



All India Institute of Medical Sciences, Bhubaneswar
At - Sijua (Patrapada), Post - Dumuduma, Bhubaneswar (Odisha) - 751 019

To be uploaded in Website: www.aiimsbhubaneswar.edu.in (Tender)

Reference No: J-11078(05)/2019-20/S&P

Dated: 24/03/2021

Sub: Procurement of FTD Atypical CAP(RUO) FTD-53.1-32-RUO[Make: FastTrack, Luxembourg] and FTD Respiratory Pathogens 21(RUO) FTD-2-32-RUO [Make: FastTrack, Luxembourg] for the Department of Anesthesiology (Project) at AIIMS, BBSR on Proprietary basis - **Inviting Comments thereon.**

The Department of Anesthesiology of AIIMS, Bhubaneswar has requested for Procurement of FTD Atypical CAP(RUO) FTD-53.1-32-RUO[Make: FastTrack, Luxembourg] and FTD Respiratory Pathogens 21(RUO) FTD-2-32-RUO [Make: FastTrack, Luxembourg] from their Indian distributor M/s Siemens Healthcare Private Limited, Mumbai.

The Notice is being uploaded for general information of prospective manufacturer/Authorized Distributor/Dealers to submit their objection/proposal/comments, if any, on proprietorship of the item.

In case the product of any manufacturer/Authorized distributor/Dealer conforms to the enclosed specifications, they may submit their proposal for the supply of the same along with the brochures, point by point compliance of the enclosed specifications along with all documentary evidence. One quotation of the product may also be submitted.

The objections/comments/proposal should be sent in sealed cover to the Office of Sr. Procurement Cum Stores Officer, AIIMS, Bhubaneswar (Odisha) – 751019 or through e-mail to spo@aiimsbhubaneswar.edu.in, aso.mpattnaik@aiimsbhubaneswar.edu.in & jao_nivedita@aiimsbhubaneswar.edu.in so as to reach on or before **date: 02-04-2021** failing which it will be presumed that no other firm is interested to offer comments/protest/object and case will be decided on its merits.

The ref. no.– **J-11078(05)/2019-20/S&P dt: 24-03-2021**, due on dated: 02-04-2021 should be superscripted on sealed envelope.

Enclosure:

1. Proprietary Article Certificate from Indenting Officer of Department of Anesthesiology(project), AIIMS, Bhubaneswar. **Annexure-I**
2. PAC of M/s Fast Track Diagnostics, Luxembourg for FTD Atypical CAP(RUO) FTD-53.1-32-RUO (Make: FastTrack, Luxembourg) **Annexure-II** and FTD Respiratory Pathogens 21(RUO) FTD-2-32-RUO (Make: FastTrack, Luxembourg) **Annexure-III**
3. Latest Price Quotation of FTD Atypical CAP(RUO) FTD-53.1-32-RUO (Make: FastTrack, Luxembourg) **Annexure-IV** and FTD Respiratory Pathogens 21(RUO) FTD-2-32-RUO (Make: FastTrack, Luxembourg) **Annexure-V**
4. OEM Authorization Certificate **Annexure-VI**
5. Brochure & Literature **Annexure-VII**

Copy to: -

- | | | |
|---|---|------------------------------|
| 1. Indenting Officer, Department of Anaesthesiology | : | for information please |
| 2. Accounts Officer | : | for information please |
| 3. IT Cell | : | for hoisting in the website. |

Sr. Procurement-cum-Stores Officer

AIIMS, BHUBANESWAR

53

Proprietary Article Certificate
Valid for the Current Financial Year

File No. and Date Reference :		
1	Description of article	
2	Forecast of quantity /annual requirement	① FAST TRACK DIAGNOSTICS RESP PATO 21 ② FAST TRACK DIAGNOSTICS ATX PICO L CAP
3	Approximate estimated value for above quantity	② + ②
4	Maker's name and address	Rs 3,03,116/-
5	Name(s) of authorized dealers/ stockists	FAST TRACK DIAGNOSTICS V. KHROU ENAI, MU AR AT
6	I approve the above purchase on PAC basis and certify that : - Note- Tick to retain only one out of (b), C-1) or (c-2) whichever is applicable and cross out others. Please do confirm (a) by ticking it - without which PAC certificate will be invalid.	
6 (a)	This is the only firm who is manufacturing / stocking this item. AND	YES
6 (b)	A Similar article is not manufactured / sold by any other firm, which could be used in lieu OR	YES
6 (c-1)	No other make/brand will be suitable for following tangible reasons (like OEM/ Warranty, spares.) OR	MANY PATHOGENS REQUIRED CAN BE CONFIRMED BY THIS.
6 (c)	No other make/brand will be suitable for following intangible reasons (if PAC was also given in the last procurement cycle, please also bring out efforts made since then to locate more sources) : OR	
7	Reference of concurrence of finance wing to the proposal :	
History of PAC Purchase of this item for past three years may be given below :		
Name of the Supplier		
Order/ Tender Reference & Date	Quantity Ordered	Basic Rate on Order (Rs.)
75 8/19-20 2/1/2020	① + ①	Rs 97,866

Signature of Approving Authority.....

Date..... Designation of Officer.....

Signature of the Indenting Officer

Suma Rebas Chandra

DR. SUBAB AHMAD
Assistant Professor
Dept. of Anesthesiology
AIIMS, BBSR- 19

Thursday, 4 March, 2021

Proprietary Certificate

To Whom It May Concern,

This document certifies and confirms that the products mentioned below are exclusively manufactured by Fast Track Diagnostics Luxembourg S.à r.l., and Proprietary in nature:

Table 1

SMN	Catalogue number	Product Name
(32) 11373929 (64) 11373930	FTD-3 (RUO)	FTD Viral gastroenteritis (RUO)
(32) 11373947 (64) 11373948	FTD-14.1 (RUO)	FTD Bacterial gastroenteritis (RUO)
(32) 11374009 (64) 11374010	FTD-53.1 (RUO)	FTD Atypical CAP (RUO)
(32) 11373921 (64) 11373922	FTD-1.1 (RUO)	FTD ACE (RUO)
(32) 11373965 (64) 11373966	FTD-27 (RUO)	FTD Pneumocystis jirovecii (RUO)
(32) 11373997 (64) 11373998	FTD-44 (RUO)	FTD Dengue differentiation (RUO)
(32) 11374007 (64) 11374008	FTD-52.1 (RUO)	FTD STD9 (RUO)
(32) 11374021 (64) 11374022	FTD-62 (RUO)	Flu differentiation (RUO)

The term of this Agreement shall be valid for 1 year until March 04, 2022.

