containing 10 ng/mL AFP; Preservative: 0.1% ProClin™ 300	1 x 0.5 mL	5 x 0.5 mL
8	AFP Calibrator 3	Diluted human serum containing 20 ng/mL AFP; Preservative: 0.1% ProClin™ 300	1 x 0.5 mL	5 x 0.5 mL
9	AFP Calibrator 4	Diluted human serum containing 50 ng/mL AFP; Preservative: 0.1% ProClin™ 300	1 x 0.5mL	5 x 0.5 mL
10	AFP Calibrator 5	Diluted human serum containing 100 ng/mL AFP; Preservative: 0.1% ProClin™ 300	1 x 0.5 mL	5 x 0.5 mL
11	AFP Calibrator 6	Diluted human serum containing 400 ng/mL AFP; Preservative: 0.1% ProClin™ 300	1 x 0.5 mL	5 x 0.5 mL
	Plate Sealers		2	10
	Package Insert		1	1

Materials Required But Not Provided

- Freshly distilled or deionized water
- Sodium hypochlorite solution for decontamination
- Absorbent paper or paper towel
- Water bath or incubator capable of maintaining 20°C to 30°C.
- Calibrated automatic or manual microwell plate washer capable of aspirating and dispensing 350 µL/well
- Disposable gloves
- Automated processor (optional)
- Calibrated micropipettes with disposable tips capable of dispensing 25, 50 and 100 µL
- Graduated cylinders for wash buffer dilution
- Vortex mixer for specimen mixing (optional)
- Disposable reagent reservoirs
- Calibrated microplate reader capable of reading at 450 nm with a 630-700 nm reference filter, or reading at 450 nm without a reference filter
- Timer

DIRECTIONS FOR USE

Allow reagents and specimens to reach room temperature (15-30°C) prior to testing. The procedure must be strictly followed. Assay must proceed to completion within time limits. Arrange the calibrators in a horizontal or vertical configuration. The procedure below assigns specific wells arranged in a vertical configuration. Configuration may depend upon software.

Step	Detailed Procedure	Simplified Procedure
	• Prepare Working Wash Buffer by diluting the Concentrated Wash Buffer 1:25. Pour the contents of the bottle containing the concentrated wash buffer in a graduated cylinder and fill it with freshly distilled or deionized water to 1000 mL for 96 wells/plate testing. The Working Wash Buffer is stable for 2 weeks at 15-30°C. **Note:** If crystals are present in the Concentrated Wash Buffer, warm it up at 37°C until all crystals dissolve. • Remove unused strips from the microwell plate, and store in the original resealable pouch at 2-8°C.	• Prepare Working Wash Buffer by diluting the Concentrated Wash Buffer 1:25 • Remove and store unused strips at 2-8°C
0	• Leave A1 as Blank well.	• Leave A1 as Blank well
1	• Add 25 µL of Calibrator 1 in wells B1 and C1. • Add 25 µL of Calibrator 2 in wells D1 and E1. • Add 25 µL of Calibrator 3 in wells F1 and G1. • Add 25 µL of Calibrator 4 in wells H1 and A2. • Add 25 µL of Calibrator 5 in wells B2 and C2. • Add 25 µL of Calibrator 6 in wells D2 and E2. The colors of Calibrator 1-6 gradually change from yellow to blue.	• B1and C1: Add 25 µL Calibrator 1 • D1and E1: Add 25 µL Calibrator 2 • F1and G1: Add 25 µL Calibrator 3 • H1and A2: Add 25 µL Calibrator 4 • B2and C2: Add 25 µL Calibrator 5 • D2and E2: Add 25 µL Calibrator 6
2	• Add 25 µL of specimen to assigned wells starting at F2.	• Starting F2: Add 25 µL specimen
3	• Add 100 µL of Conjugate to each well except for the Blank well. (Red reagent)	• Add 100 µL of Conjugate to each well
4	• Mix gently by swirling the microwell plate on a flat bench for 30 seconds.	• Mix gently • Cover the microwell plate with the

