Reszon Diagnostics INTERNATIONAL

Reasoning Possibilities In Life

CERTIFIED IQNet MANAGEMENT SYSTEM

Quality Management DQS ISO 13485

COMPANY PROFILE

Our Company

Established since 2010, Reszon Diagnostics International Sdn. Bhd. (Reszon) develops and manufactures a portfolio of innovative in vitro diagnostics (IVD) rapid test kits and ELISA kits for medical professionals and clinical diagnostic markets worldwide.

Our IVD rapid test kits allow medical professionals to diagnose diseases quickly and accurately for early detection and prevention of diseases. The simple assay procedures plus portability of our rapid test kits make them ideal for use in wide range of settings including remote areas and countries where sophisticated medical diagnostics are not available.

Our Products

- **Infectious diseases diagnosis**
  Lymphatic Filariasis, Typhoid, Malaria, Dengue
- **Drug of abuse testing**
  Single Dipstick Test, Combo Dip Card Test, Combo Cup Test
  Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Erimin, Ketamine, MDMA (Ecstasy), Methamphetamine, Methadone, Morphine, Phencyclidine, Marijuana, Tricyclic Antidepressants, Oxycodone

Our Certification

Our ISO13485 certification ensures that the quality standard of our products is constantly maintained at highest level of integrity.

Our R&D and Collaboration

Our R&D team has professional expertise in various biotechnological areas with extensive experience in respective diagnostic field. We collaborate with reputable industry leaders and scientists around the world to develop new immunodiagnostic tools in response to market demand.

Reszon also works closely with local Public Health authorities and WHO representatives in several countries in promoting disease elimination program.

Our Commitment

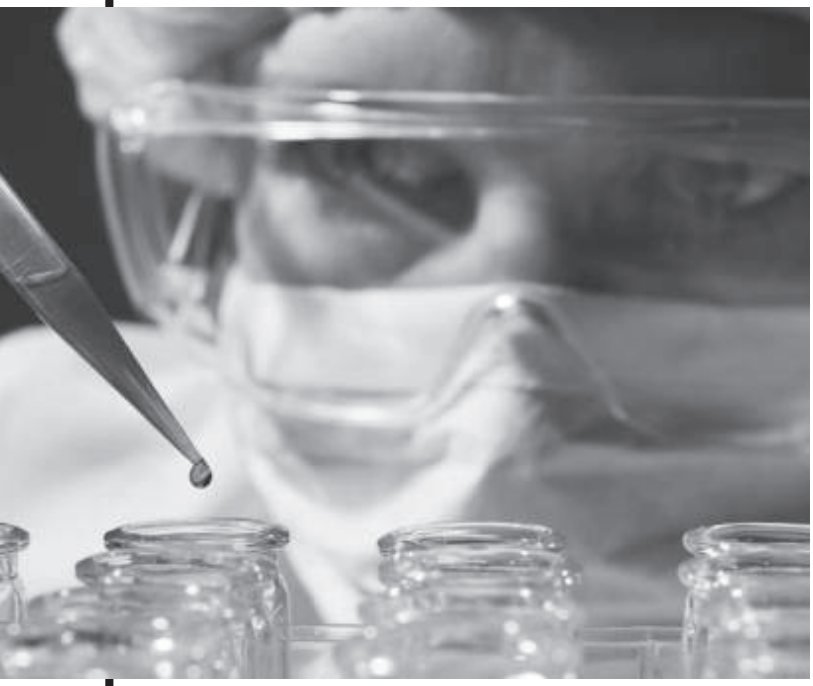
Our commitment towards quality excellence in product performance and standards, coupled with likeminded reputable distribution partners at the helm, has driven our continued success. We strive to establish mutual beneficial and long-term customer relationship with our business partners and end-users with unparalleled customer service and technical support.

Vision

To deliver better diagnostics solution to improve better health globally

Mission

- To be a global leading player in clinical diagnostics market
- To produce and deliver top notch quality and cost effective diagnostic test kits
- To constantly developing new immunodiagnostic tools with the most practical and innovative approach



QUALITY EXCELLENCE

CERTIFICATE

This is to certify that

Reszon Diagnostics International Sdn. Bhd.

Revongen Corporation Center,
No 12A, Jalan TP5,
Taman Perindustrian UEP,
47600 Subang Jaya, Selangor,
Malaysia.

has implemented and maintains a **Quality Management System**.

Scope:
Production of Immunochromatographic and PCR Based in Vitro Diagnostics Medical Devices.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

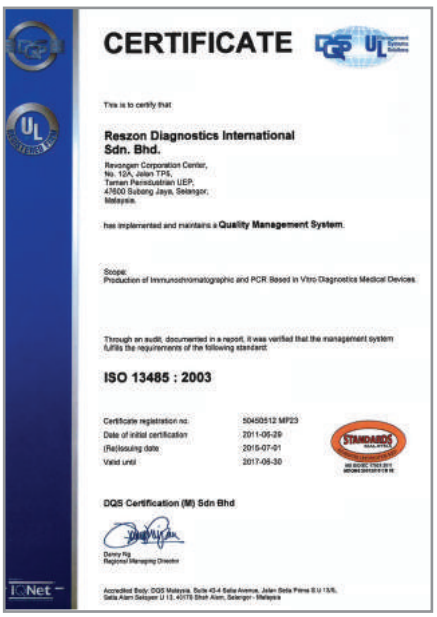
ISO 13485 : 2003 (MDA)

Certificate registration no.	50450512 MP23
Date of initial certification	2011-05-29
(Re)issuing date	2015-07-01
Valid until	2017-06-30