Sincerely,

Fast Track Diagnostics Luxembourg S.à r.l.

Schleichert Michael

Digitally signed by Schleichert
Michael
Date: 2021.03.04 12:52:13 +01'00'

Dr. Michael Schleichert
General Manager

Friday, 30 October, 2020

Proprietary Certificate

To Whom It May Concern,

This document certifies and confirms that the products mentioned below are exclusively manufactured by Fast Track Diagnostics Luxembourg S.à r.l., and Proprietary in nature:

Table 1

SMN	Catalogue number	Product Name
(32) 11373945 (64) 11373946	FTD-13 (RUO)	FTD Viral meningitis (RUO)
(32) 11373967 (64) 11373968	FTD-28 (RUO)	FTD Bacterial meningitis (RUO)
(32) 11374019 (64) 11374020	FTD-60.4 (RUO)	FTD Neuro 9 (RUO)
(32) 11373925 (64) 11373926	FTD-2P.3 (RUO)	FTD Respiratory pathogens 33 (RUO)
(32) 11373927 (64) 11373928	FTD-2 (RUO)	FTD Respiratory pathogens 21 (RUO)
(32) 11373923 (64) 11373924	FTD-2+.1 (RUO)	FTD Respiratory pathogens 21 plus (RUO)
(32) 11373983 (64) 11373984	FTD-36 (RUO)	FTD Tropical fever core (RUO)
(32) 11373995 (64) 11373996	FTD-43 (RUO)	FTD Dengue / Chik (RUO)
(32) 11373959 (64) 11373960	FTD-21.1 (RUO)	FTD FLU (RUO)
(32) 11374049 (64) 11374050	FTD-84 (RUO)	FTD Zika/Dengue/Chik (RUO)

The term of this Agreement shall be valid for 1 year until October 30, 2021.

Sincerely,

Fast Track Diagnostics Luxembourg S.à r.l.

Schleichert Michael
Digitally signed by Schleichert Michael
Date: 2020.10.30 08:58:03 +01'00'

Dr. Michael Schleichert
General Manager

Name: Dharmendra Kumar
Department: Sales
Mobile: +91 9212599677
E-mail: Dharmendra.kumar@siemens-healthineers.com

Our reference: February 4, 2021
Date: 4th February, 2021

To: Dr. Suma Ahmad
Asst Professor,
Department of Anesthesia
AIIMS, Bhubaneswar, Orissa

Subject: Siemens FTD Atypical CAP Assay

Dear Sir,
Greetings from Siemens Healthcare Pvt Ltd.,

As required, please find herewith below quotation for FTD assay reagent kits,

Product Description & Cat/que No	SMN No	Pack Size	Unit price (INR)	Qty	Total Price (INR)
FTD Atypical CAP (RUO) FTD-53.1-32-RUO	11374009	32 reactions	39678	1	39678
Special Discount					2223
Value After Discount					37455
GST@12%					4494
Grand Total					41949

Siemens Healthcare Private Limited

Unit No. 9A, Godrej One,
Vikhroli
Mumbai-400079
India

Tel: +91 022-33700600
Fax: +91 022-33700654
Toll free: 1800-208-1800
Email: hc_contact.india@siemens.com
www.siemens.co.in/healthcare

Registered Office: Unit No. 9A, 9th Floor, North Tower, Godrej One, Phoenix Nagar, Eastern Express Highway, Vikhroli East, Mumbai - 400 079 India. Telephone +91 22 33700600. Fax +91 22 33700654. Other Offices: Bengaluru, Corporate Identity number: U74985MH2015PTC264859

Page 1 of 7

Terms & Conditions

• Price : The price quoted is on F.O.R. Destination basis or such other term as agreed as per INCOTERM 2020. The prices of imported items are based on the exchange rate applicable on the date of offer. Unless frozen explicitly in writing the quoted prices are subject to price adjustment in Indian Rupees based on the exchange rate applicable on the date of filling the Bill of Entry. The price determined on the above basis would be the contract price. The prices do not include unloading charges at the site and demurrage charges, if any.

• Taxes : The Prices quoted for supplies of all goods and / or services offered are exclusive of applicable Goods and Services Tax (GST). Applicable GST would be determined based on the classification and characterization of the supplies under the GST law which would in-turn depends upon the Harmonized System of Nomenclature (HSN) and/or Service Accounting Codes of the respective supplies of goods and / or services effected under the Contract. Applicable GST based on current understanding of the scope of the supplies is indicated along with the offer price. This could undergo a change if the characterization and scope of supply as agreed finally is different from the one which is being offered currently.

Depending upon the place of supply and billing location, an Integrated GST or "Central GST plus respective State GST" be charged on the value of the supplies of goods and / or services. Siemens shall also deduct Tax Collection at Source (TCS) as per applicable law at the rate prescribed in the statute.

Purchaser agrees to pay or reimburse to the Supplier applicable GST as may be levied and any other taxes, duties, cess or imposts, as applicable at time of delivery.

Where ever applicable, the Purchaser will furnish its Road permits le-way bills in the prescribed forms under the provisions of State specific Goods and Services Tax Act for enabling smooth entry of goods into the State where delivery is to be affected. Until specific e-way bills are prescribed under State specific State GST Acts, the road permits as prescribed under the respective State VAT laws would continue to operate.