	• Cover the microwell plate with the Plate Sealer, and incubate at room temperature (20-30°C), in a water bath or in an incubator at 20-30°C for 30 minutes ± 5 minute.	Plate Sealer and incubate at room temperature (20-30°C) for 30 min
5	• Remove the Plate Sealer. • Wash each well 5 times with 350 µL of Working Wash Buffer per well, then remove the liquid. • Turn the microwell plate upside down on absorbent tissue for a few seconds. Ensure that all wells have been completely washed and dried. Note: Improper washing may cause false positive results.	• Remove the Plate Sealer • Wash each well 5 times with 350 µL of Working Wash Buffer • Turn the microwell plate upside down on absorbent tissue
6	• Add 50 µL of Substrate A to each well. (Clear Reagent) • Add 50 µL of Substrate B to each well. (Clear Reagent) Then a light blue to blue color should develop in wells corresponding to the amount of AFP present in the specimen.	• Add 50 µL of Substrate A to each well. • Add 50 µL of Substrate B to each well.
7	• Mix gently then cover microwell plate with Plate Sealer, and incubate at room temperature (20-30°C), in a water bath or in an incubator at 20-30°C for 15 minutes ± 2 minutes.	• Mix then cover microwell plate with Plate Sealer and incubate at room temperature (20-30°C) for 15 min
8	• Remove the Plate Sealer. • Add 50 µL of Stop Solution to each well. (Clear Reagent) Then a yellow color should develop in wells containing positive specimens	• Remove Plate Sealer • Add 50 µL of Stop Solution to each well
9	• Read at 450/630-700 nm within 30 minutes. Note: Microwell plate can also be read at 450 nm, but it is strongly recommended to read it at 450/630-700 nm for better results.	• Read at 450/630-700 nm within 30 min

AUTOMATED PROCESSING

Automatic EIA microplate processors may be used to perform the assay after validating the results to ensure they are equivalent to those obtained using the manual method for the same specimens. Incubation times may vary depending on the processors used but do not program less incubation times than the procedure listed above. When automatic EIA microplate processors are used, periodic validation is recommended to ensure proper results.

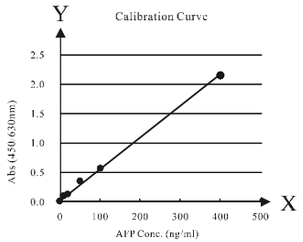
QUALITY CONTROL

Control standards are not supplied with this kit; however, it is recommended that normal, low and high controls be tested with each run as a good laboratory practice to monitor assay performance. Each laboratory should establish its own criteria for establishing mean values and acceptable ranges to determine reliability of the results.

CALCULATION OF RESULTS

Draw the calibration curve and obtain quantitative specimen results.

1. Calculate the Mean Absorbance of each Calibrator, then plot them on the Y-axis against their concentration on the X-axis on a linear graph paper and draw the calibration curve. Draw the best-fitted line through data points to obtain a standard curve. Refer to an example of the calibration curve at right.
   NOTE: Do not use the calibration curve at right to make any calculation. A calibration curve must be performed for each run.



Example of Specimen Result Calculation

Item	Well	Absorbance	Mean (Absorbance – Blank)	Concentration (ng/mL)
Unknown Specimen	F2	0.445	0.437	79.45

2. Obtain quantitative specimen results of concentrations expressed in ng/mL from their absorbance by using the calibration curve. When the alternate result unit, IU/mL, is selected, the conversion factor used by the system is by multiplying by 0.83.

NOTE: Specimens that have absorbance above Calibrator 6 should be pre-diluted using Specimen Diluent (0.02M PBS) and retested. The concentration must be multiplied by the dilution factor. Automated reading and calculation may also be performed using linear regression function on suitable computer programs.

LIMITATIONS

1. The AFP EIA Test Kit is used for the detection of AFP in human serum or plasma. Diagnosis should not be established based on a single test result. Further testing should be performed in assessing clinical status. Specimens containing precipitate may give inconsistent test results.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3. As with other sensitive immunoassays, there is the possibility that the positive result cannot be repeated due to inadequate washing from the initial test. The results may be affected due to procedural or instrument error.
4. Unusually high titers of heterophilic antibodies or rheumatoid factor (RF) may affect results. Even if test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

EXPECTED VALUES

It is recommended that each laboratory establish its own range of expected values based on patient populations. A study to determine expected values using the AFP EIA Test Kit was conducted for initial reference use only.

Population	No. Specimens	0-10.0 ng/mL	10-20 ng/mL	>20ng/mL
Normal	982	98.88%	0.92%	0.20%

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

The analytical sensitivity of the AFP EIA Test Kit is 0.6 ng/mL using the standard procedure.

Accuracy

The AFP EIA Test Kit has been compared to a leading commercial AFP EIA test using clinical specimens. A total of 654 clinical specimens ranging from 20-400 ng/mL were run and analyzed using least square regression analysis. The results show that the AFP EIA Test Kit has good correlation compared to the reference method.