DQS Certification (M) Sdn Bhd

Danny Ng
Regional Managing Director

Certificate Assessment Body: DQS Certification (M) Sdn Bhd (MDA/CAB-005)
Suite 40-4 Sela Avenue, Jalan Sela Prima S U 13/8, Sela Alam Selayan U 13,
40170 Shah Alam, Selangor - Malaysia



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Danny Ng
Regional Managing Director

Accredited Body: DQS Malaysia, Suite 40-4 Sela Avenue, Jalan Sela Prima S U 13/8,
Sela Alam Selayan U 13, 40170 Shah Alam, Selangor - Malaysia

Obelis
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

E.A.R.-CERTIFICATE
(RECITAL 29 OF THE DIRECTIVE 98/79/EC ON IN VITRO DIAGNOSTIC MEDICAL DEVICES)

DATE: 11/03/2013

MANUFACTURER:

FACILITIES:

PRODUCT CATEGORY(IES)

MODEL(S):

OBELIS s.a. - O.E.A.R.C
Registered address:
Rue Générale Wahis 53
1030 Brussels
Tel. +32 2 732 59 54 - Fax +32 2 732 60 03

SEEN
Brussels Enterprise Commerce & Industry
Elke Peck
19 MAR 2013

CE

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PRODUCT LISTING

FOR INFECTIOUS DISEASES DIAGNOSIS

LATERAL FLOW RAPID TEST

Name of Product	Cat. No.	Product Description	Test Specimen	Product Format	Intended Use	Storage Temp.	Packing Size
Reszon Lymphatic Filariasis Rapid Test Kit	RLF-RD0101	PanLF Rapid Test	S/P/WB	Cassette	Lymphatic Filariasis Infection	4-30°C	25 T/ Kit CE
	RLF-RD0201	Brugia Rapid Test	S/P/WB	Cassette	Brugian Filariasis Infection	4-30°C	25 T/ Kit CE
Reszon TYPHIDOT Rapid Test Kit	RTF-RD0101	TYPHIDOT Rapid IgM Test	S/P/WB	Cassette	Typhoid Fever	4-30°C	25 T/ Kit CE
	RTF-RD0202	TYPHIDOT Rapid IgG & IgM (Combo) Test	S/P	Cassette	Typhoid Fever	4-30°C	25 T/ Kit CE
Reszon Malaria Rapid Test Kit	RML-RD0101	Malaria Rapid (Pan/Pf) Test	WB	Cassette	Malaria Infection	4-30°C	25 T/ Kit CE
Reszon Dengue Rapid Test Kit	RDG-RD0102	Dengue Rapid IgG/IgM Test	S/P	Cassette	Dengue Fever	4-30°C	25 T/ Kit CE
	RDG-RD0202	Dengue Rapid NS1 Test	S/P/WB	Cassette	Dengue Fever	4-30°C	25 T/ Kit

ELISA KITS

Name of Product	Cat. No.	Product Description	Test Specimen	Product Format	Intended Use	Storage Temp.	Packing Size
Reszon Typhoid ELISA Test Kit	RTF-ED0102	TYPHIDOT 3 hours	S/P	Dot EIA	Typhoid Fever	2-8°C	28 T/ Kit
	EMTF00196	Typhoid ELISA IgM	S/P	ELISA	Typhoid Fever	2-8°C	96 T/ Kit
	EMTF00296	Typhoid ELISA IgG	S/P	ELISA	Typhoid Fever	2-8°C	96 T/ Kit

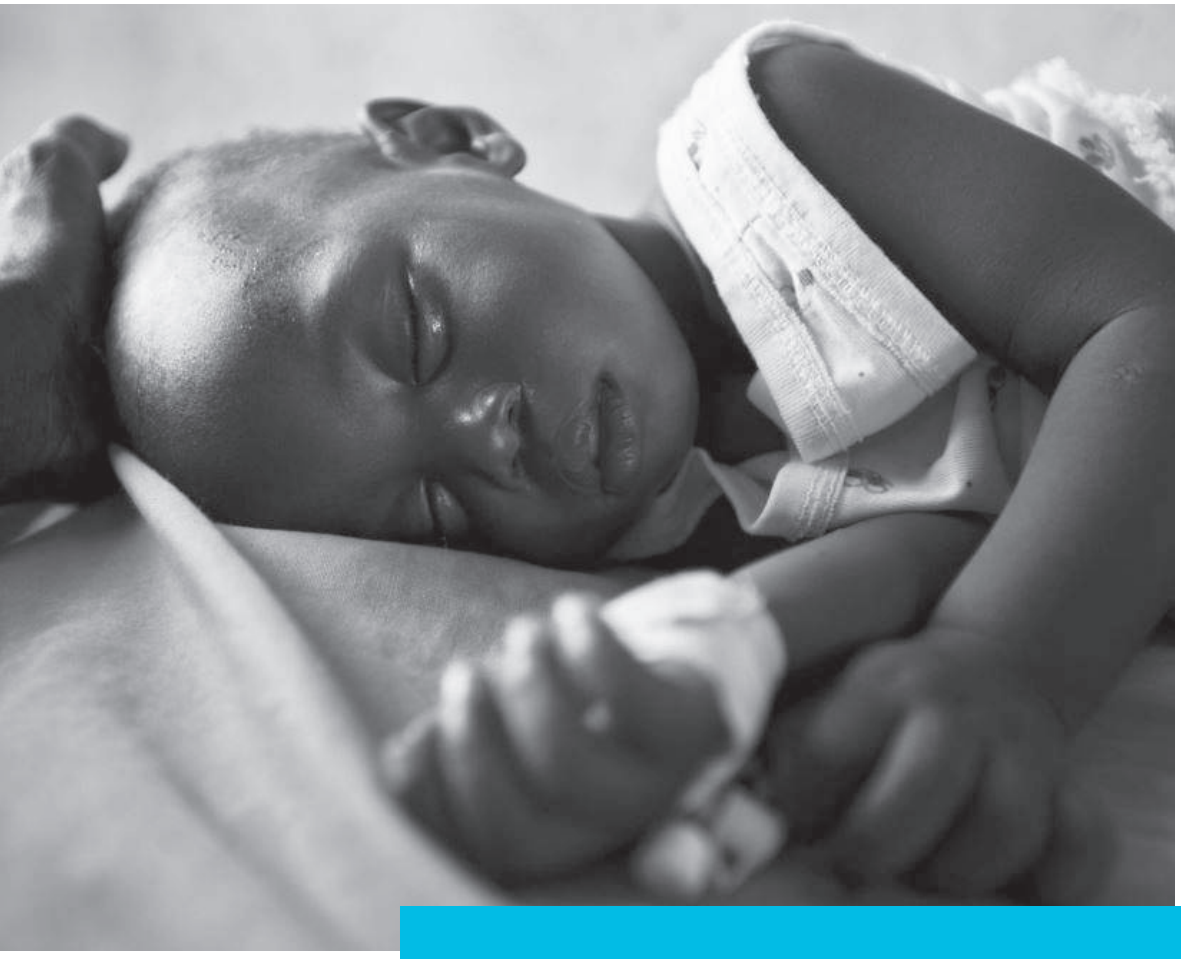
Remarks : S: Serum, **P**: Plasma, **WB**: Whole Blood