In case of change in the rates of any taxes, duties, levies or if new taxes, duties or levies are initiated by the Central / State Government / local bodies, including enactment of any legislation by Union/ State, then the same will be to the account of Purchaser and shall be reimbursed by Purchaser. Change in judicial interpretation and / or any clarification or amendment made by the relevant authorities shall be construed to be a change in the rate of taxes, duties, levies and / or imposition of new tax, duty or levy.

• Delivery, Title, Acceptance : Delivery of the instrument would be made within 4 to 8 weeks or earlier from the date of receipt of your confirmed order. Siemens will make commercially reasonable efforts to meet the delivery dates quoted or acknowledged but will not be liable for its failure to meet such dates. Siemens will make commercially reasonable efforts to meet the delivery dates quoted or acknowledged but will not be liable for its failure to meet such dates. The risk of destruction, loss or damage of the products shall be transferred to the Purchaser in accordance with the agreed INCOTERM. Upon the Purchaser making the complete payment to Siemens title to the Equipment shall pass to the Purchaser. Upon delivery of the Equipment at the Purchaser's facility the

Page 2 of 7

Suma Rabab
12/2/2021

Instrument, Logo, Pattern of Trade Name, Trade Marks or any other Intellectual Property Rights registered in the name of Siemens or used by Siemens in relation with the products or the goodwill associated therewith without the prior consent of Siemens.

Siemens may assign or extend this offer or contract concluded following acceptance of this offer in whole or in part and its rights and obligations hereunder to a Siemens' group company or any Siemens affiliates without any consent of the other party as a result of the sale of all or a substantial part of the assets or the business to which this offer or contract relates and/or in connection with any type of spin-off, (de)merger, consolidation, divestiture, dissolution or any other type of business combination or business reorganization. Furthermore, Siemens may have any obligation hereunder performed by a subcontractor without the prior written consent of the other party

The contract is concluded when the purchaser accepts Siemens' offer in writing without amendment. Insofar as acceptance is subject to alternative conditions of the purchaser, effective contract conclusion shall require a written order confirmation from Siemens. The scope, quality and all other conditions for the deliveries shall be determined exclusively by these concurring written declarations and the provisions of these General Conditions of Supply.

The contract shall come into existence only after Siemens's confirmation of purchaser's order and shall be construed and operated as Indian contract and in conformity with Indian Law and shall be subject to jurisdiction of courts in India. All correspondence & commitments between Siemens and the purchaser, to be enforceable at law, shall be in writing.

These General Conditions of Supply form an integral part of the offer and the offer shall be read and understood in conjunction with the General Conditions of Supply. The General Conditions of Supply shall be applicable and prevail, unless otherwise accepted by Siemens in writing.

Thanking you, Assuring our best services always,

Yours sincerely,

For Siemens Healthcare Pvt. Ltd.

Dharmendra Kumar
9212599677

Digital signed by Dharmendra Kumar
DN: cn=Dharmendra Kumar, o=Siemens,
email=Dharmendra.Kumar@siemens.com,
Date: 2024.02.04 10:21:16 +0530

For Siemens Healthcare Pvt. Ltd.

Ghosh Rajesh
Rajesh Ghosh
9734240870

Digital signed by Ghosh Rajesh
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email=Rajesh.Ghosh@siemens.com,
Date: 2024.02.04 10:15:37 +0530

Sumit Rajesh Ghosh
12/2/2024

25

47

Name: Dharmendra Kumar
Department: Sales
Mobile: +91 921 2599677
E-mail: Dharmendra.kumar@siemens-healthineers.com

Our reference: February 4, 2021
Date: 4th February, 2021

To
Dr. Suma Ahmad
Asst Professor,
Department of Anesthesia
AIIMS, Bhubaneswar, Orissa

Subject: Siemens FTD Respiratory Z1 Assay

Dear Sir,
Greetings from Siemens Healthcare Pvt Ltd.,

As required, please find herewith below quotation for FTD assay reagent kits,

Product Description & Catque No	SMN No	Pack Size	Unit price (INR)	Qty	Total Price (INR)
FTD Respiratory pathogens Z1 (RUQ) FTD-2-32-RUQ	11373927	32 reactions	103674	1	103674
			Special Discount		5808
			Value After Discount		97866
			GST@12%		11743
			Grand Total		109609

Suma Retabg
12/2/2021

Siemens Healthcare Private Limited

Unit No. 9A, Godrej One,
Vikhroli
Mumbai-400079
India

Tel.: +91 022-33700600
Fax: +91 022-33700654
Toll free: 1800-209-1800
Email: india@siemens-healthineers.com
www.siemens.co.in/healthcare

Registered Office: Unit No. 9A, 8th Floor, North Tower, Godrej One, Projehanagar, Eastern Express Highway, Vikhroli East, Mumbai - 400 079 India. Telephone +91 22 33700600, Fax +91 22 33700654. Other Offices: Bengaluru. Corporate Identity Number: U74999MH2015PTC264859

Terms & Conditions

• Price : The price quoted is on F.O.R. Destination basis or such other term as agreed as per INCOTERM 2020. The prices of imported items are based on the exchange rate applicable on the date of offer. Unless frozen explicitly in writing the quoted prices are subject to price adjustment in Indian Rupees based on the exchange rate applicable on the date of filing the Bill of Entry. The price determined on the above basis would be the contract price. The prices do not include unloading charges at the site and demurrage charges, if any.

• Taxes : The Prices quoted for supplies of all goods and / or services offered are exclusive of applicable Goods and Services Tax (GST). Applicable GST would be determined based on the classification and characterization of the supplies under the GST law which would in turn depends upon the Harmonized System of Nomenclature (HSN) and/or Service Accounting Codes of the respective supplies of goods and / or services effected under the Contract. Applicable GST based on current understanding of the scope of the supplies is indicated along with the offer price. This could undergo a change if the characterization and scope of supply as agreed finally is different from the one which is being offered currently.