Reproducibility

Intra-Assay: Within-run precision has been determined by using 60 replicates of two specimens: a low positive and a medium positive.
Inter-Assay: Between-run precision has been determined by 180 independent assays on the same two specimens: a low positive and a medium positive. Three different lots of the AFP EIA Test Kit have been tested using these specimens over a 3-day period.

Specimen	Intra-Assay			Inter-Assay		
	Mean AFP Concentration (ng/mL)	Standard Deviation	Coefficient of Variation (%)	Mean AFP Concentration (ng/mL)	Standard Deviation	Coefficient of Variation (%)
1	24.950	2.289	9.173	24.581	2.336	9.504
2	225.308	14.668	6.510	224.367	15.175	6.763

Recovery and Linearity

Recovery: Known amounts of AFP were added to normal human serum with endogenous AFP concentration of 1.56 ng/mL. The concentration of AFP was determined using AFP EIA Test Kit and the resulting percent recovery was calculated.

Specimen	AFP Concentration Added (ng/mL)	AFP Concentration Obtained (ng/mL)	Recovery* (%)
Level 1	20.15	22.61	104.47
Level 2	40.26	40.95	97.84
Level 3	85.67	92.77	106.47
Level 4	170.48	180.85	105.17
Level 5	338.90	333.41	97.92

* Recovery = (Concentration Obtained (ng/mL) – Endogenous Level (ng/mL))/Concentration Added (ng/mL)

Linearity: Specimens containing known concentration of AFP were diluted with normal human serum and determined. The obtained concentrations were within ±20% of the expected values.

Cross-Reactivity

The specificity of the AFP EIA Test Kit was determined by testing sera containing the compounds listed below. These compounds showed less than 20% interference in the AFP EIA Test Kit at the levels indicated.

Substance	Concentration	Substance	Concentration
Uric cid	0.09 mg/mL	Bilirubin	0.15 mg/mL
Vitamin	19.80 mg/mL	EDTA	0.20 mg/mL
Globin	0.99 mg/mL	Hemoglobin	16.67 mg/mL
Gentistic cid	0.20 mg/mL	Creatin	0.20 mg/mL
Acetaminophen	0.20 mg/mL	Cyclophosphamide	0.50 mg/mL
Oxalic cid	0.99 mg/mL	5-fluorouracil	2.00 mg/mL
Albumin	40.00 mg/mL	Cytosine arabinoside	0.30 mg/mL
Coffein	0.10 mg/mL		

Dose Hook Effect

No dose hook effect is observed up to 10,000 ng/mL of AFP.

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Index of Symbols

	Consult instructions for use	Σ	Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by	EC REP	Authorized Representative
2°C 8°C	Store between 2-8°C	LOT	Lot Number	REF	Catalog #
AFP	AFP	Substrate A	Substrate A	Substrate B	Substrate B
Specimen Diluent	Specimen Diluent	Stop Solution	Stop Solution	Conjugate	Conjugate
Wash Buffer 25x	Wash Buffer (25x)	Calibrator 1	Calibrator 1	Calibrator 2	Calibrator 2
Calibrator 3	Calibrator 3	Calibrator 4	Calibrator 4		
Calibrator 5	Calibrator 5	Calibrator 6	Calibrator 6	Package Insert	Package Insert
Microwell Plate	Microwell Plate	Plate Sealer	Plate Sealer		

***ACON* Laboratories, Inc.**
10125 Mesa Rim Road,
San Diego, CA 92121, USA

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1150463908
Effective date: 2015-07-31

Foresight®

Total PSA EIA Test Kit
Package Insert

REF I231-2031 | English

An enzyme immunoassay (EIA) for in vitro quantitative detection of Total PSA (Total Prostate Specific Antigen) in human serum or plasma.

For professional in vitro diagnostic use only.

INTENDED USE

The Total PSA EIA Test Kit is an enzyme immunoassay for *in vitro* quantitative determination of Total PSA level in human serum or plasma. It is intended as an aid in the assessment and diagnosis of prostate cancers. The determination of Total PSA levels is used to estimate the risk of prostate carcinoma in men in conjunction with digital rectal examination (DRE) or to monitor the effectiveness of prostate carcinoma treatment in patients.