FOR DRUG SCREENING

FastScreen™ DRUG OF ABUSE RAPID TEST

Cat. No.	Product Description	Test Specimen	Product Format	Cut-off (ng/ml)	Packing Size	
DT-RD01-AMP	FastScreen™ Single Drug Test, Amphetamine	Urine	Dipstick	500 1000	100 T/Kit	CE
DT-RD01-BAR	FastScreen™ Single Drug Test, Barbiturates	Urine	Dipstick	300	100 T/Kit	
DT-RD01-BZO	FastScreen™ Single Drug Test, Benzodiazepines	Urine	Dipstick	300	100 T/Kit	CE
DT-RD01-COC	FastScreen™ Single Drug Test, Cocaine	Urine	Dipstick	150 300	100 T/Kit	CE
DT-RD01-ER5	FastScreen™ Single Drug Test, Erimin	Urine	Dipstick	300	100 T/Kit	
DT-RD01-KET	FastScreen™ Single Drug Test, Ketamine	Urine	Dipstick	1000	100 T/Kit	CE
DT-RD01-MDMA	FastScreen™ Single Drug Test, MDMA (Ecstasy)	Urine	Dipstick	500	100 T/Kit	
DT-RD01-MET	FastScreen™ Single Drug Test, Methamphetamine	Urine	Dipstick	500 1000	100 T/Kit	CE
DT-RD01-MTD	FastScreen™ Single Drug Test, Methadone	Urine	Dipstick	300	100 T/Kit	
DT-RD01-MOP	FastScreen™ Single Drug Test, Morphine	Urine	Dipstick	300 2000	100 T/Kit	CE
DT-RD01-PCP	FastScreen™ Single Drug Test, Phencyclidine	Urine	Dipstick	25	100 T/Kit	
DT-RD01-THC	FastScreen™ Single Drug Test, Marijuana	Urine	Dipstick	50	100 T/Kit	CE
DT-RD01-TCA	FastScreen™ Single Drug Test, Tricyclic Antidepressants	Urine	Dipstick	1000	100 T/Kit	
DT-RD01-OXY	FastScreen™ Single Drug Test, Oxycodone	Urine	Dipstick	100	100 T/Kit	
DT-RD02,03,04,05	FastScreen™ Drug Combo Test, 2-in-1 to 5-in-1	Urine	Dip Card	-	25 T/Kit	
DT-RD06,07,08,09,10	FastScreen™ Drug Combo Test, 6-in-1 to 10-in-1	Urine	Twin Card	-	25 T/Kit	
DT-RDCP4,5,6,7	FastScreen™ Drug Cup Test, 4-in-1 to 7-in-1	Urine	Cup	-	1 T/Kit	
DT-RDCP8,9,10,11,12	FastScreen™ Drug Multiplex Cup Test, 8-in-1 to 12-in-1	Urine	Cup	-	1 T/Kit	

FOR INFECTIOUS DISEASES DIAGNOSIS



LATERAL FLOW RAPID TEST

RESZON LYMPHATIC FILARIASIS RAPID TEST KIT

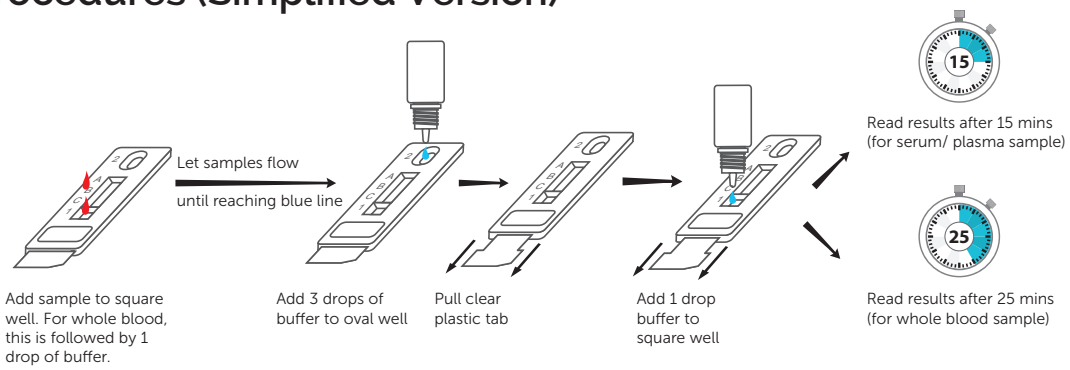
PanLF RAPID TEST

Test Description

- Rapid immunochromatography assay for lymphatic filariasis infection
- Detect specific IgG4 antibodies to *Wuchereria brancrofti, Brugia malayi* and/or *Brugia timori*
- Sample collected at any time of the day can be used
- Simple to perform & no special equipment required