Depending upon the place of supply and billing location, an Integrated GST or "Central GST plus respective State GST" be charged on the value of the supplies of goods and / or services. Siemens shall also deduct Tax Collection at Source (TCS) as per applicable law at the rate prescribed in the statute.

Purchaser agrees to pay or reimburse to the Supplier applicable GST as may be levied and any other taxes, duties, cess or imposts, as applicable at time of delivery.

Where ever applicable, the Purchaser will furnish its Road permits (e-way bills in the prescribed forms under the provisions of State specific Goods and Services Tax Act for enabling smooth entry of goods into the State where delivery is to be effected. Until specific e-way bills are prescribed under State specific State GST Acts, the road permits as prescribed under the respective State VAT laws would continue to operate.

In case of change in the rates of any taxes, duties, levies or if new taxes, duties or levies are initiated by the Central / State Government / local bodies, including enactment of any legislation by Union/ State, then the same will be to the account of Purchaser and shall be reimbursed by Purchaser. Change in judicial interpretation and / or any clarification or amendment made by the relevant authorities shall be construed to be a change in the rate of taxes, duties, levies and / or imposition of new tax, duty or levy.

• Delivery, Title, Acceptance : Delivery of the instrument would be made within 4 to 8 weeks or earlier from the date of receipt of your confirmed order. Siemens will make commercially reasonable efforts to meet the delivery dates quoted or acknowledged but will not be liable for its failure to meet such dates. Siemens will make commercially reasonable efforts to meet the delivery dates quoted or acknowledged but will not be liable for its failure to meet such dates. The risk of destruction, loss or damage of the products shall be transferred to the Purchaser in accordance with the agreed INCOTERM. Upon the Purchaser making the complete payment to Siemens title to the Equipment shall pass

Trade
Name/Intellect
ual Property

Instrument, Logo, Pattern of Trade Name, Trade Marks or any other Intellectual Property Rights registered in the name of Siemens or used by Siemens in relation with the products or the goodwill associated therewith without the prior consent of Siemens.

Subletting and
Assignment

Siemens may assign or extend this offer or contract concluded following acceptance of this offer in whole or in part and its rights and obligations hereunder to a Siemens' group company or any Siemens affiliates without any consent of the other party as a result of the sale of all or a substantial part of the assets or the business to which this offer or contract relates and/or in connection with any type of spin-off, (de)merger, consolidation, divestiture, dissolution or any other type of business combination or business reorganization. Furthermore, Siemens may have any obligation hereunder performed by a subcontractor without the prior written consent of the other party

Legal
Construction

The contract is concluded when the purchaser accepts Siemens' offer in writing without amendment. Insofar as acceptance is subject to alternative conditions of the purchaser, effective contract conclusion shall require a written order confirmation from Siemens. The scope, quality and all other conditions for the deliveries shall be determined exclusively by these concurring written declarations and the provisions of these General Conditions of Supply.

The contract shall come into existence only after Siemens's confirmation of purchaser's order and shall be construed and operated as Indian contract and in conformity with Indian Law and shall be subject to jurisdiction of courts in India. All correspondence & commitments between Siemens and the purchaser, to be enforceable at law, shall be in writing.

These General Conditions of Supply form an integral part of the offer and the offer shall be read and understood in conjunction with the General Conditions of Supply. The General Conditions of Supply shall be applicable and prevail, unless otherwise accepted by Siemens in writing.

Thanking you, Assuring our best services always,

Yours sincerely,

For Siemens Healthcare Pvt. Ltd.

Dharmendra
Kumar

Digitally signed by Dharmendra Kumar
DN: cn=Dharmendra Kumar, o=Siemens
Healthineers, email=Dharmendra.Kumar@siemens-healthineers.com
Date: 2023.02.24 12:21:41 +0530

For Siemens Healthcare Pvt. Ltd.

Ghosh
Rajesh

Digitally signed by Ghosh Rajesh
DN: cn=Ghosh Rajesh, o=Siemens
Healthineers, email=Ghosh.Rajesh@siemens-healthineers.com
Date: 2023.02.24 12:25:42 +0530

Dharmendra Kumar
9212599677

Rajesh Ghosh
9734240870

Syma Reddy
12/2/2024

Fast Track Diagnostics Luxembourg S.à r.l.
 29, Rue Henri Koch
 4354 Esch-sur-Alzette
 Luxembourg

Authorization No- GB/MAF/DX/1766
 Date-28.12.2020

Requesting Entity- Siemens Healthcare Private Limited
 9A, 9th Floor, North Tower, Godrej One,
 Pirojshahnagar, Eastern Express Highway, Vikhroli East,
 Mumbai – 400079

Manufacturer's Authorization

We, M/s. Fast Track Diagnostics, Luxembourg S.à r.l who are official manufacturers of FTD range of products (As per Annexure-1) having factories at 29, Rue Henri Koch, 4354 Esch-sur-Alzette, Luxembourg do hereby authorize Messrs Siemens Healthcare Private Limited having registered address at Unit No. 9A, 9th Floor, North Tower, Godrej One, Pirojshahnagar, Eastern Express Highway, Vikhroli East, Mumbai – 400079 India to import, promote, sell, participate in tenders and further authorize business partners for participation in bids for the above goods manufactured by us on its own name and account.

Siemens Healthcare Private Limited is authorized to participate in both public and private tenders on its own behalf for the supply of above mentioned products.

This certificate of authorization shall be valid for two years from the date of execution.