SUMMARY

Prostate Specific antigen (PSA) is a single chain glycoprotein with a molecular weight of 28.4 kDA. [1] The protein is a serine protease with chymotrypsin-like activity. [2] Prostate-specific antigen (PSA) is a protein produced by cells of the prostate gland. In the seminal fluid, PSA cleaves seminal vesicle specific proteins into several very low molecular weight proteins, as a part of the process of liquefaction of the seminal coagulum. Low levels of PSA in serum of healthy individuals are because of minimal leakage of this protein into the blood. Elevated levels are seen in patients with nodular hyperplasia of prostate, adenocarcinoma of prostate and prostatitis as well as after manipulating prostate gland by digital rectal examination, transrectal ultrasonography, catheterization, prostate biopsy and after radical prostatectomy.[3] The higher a man's PSA level, the more likely it is that cancer is present, but there are other possible reasons for an elevated PSA level. The normal value for Total PSA is considered to be less than 4.0 ng/mL (nanograms per milliliter of blood). Total PSA level in men greater than 10.0 ng/mL are at an increased risk for prostate cancer. Levels between 4.0 ng/mL and 10.0 ng/mL may indicate prostate cancer, BPH, or prostatitis. [4]

The Total PSA EIA Test Kit is an immunoassay for the quantitative detection of the presence of Total Prostate Specific Antigen (Total PSA) in serum or plasma specimen. The test utilizes monoclonal antibodies to selectively detect Total PSA in serum or plasma.

PRINCIPLE

The Total PSA EIA Test Kit is a solid phase enzyme immunoassay based on a sandwich principle for the quantitative detection of Total PSA in human serum or plasma. The microwell plate is coated with monoclonal antibodies specific to PSA. During testing, the specimen and the enzyme-conjugated PSA antibodies are added to the antibody coated microwell plate and then incubated. If the specimen contains PSA, it will bind to the antibodies coated on the microwell plate and simultaneously bind to the conjugate to form immobilized antibody-PSA-conjugate complexes. If the specimen does not contain PSA, the complexes will not be formed. After initial incubation, the microwell plate is washed to remove unbound materials. Substrate A and substrate B are added and then incubated to produce a blue color, indicating the amount of Total PSA present in the specimen. Sulfuric acid solution is added to the microwell plate to stop the reaction which produces a color change from blue to yellow. The color intensity, which corresponds to the amount of Total PSA present in the specimen, is measured with a microplate reader at 450/630-700 nm or 450 nm. The absorbance of the specimen is then compared to a calibration curve to obtain the amount of Total PSA present in the specimen.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not mix reagents from other kits with different lot numbers.
- Avoid cross contamination between reagents to ensure valid test results.
- Add all the calibrators, controls, and specimens into the wells within 15 minutes to minimize the change in absorbance which may affect the results.
- Follow the wash procedure to ensure optimum assay performance.
- Use Plate Sealer to cover microwell plate during incubation to minimize evaporation.
- Use a new pipette tip for each specimen assayed.
- Ensure that the bottom of the plate is clean and dry and that no bubbles are present on the surface of the liquid before reading the plate. Do not allow wells to dry out during the assay procedure.
- Do not touch the bottom of the wells with pipette tips. Do not touch the bottom of the microwell plate with fingertips.
- Do not allow sodium hypochlorite fumes from chlorine bleach or other sources to contact the microwell plate during the assay as the color reaction may be inhibited.
- All equipment should be used with care, calibrated regularly and maintained following the equipment manufacturer's instructions.

HEALTH AND SAFETY INFORMATION

- PSA antigen used for calibrators in this kit derived from human seminal fluids, from which the donors were found to be negative for anti-HCV, anti-HIV-1/2 and HBsAg. In calibrators and conjugate solution, there are bovine blood derivatives, which were tested to be negative for sterility test, phage, fungus, adnovirus, parvovirus, reovirus, anti-diarrhea virus, anti-FMD virus and anti-JEV. But no known test methods can offer complete assurance that products derived from human and animal sources will not transmit infectious agents. Therefore, all human and animal sourced derivatives should be considered potentially infectious. It is recommended that these reagents and human specimens be handled using established good laboratory working practices.
- Wear disposable gloves and other protective clothing such as laboratory coats and eye protection while handling kit reagents and specimens. Wash hands thoroughly when finished.
- ProClin™ 300 is included as a preservative in the Conjugate, Concentrated Wash Buffer, Substrate and Calibrators. Avoid any contact with skin or eyes.
- Do not eat, drink or smoke in the area where the specimens or kits are handled. Do not pipette by mouth.
- Avoid any contact of the Substrate and Stop Solution with skin or mucosa. The Stop Solution contains 0.5M sulfuric acid which is a strong acid. If spills occur, wipe immediately with large amounts of water. If the acid contacts the skin or eyes, flush with large amounts of water and seek medical attention.
- Non-disposable apparatus should be sterilized after use. The preferred method is to autoclave for one hour at 121°C. Disposables should be autoclaved or incinerated. Do not autoclave materials containing sodium hypochlorite.
- Handle and dispose all specimens and materials used to perform the test as if they contained infectious agents. Observe established precautions against microbiological hazards throughout all the procedures and follow the standard procedures for proper disposal of specimens.
- Observe Good Laboratory Practices when handling chemicals and potentially infectious material. Discard all contaminated material, specimens and reagents of human origin after proper decontamination and by following local, state and federal regulations.
- Neutralized acids and other liquids should be decontaminated by adding sufficient volume of sodium hypochlorite to obtain a final concentration of at least 1.0%. A 30 minute exposure to a 1.0% sodium hypochlorite may be necessary to ensure effective decontamination.