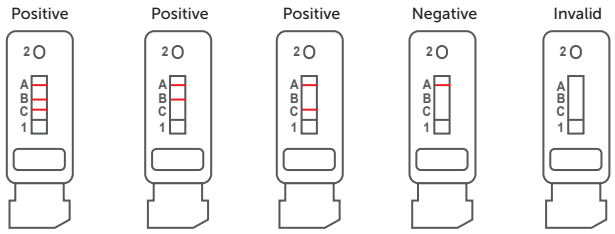
Specimen	Human whole blood/serum/plasma
Specimen volume	35 µl (whole blood) / 30 µl (serum/plasma)
Specificity	99-100%
Sensitivity	94-100%
Assay time	15-25 mins

Procedures (Simplified Version)



Result Interpretation

A : Control Line
B&C : Test Line



Ordering Information

Cat. No.	Product Name	Detection	Packing Size
RLF-RD0101	PanLF Rapid Test	Antibodies specific to *W. brancrofti, B. malayi* and/or *B. timori*	25 T/ Kit

RESZON LYMPHATIC FILARIASIS RAPID TEST KIT

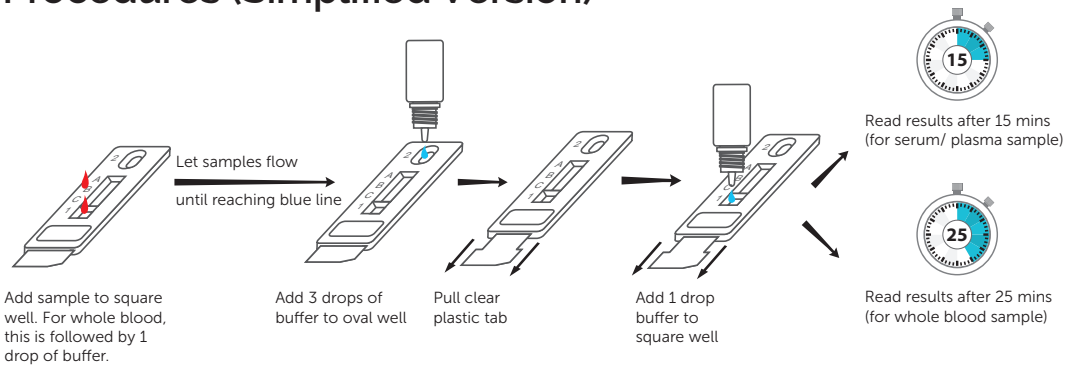
BRUGIA RAPID TEST

Test Description

- Rapid immunochromatography assay for brugian filariasis infection
- Detect specific IgG4 antibodies to *Brugia malayi* and/or *Brugia timori*
- Sample collected at any time of the day can be used
- Simple to perform & no special equipment required

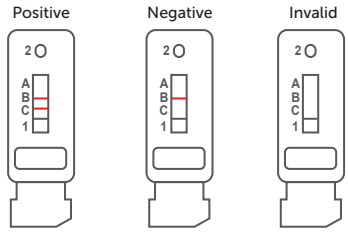
Specimen	Human whole blood/serum/plasma
Specimen volume	35 µl (whole blood) / 30 µl (serum/plasma)
Specificity	97-100%
Sensitivity	92-100%
Assay time	15-25 mins

Procedures (Simplified Version)



Result Interpretation

B : Control Line
C : Test Line



Ordering Information

Cat. No.	Product Name	Detection	Packing Size
RLF-RD0201	Brugia Rapid Test	Antibodies specific to *B. malayi* and/or *B. timori*	25 T/ Kit

RESZON TYPHIDOT RAPID TEST KIT

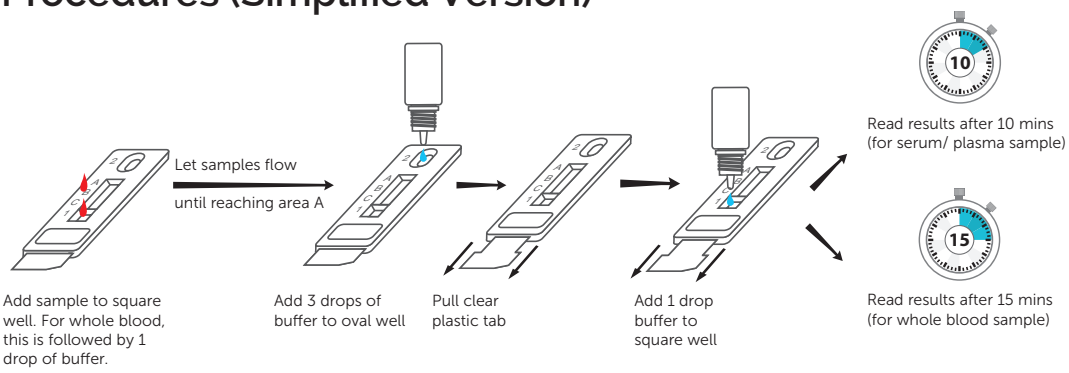
TYPHIDOT RAPID IgM TEST

Test Description

- Rapid immunochromatography assay for early detection of typhoid fever
- Detect specific IgM antibodies to specific outer membrane protein antigen of *Salmonella typhi*
- Simple to perform & no special equipment required