Yours Faithfully,



Thorsten Preiss, Director / CFO

For and on behalf of M/s. Fast Track Diagnostics, Luxembourg S.à r.l

Phone: +352 621 219 572
 Email: thorsten.preiss@siemens-healthineers.com

12 / 2 / 2024

Annexure-1

List of Products

Product Description	Catalogue No. RUO	SMN No. RUO
FTD Viral meningitis (RUO)	FTD-13-32-RUO	11373945
FTD Viral meningitis (RUO)	FTD-13-64-RUO	11373946
FTD Bacterial gastroenteritis (RUO)	FTD-14.1-32-RUO	11373947
FTD Bacterial gastroenteritis (RUO)	FTD-14.1-64-RUO	11373948
FTD Respiratory pathogens 21 (RUO)	FTD-2-32-RUO	11373927
FTD Respiratory pathogens 21 (RUO)	FTD-2-64-RUO	11373928
FTD Stool parasites (RUO)	FTD-20.1-32-RUO	11373957
FTD Stool parasites (RUO)	FTD-20.1-64-RUO	11373958
FTD Urethritis basic (RUO)	FTD-33.1-32-RUO	11373977
FTD Urethritis basic (RUO)	FTD-33.1-64-RUO	11373978
FTD Viral gastroenteritis (RUO)	FTD-3-32-RUO	11373929
FTD Viral gastroenteritis (RUO)	FTD-3-64-RUO	11373930
FTD FLU/HRSV (RUO)	FTD-48.1-32-RUO	11374003
FTD FLU/HRSV (RUO)	FTD-48.1-64-RUO	11374004
FTD Vesicular rash (RUO)	FTD-7-32-RUO	11373935
FTD Vesicular rash (RUO)	FTD-7-64-RUO	11373936
FTD ACE (RUO)	FTD-1.1-32-RUO	11373921
FTD ACE (RUO)	FTD-1.1-64-RUO	11373922
FTLy Respiratory pathogens 21 (RUO)	FTLy-2-32-H-RUO	11412043
FTLy Respiratory pathogens 21 (RUO)	FTLy-2-32-L-RUO	11412045
FTLy Respiratory pathogens 21 (RUO)	FTLy-2-64-H-RUO	11412044
FTLy Respiratory pathogens 21 (RUO)	FTLy-2-64-L-RUO	11412046
FTLy Respiratory pathogens 21 PLUS (RUO)	FTLy-2+.1-32-H-RUO	11412073
FTLy Respiratory pathogens 21	FTLy-2+.1-32-L-RUO	11412075

PLUS (RUO)		11412074
FTLyo Respiratory pathogens 21 PLUS (RUO)	FTIyo-2+1-64-H-RUO	11412074
FTLyo Respiratory pathogens 21 PLUS (RUO)	FTIyo-2+1-64-L-RUO	11412076
FTD Respiratory pathogens 21 PLUS (RUO)	FTD-2+1-32-RUO	11373923
FTD Respiratory pathogens 21 PLUS (RUO)	FTD-2+1-64-RUO	11373924
FTLyo Respiratory pathogens 33 (RUO)	FTIyo-2P.3-32-H-RUO	11412079
FTLyo Respiratory pathogens 33 (RUO)	FTIyo-2P.3-32-L-RUO	11412081
FTLyo Respiratory pathogens 33 (RUO)	FTIyo-2P.3-64-H-RUO	11412080
FTLyo Respiratory pathogens 33 (RUO)	FTIyo-2P.3-64-L-RUO	11412082
FTD Respiratory pathogens 33 (RUO)	FTD-2P.3-32-RUO	11373925
FTD Respiratory pathogens 33 (RUO)	FTD-2P.3-64-RUO	11373926
FTLyo Viral gastroenteritis (RUO)	FTIyo-3S-32-H-RUO	11412055
FTLyo Viral gastroenteritis (RUO)	FTIyo-3S-32-L-RUO	11412057
FTLyo Viral gastroenteritis (RUO)	FTIyo-3S-64-H-RUO	11412056
FTLyo Viral gastroenteritis (RUO)	FTIyo-3S-64-L-RUO	11412058
FTLyo Vesicular rash (RUO)	FTIyo-7-32-H-RUO	11412049
FTLyo Vesicular rash (RUO)	FTIyo-7-32-L-RUO	11412051
FTLyo Vesicular rash (RUO)	FTIyo-7-64-H-RUO	11412050
FTLyo Vesicular rash (RUO)	FTIyo-7-64-L-RUO	11412052
FTD Dermatophytes (RUO)	FTD-9.1-32-RUO	11373939
FTD Fever and rash (RUO)	FTD-9.1-64-RUO	11373940
FTD-10.2-32-RUO	FTD-10.2-32-RUO	11373941
FTD-10.2-64-RUO	FTD-10.2-64-RUO	11373942
FTD-12.1-32-RUO	FTD-12.1-32-RUO	11373943
FTD-12.1-64-RUO	FTD-12.1-64-RUO	11373944
FTLyo Viral meningitis (RUO)	FTIyo-13-32-H-RUO	11412061
FTLyo Viral meningitis (RUO)	FTIyo-13-32-L-RUO	11412063
FTLyo Viral meningitis (RUO)	FTIyo-13-64-H-RUO	11412062
FTLyo Viral meningitis (RUO)	FTIyo-13-64-L-RUO	11412064
FTLyo Bacterial gastroenteritis (RUO)	FTIyo-14.1-32-H-RUO	11412007
FTLyo Bacterial gastroenteritis (RUO)	FTIyo-14.1-32-L-RUO	11412009