STORAGE AND STABILITY

- Unopened test kits should be stored at 2-8°C upon receipt. All unopened reagents are stable through the expiration date printed on the box if stored between 2-8°C. Once opened, all reagents are stable for up to 3 months after the first opening date if stored between 2-8°C. Return reagents to 2-8°C immediately after use.
- Allow the sealed pouch to reach room temperature before opening the pouch and remove the required number of strips to prevent condensation of the microwell plate. The remaining unused strips should be stored in the original resealable pouch with desiccant supplied at 2-8°C and can be used within 3 months of the opening date. Return the remaining unused strips and supplied desiccant to the original resealable pouch, firmly press the seal closure to seal the pouch completely and immediately store at 2-8°C.
- Concentrated Wash Buffer may be stored at room temperature to avoid crystallization. If crystals are present, warm up the solution at 37°C. Working Wash Buffer is stable for 2 weeks at room temperature.
- Do not expose reagents especially the Substrate to strong light or hypochlorite fumes during storage or incubation steps.
- Do not store Stop Solution in a shallow dish or return it to the original bottle after use.

SPECIMEN COLLECTION AND PREPARATION

- The Total PSA EIA Test Kit can be performed using only human serum or plasma collected from venipuncture whole blood.
- Sodium Fluoride-Potassium Oxalate, Sodium Citrate, Lithium heparin, and K2 EDTA collection tubes may be used to collect venipuncture whole blood and plasma specimens. The preservative sodium azide inactivates horseradish peroxide and may lead to erroneous results.
- Separate serum from blood as soon as possible to avoid hemolysis. Grossly hemolytic, lipidic or turbid samples should not be used. Specimen with extensive particulate should be clarified by centrifugation prior to use. Do not use specimens with fibrin particles or contaminated with microbial growth.
- Serum specimens may be stored at 2-8°C for up to 7 days prior to assaying. For long term storage, specimens should be kept frozen below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

REAGENTS AND COMPONENTS

Materials Provided

No.	Reagent	Component Description	Quantity	
			96 wells/kit	480 wells/kit
	Total PSA Microwell Plate	Microwell plate coated with monoclonal Anti-PSA	1 plate (96 wells/plate)	5 plates (96 wells/plate)
1	Total PSA Conjugate	One vial containing Anti-PSA bound to peroxidase; Preservative: 0.1% ProClin™ 300	1 x 12 mL	5 x 12 mL
2	Concentrated Wash Buffer (25x)	Tris-HCl buffer containing 0.1% Tween 20; Preservative: 0.1% ProClin™ 300	1 x 40 mL	5 x 40 mL
2A	Specimen Diluent	0.02M Phosphate buffered saline (PBS) buffer Preservative: 0.1% ProClin™ 300	1 x 12 mL	5 x 12 mL
3	Substrate A	Citrate-phosphate buffer containing hydrogen peroxide; Preservative: 0.1% ProClin™ 300	1 x 8 mL	5 x 8 mL
4	Substrate B	Buffer containing tetramethylbenzidine (TMB); Preservative: 0.1% ProClin™ 300	1 x 8 mL	5 x 8 mL
5	Stop Solution	0.5M Sulfuric acid	1 x 8 mL	5 x 8 mL
6	Total PSA Calibrator 1	Buffer Preservative: 0.1% ProClin™ 300	1 x 0.5 mL	5 x 0.5 mL
7	Total PSA Calibrator 2	Buffer containing 2 ng/mL PSA; Preservative: 0.1% ProClin™ 300	1 x 0.5 mL	5 x 0.5 mL
8	Total PSA Calibrator 3	Buffer containing 10 ng/mL PSA; Preservative: 0.1% ProClin™ 300	1 x 0.5mL	5 x 0.5 mL
9	Total PSA Calibrator 4	Buffer containing 25 ng/mL PSA; Preservative: 0.1% ProClin™ 300	1 x 0.5 mL	5 x 0.5 mL
10	Total PSA Calibrator 5	Buffer containing 50 ng/mL PSA; Preservative: 0.1% ProClin™ 300	1 x 0.5 mL	5 x0.5 mL
11	Total PSA Calibrator 6	Buffer containing 100 ng/mL PSA; Preservative: 0.1% ProClin™ 300	1 x 0.5 mL	5 x 0.5 mL
	Plate Sealers		2	10
	Package Insert		1	1