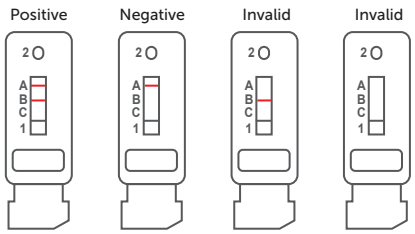
Specimen	Human whole blood/serum/plasma
Specimen volume	35 µl (whole blood) / 30 µl (serum/plasma)
Specificity	96.7%
Sensitivity	85.9%
Assay time	15-20 mins

Procedures (Simplified Version)



Result Interpretation

A : Control Line
B : Test Line



Ordering Information

Cat. No.	Product Name	Detection	Packing Size
RTF-RD0101	TYPHIDOT Rapid IgM Test	Antibodies specific to *Salmonella typhi*	25 T/ Kit

RESZON TYPHIDOT RAPID TEST KIT

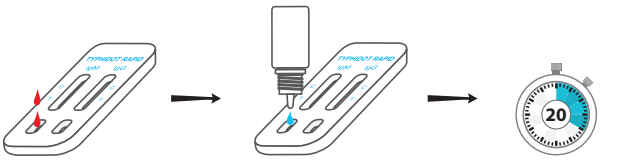
TYPHIDOT RAPID IgG/IgM (COMBO) TEST

Test Description

- Rapid immunochromatography assay for detection of typhoid fever
- Detect specific IgG/IgM to specific outer membrane protein antigen of *Salmonella typhi*
- Simple to perform & no special equipment required

Specimen	Serum/plasma
Specimen volume	45 µl (serum/plasma)
Specificity	80%
Sensitivity	90%
Assay time	20 mins

Procedures (Simplified Version)



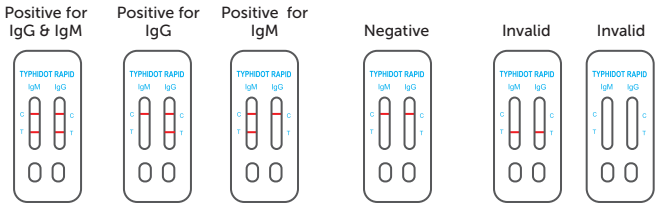
Add sample to each sample well

Add 1 drop of buffer to each sample well

Read results after 20 minutes

Result Interpretation

C : Control Line
T : Test Line



Ordering Information

Cat. No	Product Name	Detection	Packing Size
RTF-RD0202	TYPHIDOT Rapid IgG IgM (combo) Test	Antibodies specific to *Salmonella typhi*	25 T/ Kit

RESZON MALARIA RAPID TEST KIT

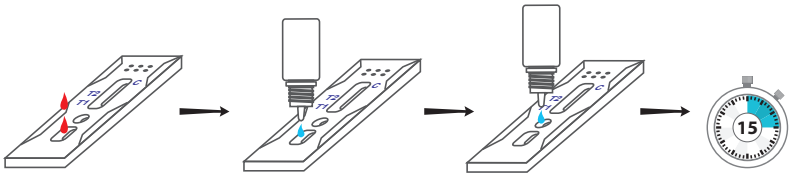
MALARIA RAPID (Pan/Pf) TEST

Test Description

- Rapid immunochromatography assay for qualitative detection and differentiation of *Plasmodium falciparum* and/or *Plasmodium vivax, Plasmodium ovale* and *Plasmodium malariae* antigen in whole blood
- Simple to perform & no special equipment required

Specimen	Whole blood
Specimen volume	3 µl
Specificity	98%
Sensitivity	97-100%
Assay time	15 mins

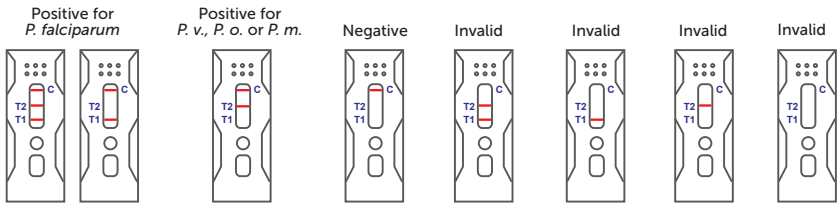
Procedures (Simplified Version)



Add sample to sample well → Add 1 drop of lysing/wash buffer to sample well → Add 5 drops of lysing/wash buffer to buffer well → Read results after 15 minutes

Result Interpretation

C : Control Line
2 : All tests
1. P.f. test



Ordering Information

Cat. No	Product Name	Detection	Packing Size
RML-RD0101	Malaria Rapid (Pan/Pf) Test	*P. falciparum* and/or *P. vivax, P. ovale* and *P. malariae* antigen	25 T/ Kit

RESZON DENGUE RAPID TEST KIT

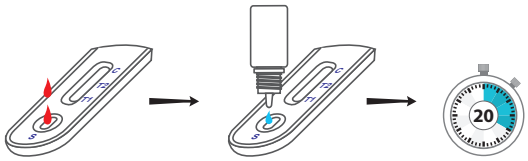
DENGUE RAPID IgG/IgM TEST

Test Description

- Rapid immunochromatography assay for detection of dengue fever
- Detect specific IgG/IgM antibodies to dengue virus
- Can be used for presumptive distinction between a primary and secondary dengue infection
- Simple to perform & no special equipment required

Specimen	Human whole blood/serum/plasma
Specimen volume	10 µl
Specificity	95%
Sensitivity	96%
Assay time	20 mins