FTLyo Bacterial gastroenteritis (RUO)	FTIyo-14.1-64-H-RUO	11412008
FTLyo Bacterial gastroenteritis (RUO)	FTIyo-14.1-64-L-RUO	11412010
FTD Eye (RUO)	FTD-15.1-32-RUO	11373949
FTD Eye (RUO)	FTD-15.1-64-RUO	11373950
FTD Gonorrhoeae confirmation (RUO)	FTD-17-32-RUO	11373953
FTD Gonorrhoeae confirmation (RUO)	FTD-17-64-RUO	11373954
FTD Genital ulcer (RUO)	FTD-19-32-RUO	11373955
FTD Genital ulcer (RUO)	FTD-19-64-RUO	11373956
FTLyo Flu (RUO)	FTIyo-21.1-32-H-RUO	11414111
FTLyo Flu (RUO)	FTIyo-21.1-32-L-RUO	11414113
FTLyo Flu (RUO)	FTIyo-21.1-64-H-RUO	11414112
FTLyo Flu (RUO)	FTIyo-21.1-64-L-RUO	11414114
FTD Flu (RUO)	FTD-21.1-32-RUO	11373959
FTD Flu (RUO)	FTD-21.1-64-RUO	11373960
FTLyo EPA (RUO)	FTIyo-23-32-H-RUO	11412019
FTLyo EPA (RUO)	FTIyo-23-32-L-RUO	11412021
FTLyo EPA (RUO)	FTIyo-23-64-H-RUO	11412020
FTLyo EPA (RUO)	FTIyo-23-64-L-RUO	11412022
FTD EPA (RUO)	FTD-23-32-RUO	11373961
FTD EPA (RUO)	FTD-23-64-RUO	11373962
FTD Pneumocystis jirovecii (RUO)	FTD-27-32-RUO	11373965
FTD Pneumocystis jirovecii (RUO)	FTD-27-64-RUO	11373966
FTLyo Bacterial meningitis (RUO)	FTIyo-28-32-H-RUO	11412013
FTLyo Bacterial meningitis (RUO)	FTIyo-28-32-L-RUO	11412015
FTLyo Bacterial meningitis (RUO)	FTIyo-28-64-H-RUO	11412014
FTLyo Bacterial meningitis (RUO)	FTIyo-28-64-L-RUO	11412016
FTD Bacterial meningitis (RUO)	FTD-28-32-RUO	11373967
FTD Bacterial meningitis (RUO)	FTD-28-64-RUO	11373968
FTD Bacterial pneumonia CAP (RUO)	FTD-29.1-32-RUO	11373969
FTD Bacterial pneumonia CAP (RUO)	FTD-29.1-64-RUO	11373970
FTD Bordetella (RUO)	FTD-31.1-32-RUO	11373973
FTD Bordetella (RUO)	FTD-31.1-64-RUO	11373974
FTLyo Urethritis basic (RUO)	FTIyo-33.1-32-H-RUO	11412181
FTLyo Urethritis basic (RUO)	FTIyo-33.1-32-L-RUO	11412183
FTLyo Urethritis basic (RUO)	FTIyo-33.1-64-H-RUO	11412182
FTLyo Urethritis basic (RUO)	FTIyo-33.1-64-L-RUO	11412184

Luma Rabab Ghomdi
13/2/2021

FTLyO Enteric Fever (RUO)	FTLyO-33.1-64-L-RUO	11412193
FTLyO Enteric Fever (RUO)	FTLyO-35-32-L-RUO	11412195
FTLyO Enteric Fever (RUO)	FTLyO-35-64-H-RUO	11412194
FTLyO Enteric Fever (RUO)	FTLyO-35-64-L-RUO	11412196
FTD Tropical fever core (RUO)	FTD-36-32-RUO	11373983
FTD Tropical fever core (RUO)	FTD-36-64-RUO	11373984
FTD Malaria differentiation (RUO)	FTD-40-32-RUO	11373991
FTD Malaria differentiation (RUO)	FTD-40-64-RUO	11373992
FTD Urethritis plus (RUO)	FTD-42.1-32-RUO	11373993
FTD Urethritis plus (RUO)	FTD-42.1-64-RUO	11373994
FTD Dengue/Chik (RUO)	FTD-43-32-RUO	11373995
FTD Dengue/Chik (RUO)	FTD-43-64-RUO	11373996
FTD Dengue differentiation (RUO)	FTD-44-32-RUO	11373997
FTD Dengue differentiation (RUO)	FTD-44-64-RUO	11373998
FTD Measles (RUO)	FTD-46-32-RUO	11374001
FTD Measles (RUO)	FTD-46-64-RUO	11374002
FTLyO Flu/HRSV (RUO)	FTLyO-48.1-32-H-RUO	11412025
FTLyO Flu/HRSV (RUO)	FTLyO-48.1-32-L-RUO	11412027
FTLyO Flu/HRSV (RUO)	FTLyO-48.1-64-H-RUO	11412026
FTLyO Flu/HRSV (RUO)	FTLyO-48.1-64-L-RUO	11412028
FTLyO Mers-CoV (RUO)	FTLyO-50.1-32-H-RUO	11412031
FTLyO Mers-CoV (RUO)	FTLyO-50.1-32-L-RUO	11412033
FTLyO Mers-CoV (RUO)	FTLyO-50.1-64-H-RUO	11412032
FTLyO Mers-CoV (RUO)	FTLyO-50.1-64-L-RUO	11412034
FTD Mers-CoV (RUO)	FTD-50.1-32-RUO	11374005
FTD Mers-CoV (RUO)	FTD-50.1-64-RUO	11374006
FTD STD9 (RUO)	FTD-52.1-32-RUO	11374007
FTD STD9 (RUO)	FTD-52.1-64-RUO	11374008
FTD Atypical CAP (RUO)	FTD-53.1-32-RUO	11374009
FTD Atypical CAP (RUO)	FTD-53.1-64-RUO	11374010
FTD BKV (RUO)	FTD-55.1-32-RUO	11374013
FTD BKV (RUO)	FTD-55.1-64-RUO	11374014
FTD hCoV (RUO)	FTD-56.1-32-RUO	11374015
FTD hCoV (RUO)	FTD-56.1-64-RUO	11374016
FTD EAV (RUO)	FTD-57-32-RUO	11374017
FTD EAV (RUO)	FTD-57-64-RUO	11374018
FTD Neuro 9 (RUO)	FTD-60.4-32-RUO	11374019
FTD Neuro 9 (RUO)	FTD-60.4-64-RUO	11374020
FTD Flu differentiation (RUO)	FTD-62-32-RUO	11374021
FTD Flu differentiation (RUO)	FTD-62-64-RUO	11374022

FTD Hepatitis E (RUO)	FTD-67.1-32-RUO	11374029
FTD Hepatitis E (RUO)	FTD-67.1-64-RUO	11374030
Fast-track mastermix - 100 reactions (RUO)	FTD-70-100	10921810
FTD Zika / Dengue / Chik (RUO)	FTD-84-32-RUO	11374049
FTD Zika / Dengue / Chik (RUO)	FTD-84-64-RUO	11374050

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1. Identification of the manufacturer

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2. Identification of the product

FTD Atypical CAP (RUO)

Category: Multiplex Real-Time PCR reagents to identify *Legionella pneumophila*/*Legionella longbeachae*, *Chlamydomonas pneumoniae* and *Mycoplasma pneumoniae*.