Note: The calibrators were calibrated using a reference preparation, which was assayed against the WHO IRP (96/670)

Materials Required But Not Provided

- Freshly distilled or deionized water
- Sodium hypochlorite solution for decontamination
- Absorbent paper or paper towel
- Water bath or incubator capable of maintaining 20°C to 30°C.
- Calibrated automatic or manual microwell plate washer capable of aspirating and dispensing 350 µL/well
- Disposable gloves
- Automated processor (optional)
- Calibrated micropipettes with disposable tips capable of dispensing 20 ,50 and 100 µL
- Graduated cylinders for wash buffer dilution
- Vortex mixer for specimen mixing (optional)
- Disposable reagent reservoirs
- Calibrated microplate reader capable of reading at 450 nm with a 630-700 nm reference filter, or reading at 450 nm without a reference filter
- Timer

DIRECTIONS FOR USE

Allow reagents and specimens to reach room temperature (20-30°C) prior to testing. The procedure must be strictly followed. Assay must proceed to completion within time limits. Arrange the calibrators in a horizontal or vertical configuration. The procedure below assigns specific wells arranged in a vertical configuration. Configuration may depend upon software.

Step	Detailed Procedure	Simplified Procedure
	• Prepare Working Wash Buffer by diluting the Concentrated Wash Buffer 1:25. Pour the contents of the bottle containing the concentrated wash buffer in a graduated cylinder and fill it with freshly distilled or deionized water to 1000 mL for 96 wells/plate testing. The Working Wash Buffer is stable for 2 weeks at 20-30°C. **Note:** If crystals are present in the Concentrated Wash Buffer, warm it up at 37°C until all crystals dissolve. • Remove unused strips from the microwell plate, and store in the original resealable pouch at 2-8°C.	• Prepare Working Wash Buffer by diluting the Concentrated Wash Buffer 1:25 • Remove and store unused strips at 2-8°C
0	• Leave A1 as Blank well.	• Leave A1 as Blank well
1	• Add 20 µL of Calibrator 1 in wells B1 and C1. • Add 20 µL of Calibrator 2 in wells D1 and E1. • Add 20 µL of Calibrator 3 in wells F1 and G1. • Add 20 µL of Calibrator 4 in wells H1 and A2. • Add 20 µL of Calibrator 5 in wells B2 and C2. • Add 20 µL of Calibrator 6 in wells D2 and E2. The colors of Calibrator 1-6 gradually change from clear to blue.	• B1 and C1: Add 20 µL Calibrator 1 • D1 and E1: Add 20 µL Calibrator 2 • F1 and G1: Add 20 µL Calibrator 3 • H1 and A2: Add 20 µL Calibrator 4 • B2 and C2: Add 20 µL Calibrator 5 • D2 and E2: Add 20 µL Calibrator 6
2	• Add 20 µL of specimen to assigned well starting at F2.	• Starting F2: Add 20 µL specimen
3	• Add 100 µL of Conjugate to each well except for the Blank well. (Red Reagent)	• Add 100 µL of Conjugate to each well