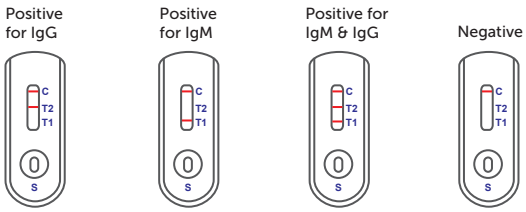
Procedures (Simplified Version)



Add sample to sample well. → Add 2 drops of buffer to sample well → Read results after 20 minutes

Result Interpretation

C: Control Line
T2 : Test Line 2 (for IgG)
T1 : Test Line 1 (for IgM)



Ordering Information

Cat. No	Product Name	Detection	Packing Size
RDG-RD0102	Dengue Rapid IgG/IgM Test	Antibodies specific to dengue virus	25 T/ Kit

RESZON DENGUE RAPID TEST KIT

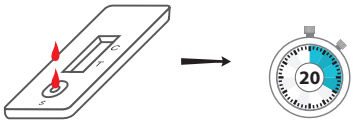
DENGUE RAPID NS1 TEST

Test Description

- Rapid immunochromatography assay for detection of dengue fever
- Detect specific NS1 antigen to dengue virus
- Simple to perform & no special equipment required

Specimen	Human whole blood/serum/plasma
Specimen volume	70 µl
Specificity	96%
Sensitivity	80%
Assay time	15-20 mins

Procedures (Simplified Version)

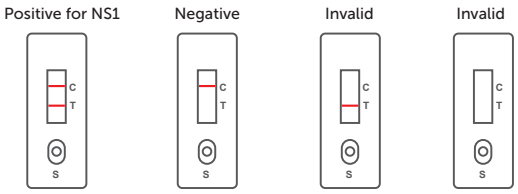


Add sample to sample well.

Read results after 15-20 minutes

Result Interpretation

C : Control Line
T : Test Line



Ordering Information

Cat. No	Product Name	Detection	Packing Size
RDG-RD0202	Dengue Rapid NS1 Test	Dengue NS1 antigen	25 T/ Kit

FOR INFECTIOUS DISEASES DIAGNOSIS

ELISA KITS

RESZON TYPHOID ELISA TEST KIT

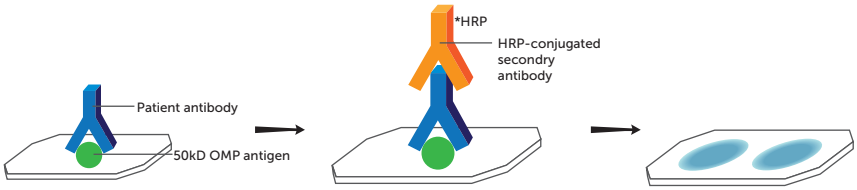
TYPHIDOT 3 HOURS

Test Description

- Rapid dot EIA test for diagnosis of typhoid fever
- Detect specific IgG & IgM antibodies to specific outer membrane protein antigen of *Salmonella typhi*

Format	Dot blot strip
Specimen	Serum
Specimen volume	20 µl
Specificity	> 90%
Sensitivity	> 90%
Assay time	3 hours

Procedures (Simplified Version)



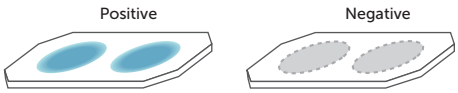
Add patient serum sample to pre-dotted antigen strip. Wash away unbound patient antibody.

Add HRP conjugated secondary antibody. Wash away unbound secondary antibody.

Add substrate and read results

Result Interpretation

Positive reading is indicated by the blue colour as intense as or more intense than that of the positive control



Ordering Information

Cat. No	Product Name	Detection	Packing Size
RTF-ED0102	TYPHIDOT 3 hours	Antibodies specific to *Salmonella typhi*	28 T/ Kit

RESZON TYPHOID ELISA TEST KIT

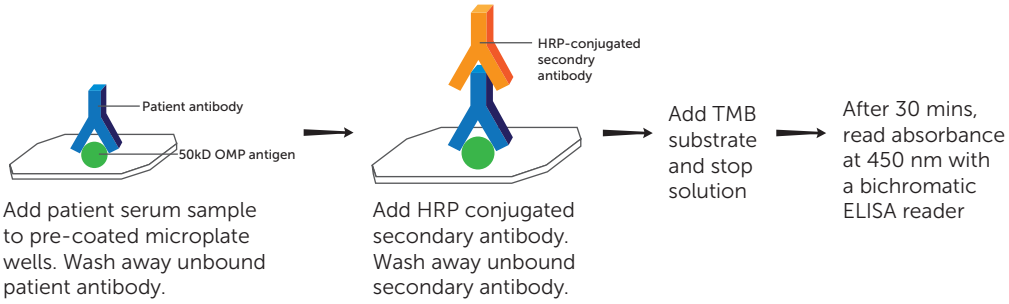
TYPHOID ELISA IgM/TYPHOID ELISA IgG

Test Description

- An indirect ELISA test for diagnosis of typhoid fever
- Detect specific IgG or IgM antibodies to specific outer membrane protein antigen of *Salmonella typhi*

Specimen	Serum
Specimen volume	10 µl
Specificity	80-95%
Sensitivity	80-95%
Assay time	3-4 hours

Procedures (Simplified Version)



Result Calculation & Interpretation

$$\text{P/N OMP test} = \frac{\text{Mean OD of test sample}}{\text{Mean OD of negative sample}}$$

Positive : P/N value equal or above 2.0 (for IgM)
: P/N value equal or above 3.0 (for IgG)

Negative : P/N value below 2.0 (for IgM)
: P/N value below 3.0 (for IgG)