Reference: 32 reactions: FTD-53.1-32-RUO (SMN: 11374009); 64 reactions: FTD-53.1-64-RUO (SMN: 11374010)

Indication: Research use only (RUO). Not for use in diagnostic procedures.

3. General information

FTD Atypical CAP (RUO) contains reagents to identify *Legionella pneumophila* / *Legionella longbeachae*, *Chlamydomonas pneumoniae*, *Mycoplasma pneumoniae* and *Streptococcus equi* which serves as an internal control (IC).

Table 1: FTD Atypical CAP (RUO) components (PP = primer and probe, IC = internal control, PC = positive control, NC = negative control).

Components	Contents	FTD-53.1-32-RUO	FTD-53.1-64-RUO
		SMN: 11374009	SMN: 11374010
CAP2 PP	Primer/Probe mix for <i>L. pneumophila</i> / <i>longbeachae</i> , <i>M. pneumoniae</i> , <i>C. pneumoniae</i> & IC (<i>S. equi</i>)	1 x 48 µl	2 x 48 µl
CAP2 PC	Positive control (plasmid pool) for the identification of <i>L. pneumophila</i> / <i>longbeachae</i> , <i>M. pneumoniae</i> & <i>C. pneumoniae</i>	1 x 150 µl	2 x 150 µl
NC	Negative control	1 x 2000 µl	1 x 4000 µl
IC	Internal control	1 x 128 µl	2 x 128 µl
Enzyme	25x RT-PCR Enzyme mix (Fast-track mastermix)	1 x 32 µl	2 x 32 µl
Buffer	2x RT-PCR Buffer (Fast-track mastermix)	1 x 400 µl	2 x 400 µl

The box itself and each vial are labeled with the lot number.

4. Principle of the method

Targeted RNA is reverse transcribed into cDNA during the reverse transcription step. The different targeted DNA molecules are then amplified simultaneously in the same tube by real-time PCR. The presence of specific sequences is detected by an increase in fluorescence observed from the relevant dual-labelled probe.

5. Procedure overview

Nucleic acid extraction

Use extraction methods that yield high quality and inhibitor-free purified nucleic acids. To be used with all the PP mixes, the eluate must have a minimum volume of 10 µl.

Add 2 µl of IC (per 55 µl elution volume) directly to your sample and the NC after the lysis stage of the extraction process. Do not extract the PC.

PCR setup

- > To prepare a PCR master mix for one reaction, mix: 1.5 µl PP + 1 µl Enzyme + 12.5 µl Buffer.
- > Aliquot 15 µl of PCR master mix in each well of a PCR plate compatible with the PCR cycle that will be used
- > Add 10 µl of PC or of the extracted NC or of extracted samples to the aliquoted PCR master mix.

For the recommended settings for real-time PCR instruments refer to Table 2.

Table 2: Recommended settings for real-time PCR instruments.

PP Mix and Thermocycler Detection Settings			
	Master Mix	Dye	Detection Wave Length (nm) ^[a]
	CAP2		
Pathogen	<i>L. pneumophila/longbeachae</i>	green	520
	<i>C. pneumoniae</i>	yellow	550
	IC (<i>S. equi</i>)	orange	610
	<i>M. pneumoniae</i>	red	670

^[a] Excitation wavelengths listed are from Applied Biosystems® 7500 Real-Time PCR System. Wavelengths may vary for other Real-Time PCR Systems.

- > Run the PCR program (refer to Table 3)

Table 3: Recommended PCR program.

Stage	Cycles	Acquisition	Temperature	Time
Hold	/	/	50°C	15 minutes
Hold	/	/	94°C	1 minute
Cycling	40	/	94°C	8 seconds
		Yes	60°C	1 minute

Detailed information on programming of the real-time PCR instrument can be found in the instruction manual provided by the manufacturer of the machine.

6. Precautions and warnings

6.1 Safety Information

Warning notice: the internal control contains lysis buffer.

Hazardous pictogram:



Signal word: Warning

Hazardous statements:

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

Precautionary statements:

Prevention:

P280: Wear protective gloves/protective clothing/eye protection/face protection.

6.2 Handling requirements

Use of this product should be limited to personnel trained in the techniques of PCR. Take the normal precautions required for handling all laboratory reagents. Do not mix reagents from different lots. Do not use the product after its expiration date.

6.3 Safe waste disposal

Dispose of unused reagents and waste in accordance with country, state or local regulations.

7. Storage and stability conditions

The components of the FTD product should be stored in the original packaging between -30°C and -10°C and are stable until the expiration date stated on the label. Freeze the product immediately after use.

Note: Avoid repeated freeze/thaw of reagents.

FTD 53.1 - 32_64 - PACKAGE INSERT - RUO - v2 - 2019_03 EN

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1. Identification of the manufacturer

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2. Identification of the product

FTD Respiratory pathogens 21 (RUO)

Category: Multiplex Real-Time PCR reagents to identify respiratory pathogens.

Reference: 32 reactions: FTD-2-32-RUO (SMN: 11373927); 64 reactions: FTD-2-64-RUO (SMN: 11373928)

Indication: Research use only (RUO). Not for use in diagnostic procedures.