4	• Mix gently by swirling the microwell plate on a flat bench for 30 seconds. • Cover the microwell plate with the Plate Sealer, and incubate at room temperature (20-30°C), in a room, a water bath or an incubator for 30 minutes ± 5 minute.	• Mix gently • Cover the microwell plate with the Plate Sealer and incubate at room temperature (20-30°C) for 30 min
5	• Remove the Plate Sealer. • Wash each well 5 times with 350 µL of Working Wash Buffer per well, then remove the liquid. • Turn the microwell plate upside down on absorbent tissue for a few seconds. Ensure that all wells have been completely washed and dried. Note: Improper washing may cause false positive results.	• Remove the Plate Sealer • Wash each well 5 times with 350 µL of Working Wash Buffer • Turn the microwell plate upside down on absorbent tissue
6	• Add 50 µL of Substrate A to each well. (Clear Reagent) • Add 50 µL of Substrate B to each well. (Clear Reagent) Then a light blue to blue color should develop in wells corresponding to the amount of PSA present in the specimen.	• Add 50 µL of Substrate A to each well • Add 50 µL of Substrate B to each well
7	• Mix gently then cover microwell plate with Plate Sealer, and incubate at room temperature (20-30°C), in a room, a water bath or an incubator for 15 minutes ± 2 minutes.	• Mix then cover microwell plate with Plate Sealer and incubate at room temperature (20-30°C) for 15 min
8	• Remove the Plate Sealer. • Add 50 µL of Stop Solution to each well. (Clear Reagent) Then a yellow should develop in wells containing positive specimens.	• Remove Plate Sealer • Add 50 µL of Stop Solution to each well
9	• Read at 450/630-700 nm within 30min Note: Microwell plate can also be read at 450 nm, but it is strongly recommended to read it at 450/630-700 nm for better results.	• Read at 450/630-700 nm within 30min

AUTOMATED PROCESSING

Automatic EIA microplate processors may be used to perform the assay after validating the results to ensure they are equivalent to those obtained using the manual method for the same specimens. Incubation times may vary depending on the processors used but do not program less incubation times than the procedure listed above. When automatic EIA microplate processors are used, periodic validation is recommended to ensure proper results.

QUALITY CONTROL

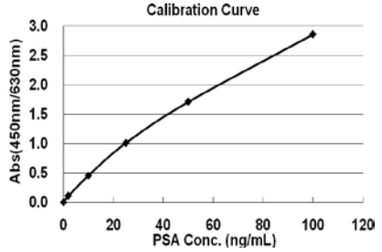
Control standards are not supplied with this kit; however, it is recommended that normal, low and high controls be tested with each run as a good laboratory practice to monitor assay performance. Each laboratory should establish its own criteria for establishing mean values and acceptable ranges to determine reliability of the results.

CALCULATION OF RESULTS

Draw the calibration curve and obtain quantitative specimen results.

1. Calculate the Mean Absorbance of each Calibrator, then plot them on the Y-axis against their concentration on the X-axis on a linear graph paper and draw the calibration curve. Draw the best-fitted line through data points and zero point to obtain a standard curve. Refer to an example of the calibration curve at right.

NOTE: Do not use the calibration curve at right to make any calculation. A calibration curve must be performed for each run.



Example of Specimen & Calibrators Result Calculation

Item	Well	Absorbance	Mean (Absorbance – Blank)	Total PSA Concentration (ng/mL)
Blank Well	A1	0.004	/	/
Calibrator 1	B1	0.006	0.002	0
	C1	0.006		
Calibrator 2	D1	0.111	0.108	2
	E1	0.113		
Calibrator 3	F1	0.461	0.455	10
	G1	0.456		
Calibrator 4	H1	1.011	1.009	25
	A2	1.014		
Calibrator 5	B2	1.712	1.711	50
	C2	1.718		
Calibrator 6	D2	2.888	2.863	100
	E2	2.845		
Specimen	F2	0.852	0.848	20.364

2. Obtain quantitative specimen results of concentrations expressed in ng/mL from their absorbance by using the calibration curve.

NOTE: Specimens that have absorbance above Calibrator 6 should be pre-diluted using Specimen Diluent and retested. The concentration must be multiplied by the dilution factor. Automated reading and calculation may also be performed using linear regression function on suitable computer programs.

LIMITATIONS

1. The Total PSA EIA Test Kit is used for the detection of Total PSA in human serum or plasma. Diagnosis should not be established based on a single test result. Further testing should be performed in assessing clinical status. Specimens containing precipitate may give inconsistent test results.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3. As with other sensitive immunoassays, there is the possibility that the positive result cannot be repeated due to inadequate washing from the initial test. The results may be affected due to procedural or instrument error.
4. Unusually high titers of heterophilic antibodies or rheumatoid factor (RF) may affect results. Even if test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

EXPECTED VALUES

It is recommended that each laboratory establish its own range of expected values based on patient populations. A study to determine expected values using the Total PSA EIA Test Kit was conducted for initial reference use only.

Population	No. Specimens	0-4.0 ng/mL	4.0-10 ng/mL	>10ng/mL
Normal	384	99.5%	0.25%	0.25%

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

The analytical sensitivity of the Total PSA EIA Test Kit is <0.1ng /mL.