Ordering Information

Cat. No	Product Name	Detection	Packing Size
EMTF00196	Typhoid ELISA IgM	Antibodies specific to *Salmonella typhi*	96 T/ Kit
EMTF00296	Typhoid ELISA IgG	Antibodies specific to *Salmonella typhi*	96 T/ Kit

FOR DRUG SCREENING

DRUG OF ABUSE RAPID TEST

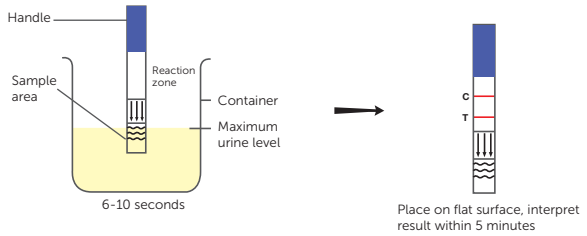
FastScreen™ DRUG OF ABUSE RAPID TEST

Test Description

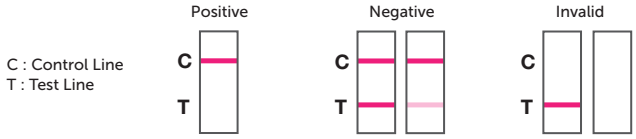
- Easy, fast and visually readable urine drug screening test.
- Use a rapid, competitive binding immunoassay for qualitative determination of different drugs and drugs metabolites in human urine
- No sample preparation required

Format	Dip stick
Assay time	5 mins

Procedures (Simplified Version)

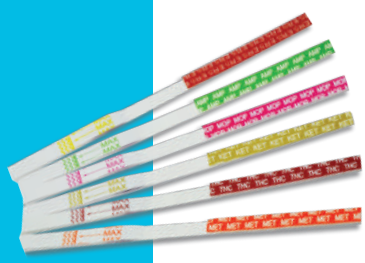


Result Interpretation



Ordering Information

Cat. No.	Product Description	Test Specimen	Test Format	Cut-off (ng/ml)	Packing Size
DT-RD01-AMP	FastScreen™ Single Drug Test, Amphetamine	Urine	Dipstick	500/1000	100 T/Kit CE
DT-RD01-BAR	FastScreen™ Single Drug Test, Barbiturates	Urine	Dipstick	300	100 T/Kit
DT-RD01-BZO	FastScreen™ Single Drug Test, Benzodiazepines	Urine	Dipstick	300	100 T/Kit CE
DT-RD01-COC	FastScreen™ Single Drug Test, Cocaine	Urine	Dipstick	150/300	100 T/Kit CE
DT-RD01-ER5	FastScreen™ Single Drug Test, Erimin	Urine	Dipstick	300	100 T/Kit
DT-RD01-KET	FastScreen™ Single Drug Test, Ketamine	Urine	Dipstick	1000	100 T/Kit CE
DT-RD01-MDMA	FastScreen™ Single Drug Test, MDMA (Ecstasy)	Urine	Dipstick	500	100 T/Kit
DT-RD01-MET	FastScreen™ Single Drug Test, Methamphetamine	Urine	Dipstick	500/1000	100 T/Kit CE
DT-RD01-MTD	FastScreen™ Single Drug Test, Methadone	Urine	Dipstick	300	100 T/Kit
DT-RD01-MOP	FastScreen™ Single Drug Test, Morphine	Urine	Dipstick	300/2000	100 T/Kit CE
DT-RD01-PCP	FastScreen™ Single Drug Test, Phencyclidine	Urine	Dipstick	25	100 T/Kit
DT-RD01-THC	FastScreen™ Single Drug Test, Marijuana	Urine	Dipstick	50	100 T/Kit
DT-RD01-TCA	FastScreen™ Single Drug Test, Tricyclic Antidepressants	Urine	Dipstick	1000	100 T/Kit
DT-RD01-OXY	FastScreen™ Single Drug Test, Oxycodone	Urine	Dipstick	100	100 T/Kit



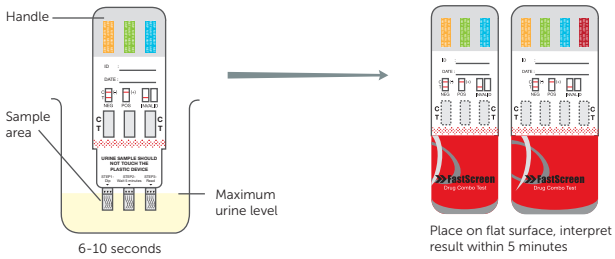
FastScreen™ DRUG COMBO TEST

Test Description

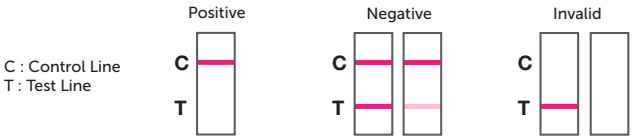
- Use a rapid, competitive binding immunoassay for qualitative determination of different drugs and drugs metabolites in human urine
- No sample preparation required
- Able to detect from 2 to 10 different drug combinations at the same time
- Easy result interpretation as each drug type is clearly labeled and color-coded

Format	Dip card / Twin card
Assay time	5 mins

Procedures (Simplified Version)