3. General information

FTD Respiratory pathogens 21 (RUO) contains reagents to identify influenza A virus (IAV), influenza A(H1N1) virus (swine lineage) (IAV(H1N1) swl), influenza B virus (IBV), human coronaviruses (HCoV) NL63, 229E, OC43 and HKU1, human parainfluenza viruses (HPIV) 1, 2, 3 and 4, human metapneumoviruses (HMPV) A and B, human rhinovirus (HRV), human respiratory syncytial viruses (HRSV) A and B, human adenovirus (HAdV), enterovirus (EV), human parechovirus (HPeV), human bocavirus (HBoV), *Mycoplasma pneumoniae* and equine arteritis virus (EAV) which serves as an internal control (IC).

Table 1: FTD Respiratory pathogens 21 (RUO) components (PP = primer and probe, IC = internal control, PC = positive control, NC = negative control).

Components	Contents	FTD-2-32-RUO	FTD-2-64-RUO
		SMN: 11373927	SMN: 11373928
1. FluRhino PP	Primer/probe mix for IAV, IBV, IAV(H1N1) swl & HRV	1 x 48 µl	2 x 48 µl
2. COR PP	Primer/probe mix for HCoV OC43, HCoV NL63, HCoV 229E & HCoV HKU1	1 x 48 µl	2 x 48 µl
3. ParaEAV PP	Primer/probe mix for HPIV-2, HPIV-3, HPIV-4 & IC (EAV)	1 x 48 µl	2 x 48 µl
4. BoMpPf1 PP	Primer/probe mix for HBoV, <i>M. pneumoniae</i> , HPIV-1 & HMPV A and B	1 x 48 µl	2 x 48 µl
5. RsEPA PP	Primer/probe mix for HRSV A and B, HAdV, EV & HPeV	1 x 48 µl	2 x 48 µl
Resp21 PC	Positive control (plasmid pool) for the identification of IAV, IBV, IAV(H1N1) swl, HRV, HCoV NL63, HCoV 229E, HCoV OC43, HCoV HKU1, HPIV-1-4, HMPV, HBoV, <i>M. pneumoniae</i> , HRSV, HAdV, EV & HPeV. To be used with PPmixes 1-5.	1 x 750 µl	2 x 750 µl
NC	Negative control	1 x 2000 µl	1 x 4000 µl
IC	Internal control	1 x 128 µl	2 x 128 µl
Enzyme	25x RT-PCR Enzyme mix (Fast-track mastermix)	1 x 160 µl	2 x 160 µl
Buffer	2x RT-PCR Buffer (Fast-track mastermix)	2 x 1000 µl	4 x 1000 µl

The box itself and each vial are labeled with the lot number.

4. Principle of the method

Targeted RNA is reverse transcribed into cDNA during the reverse transcription step. The different targeted DNA molecules are then amplified simultaneously in the same tube by real-time PCR. The presence of specific sequences is detected by an increase in fluorescence observed from the relevant dual-labelled probe.

5. Procedure overview

Nucleic acid extraction

Use extraction methods that yield high quality and inhibitor-free purified nucleic acids. A minimum of 50 µl of eluate is required to measure all pathogens.

Add 2 µl of IC (per 55 µl elution volume) directly to your sample and the NC after the lysis stage of the extraction process. Do not extract the PC.

- > To prepare a PCR master mix for one reaction, mix: 1.5 µl PP + 1 µl Enzyme + 12.5 µl Buffer.
- > Aliquot 15 µl of PCR master mix in each well of a PCR plate compatible with the PCR cycle that will be used
- > Add 10 µl of PC or of the extracted NC or of extracted samples to the aliquoted PCR master mix.

For the recommended settings for real-time PCR instruments refer to Table 2.

Table 2: Recommended settings for real-time PCR instruments.

PP Mix and Thermocycler Detection Settings						
	Master Mix					Dye
	FluRhino	COR	ParaEAV	BoMpPf1	RaEPA	
Pathogen	IAV	HCoV 229E	HPIV-3	HPIV-1	HRSV A and B	green
	HRV	HCoV NL63	HPIV-2	HMPV A and B	HPeV	yellow
	IBV	HCoV HKU1	HPIV-4	HBoV	EV	orange
	IAV(H1N1)swl	HCoV OC43	IC (EAV)	<i>M. pneumoniae</i>	HAdV	red

^[a] Excitation wavelengths listed are from Applied Biosystems® 7500 Real-Time PCR System. Wavelengths may vary for other Real-Time PCR Systems.

- > Run the PCR program (refer to Table 3)

Table 3: Recommended PCR program.

Stage	Cycles	Acquisition	Temperature	Time
Hold	/	/	50°C	15 minutes
Hold	/	/	94°C	1 minute
Cycling	40	/	94°C	8 seconds
		Yes	60°C	1 minute

Detailed information on programming of the real-time PCR instrument can be found in the instruction manual provided by the manufacturer of the machine.

6. Precautions and warnings

6.1 Safety information

Safety data sheets (SDS) are available at <https://www.siemens-healthineers.com/sds>.



FTD SARS-CoV-2 IC contains lysis buffer.

Hazardous ingredient: maleic acid (0.1% [w/w])

H317: May cause an allergic skin reaction.

WARNING

P280: Wear protective gloves/ protective clothing/ eye protection/ face protection.

P302+P352: IF ON SKIN: Wash with plenty of soap and water.

P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

P362+P364: Take off contaminated clothing and wash it before reuse.

6.2 Handling requirements

Use of this product should be limited to personnel trained in the techniques of PCR. Take the normal precautions required for handling all laboratory reagents. Do not mix reagents from different lots. Do not use the product after its expiration date.

6.3 Safe waste disposal

Dispose of unused reagents and waste in accordance with country, state or local regulations.

7. Storage and stability conditions

The components of the FTD product should be stored in the original packaging between -30°C and -10°C and are stable until the expiration date stated on the label. Freeze the product immediately after use.

Note: Repeated freeze/thaw of reagents may reduce sensitivity.