Accuracy

The Total PSA EIA Test Kit has been compared to a leading commercial Total PSA test using clinical specimens. A total of 116 clinical specimens ranging from 0-100 ng/mL were run and analyzed using least square regression analysis. The results show that the Total PSA EIA Test Kit has good correlation compared to the reference method.

No. Specimens	Range (ng/mL)	Slope	Correlation Coefficient
116	0-100	1.21	0.98

Reproducibility

Intra-Assay: Within-run precision has been determined by using 10 replicates of three specimens: a low positive, a medium positive and a high positive.

Inter-Assay: Between-run precision has been determined by 270 independent assays on the same three specimens: a low positive, a medium positive and a high positive. Three different lots of the Total PSA EIA Test Kit have been tested using these specimens over a 3-day period.

Specimen	Intra-Assay			Inter-Assay		
	Mean (ng/mL)	Standard Deviation	Coefficient of Variation (%)	Mean (ng/mL)	Standard Deviation	Coefficient of Variation (%)
1	8.60	0.749	8.71	8.28	0.688	8.31
2	19.95	1.187	5.95	20.42	1.425	6.98
3	41.51	1.056	2.54	41.31	1.821	4.41

Recovery and Linearity

Recovery: Known amounts of Total PSA were added to normal human serum with endogenous Total PSA concentration of 0.658 ng/mL and 1.581 ng/mL. The concentration of Total PSA was determined using Total PSA EIA Test Kit and the resulting percent recovery was calculated.

Specimen	Endogenous Level (ng/mL)	Total PSA Concentration Added (ng/mL)	Total PSA Concentration Obtained (ng/mL)	Recovery* (%)
1-Level 1	0.658	18.18	19.474	103.5%
1-Level 2	0.658	45.45	46.865	101.7%
2-Level 1	1.581	18.18	18.330	92.1%
2-Level 2	1.581	45.45	43.985	93.3%

* Recovery = (Concentration Obtained (ng/mL) – Endogenous Level (ng/mL))/Concentration Added (ng/mL)

Linearity: Specimens containing known concentration of Total PSA were diluted with normal human serum and determined. The obtained concentrations were within ±20% of the expected values.

Interference

The specificity of the Total PSA EIA Test Kit was determined by testing sera containing the compounds listed below. These compounds showed less than 20% interference in the Total PSA EIA Test Kit at the levels indicated.

Substance	Concentration	Substance	Concentration
Hemoglobin	16.67 mg/mL	Ascorbic Acid	60 µg/mL
Bilirubin	150 µg/mL	Acetaminophen	200 µg/mL
Caffeine	100 µg/mL		

Cross-Reactivity

The following substances and concentrations have also been tested using Total PSA EIA Test Kit and no cross-reactivity was observed.

Substance	Concentration	Substance	Concentration
Follitropin (hFSH)	100 mIU/mL	TSH	40 mIU/mL
Chorionic Gonadotropin (hCG)	15 IU/mL	CA125	1500 IU/mL
CEA	10 µg/mL	PRL	160 ng/mL
LH	140 mIU/mL	CA153	3200 U/mL
AFP	10 µg/mL	CA199	500 U/mL

Dose Hook Effect

No dose hook effect is observed up to 25000 ng/mL of PSA.

BIBLIOGRAPHY

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2. Christensson A., et al, *Eur J Biochem,* 194 :755-63 (1990).
3. T. Rafi,A. Sattar,N., et al, "The Comparison of Percent Free PSA with Total PSA in the diagnosis of Prostate Cancer", *JPMA,* (2003).
4. Lab Test Online, "PSA", *American Association for Clinical Chemistry* (2011).

Index of Symbols

	Consult instructions for use	Σ	Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by	EC REP	Authorized Representative
2°C 8°C	Store between 2-8°C	LOT	Lot Number	REF	Catalog #
Total PSA	Total PSA	Substrate A	Substrate A	Substrate B	Substrate B
Specimen Diluent	Specimen Diluent	Stop Solution	Stop Solution	Conjugate	Conjugate
Wash Buffer 25x	Wash Buffer (25x)	Calibrator 1	Calibrator 1	Calibrator 2	Calibrator 2
Calibrator 3	Calibrator 3	Calibrator 4	Calibrator 4		
Calibrator 5	Calibrator 5	Calibrator 6	Calibrator 6	Package Insert	Package Insert
Microwell Plate	Microwell Plate	Plate Sealer	Plate Sealer		

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