Result Interpretation



Ordering Information

Cat. No.	Product Description	Test Specimen	Test Format	Packing Size
DT-RD02	FastScreen™ Drug Combo Test 2-in-1	Urine	Dip Card	25 T/Kit
DT-RD03	FastScreen™ Drug Combo Test 3-in-1	Urine	Dip Card	25 T/Kit
DT-RD04	FastScreen™ Drug Combo Test 4-in-1	Urine	Dip Card	25 T/Kit
DT-RD05	FastScreen™ Drug Combo Test 5-in-1	Urine	Dip Card	25 T/Kit
DT-RD06	FastScreen™ Drug Combo Test 6-in-1	Urine	Twin Card	25 T/Kit
DT-RD07	FastScreen™ Drug Combo Test 7-in-1	Urine	Twin Card	25 T/Kit
DT-RD08	FastScreen™ Drug Combo Test 8-in-1	Urine	Twin Card	25 T/Kit
DT-RD09	FastScreen™ Drug Combo Test 9-in-1	Urine	Twin Card	25 T/Kit
DT-RD10	FastScreen™ Drug Combo Test 10-in-1	Urine	Twin Card	25 T/Kit

*Drug combinations can be customized based on customer's preferences

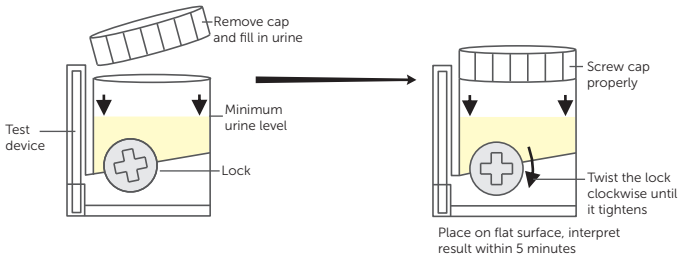
FastScreen™ DRUG CUP RAPID TEST

Test Description

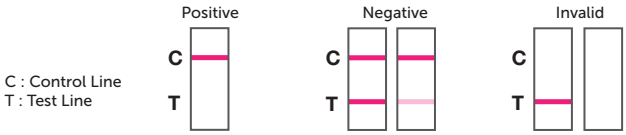
- Rapid, competitive binding immunoassay for qualitative determination of different drugs and drugs metabolites in human urine
- Use a self-contained, one-step closed system with a secure lid to ensure total integrity of urine specimen
- Comes with integrated key activator (no dipping or pouring required)
- Able to detect from 4 to 12 different drug combinations at the same time
- Easy result interpretation as each drug type is clearly labeled and color-coded

Format	Cup/ Multiplex cup
Assay time	5 mins

Procedures (Simplified Version)



Result Interpretation



Ordering Information

Cat. No.	Product Description	Test Specimen	Test Format	Packing Size
DT-RDCP4	FastScreen™ Drug Cup Test 4-in-1	Urine	Cup	1 T/ Kit
DT-RDCP5	FastScreen™ Drug Cup Test 5-in-1	Urine	Cup	1 T/ Kit
DT-RDCP6	FastScreen™ Drug Cup Test 6-in-1	Urine	Cup	1 T/ Kit
DT-RDCP7	FastScreen™ Drug Cup Test 7-in-1	Urine	Cup	1 T/ Kit
DT-RDCP8	FastScreen™ Drug Multiplex Cup Test 8-in-1	Urine	Cup	1 T/ Kit
DT-RDCP9	FastScreen™ Drug Multiplex Cup Test 9-in-1	Urine	Cup	1 T/ Kit
DT-RDCP10	FastScreen™ Drug Multiplex Cup Test 10-in-1	Urine	Cup	1 T/ Kit
DT-RDCP11	FastScreen™ Drug Multiplex Cup Test 11-in-1	Urine	Cup	1 T/ Kit
DT-RDCP12	FastScreen™ Drug Multiplex Cup Test 12-in-1	Urine	Cup	1 T/ Kit

Contact Us

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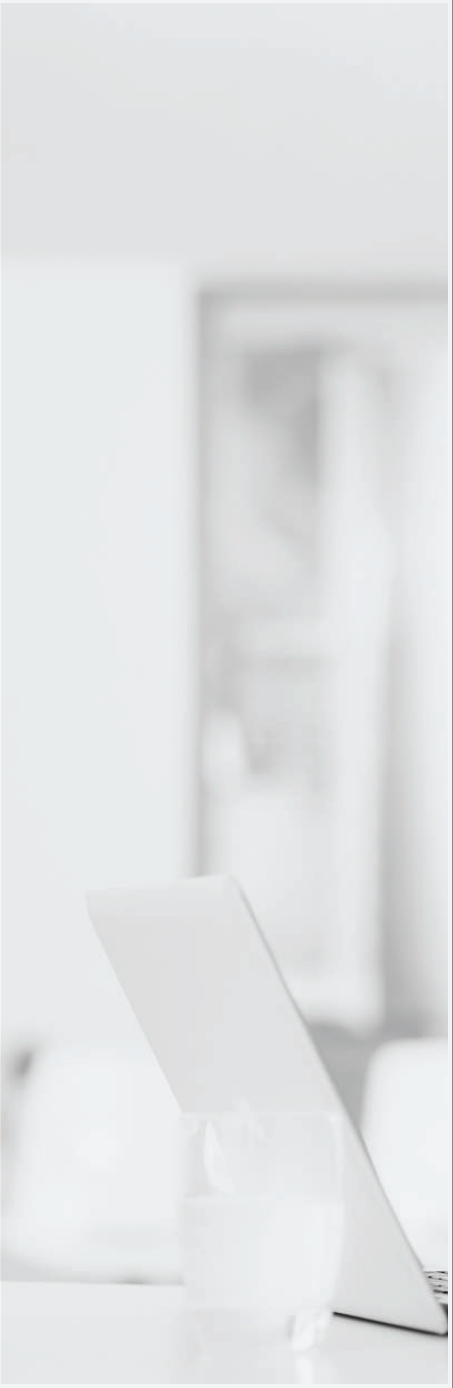
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