



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

Reference No: AIIMS/BBSR/Peds/2019/BD-3

Dated: 23/03/2021

Sub: Procurement of FTD Neuro 9(RUO) FTD-60.4-64-RUO[Make: Fast Track] for the Department of Pediatric (Project) at AIIMS, BBSR on Proprietary basis - **Inviting Comments thereon.**

The Department of Pediatric of AIIMS, Bhubaneswar has requested for Procurement of FTD Neuro 9(RUO) [Make: Fast Track] from there 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.rnpattnaik@aiimsbhubaneswar.edu.in & jao_nivedita@aiimsbhubaneswar.edu.in so as to reach on or before **date: 01-04-2021** 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.– **AIIMS/BBSR/Peds/2019/BD-3** dt: 23-03-2021, due on dated: 01-04-2021 should be superscripted on sealed envelope.

Enclosure:

1. Proprietary Article Certificate from Indenting Officer of Department of Pediatric (project), AIIMS, Bhubaneswar. **Annexure-I**
2. PAC of M/s Fast Track Diagnostics, Luxembourg for FTD Neuro 9(RUO) FTD-60.4-64-RUO [Make: Fast Track] **Annexure-II**
3. Latest Price Quotation of FTD Neuro 9(RUO) FTD-60.4-64-RUO [Make: Fast Track] **Annexure-III**
4. OEM Authorization Certificate **Annexure-IV**
5. Brochure & Literature **Annexure-V**

Copy to: -

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

Sr. Procurement-cum-Stores Officer

AIIMS, BHUBANESWAR

Proprietary Article Certificate
Valid for the Current Financial Year

File No. and Date Reference :		
1	Description of article	FTD Neuro-9 kit.
2	Forecast of quantity /annual requirement	2X64
3	Approximate estimated value for above quantity	2,98,025/-
4	Maker's name and address	Fast track diagnostic, Luxembourg
5	Name(s) of authorized dealers/ stockists	Siemens Healthcare Pvt. Ltd., Mumbai
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	✓
6 (b)	A Similar article is not manufactured / sold by any other firm, which could be used in lieu OR	✓
6 (c-1)	No other make/brand will be suitable for following tangible reasons (like OEM/ Warranty, spares.): OR Multiple Neuro-9 kit only available, standardized from FTD	
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.)
858/(19-20) 29.01.20	03	73,118 (Each)

Signature of the Indenting Officer

Signature of Approving Authority.....

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

Dr. Bhagirathi Dwivedi
Additional Professor
Department of Paediatric
AIIMS Bhubaneswar Odisha

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

Dr. Bhagirathi Dwivedi
Additional Professor
Department of Paediatric
AIIMS, Bhubaneswar Odisha

To
Dr. Bhagirathi Dwibedi,
All India Institute of Medical Sciences,
Bhubaneswar
Odisha

Name Subhash Nandi
Department Sales
E Mail : subhash.nandi@siemens-healthineers.com
Our reference KRO/Q/21/220221
Date .01-03-2021

Sub:- **Siemens FTD Reagents Quotation**

Dear Sir,

We are pleased to quote our Products against items referred above. The quotation is submitted as follows along with the commercial terms of supply.

Product Description	Part Number	SAP Code	Pack	Value
FTD Neuro 9 (RUO)	FTD-60.4-64-RUO	11374020	64 Rxn	1,41,916.71

Commercial terms of supply :-

PRICE : Price quoted are F.O.R. destination basis.
TAX : GST 5% will be charged extra at the time of supply.
DELIVERY : Within 2/3 weeks upon receipt of your firm order, the goods will be delivered
Packing & Forwarding : Inclusive
PAYMENT : To be made against order
VALIDITY : Products quoted above are valid up to 21-03-2021

Thanking you once again for your valued order and assuring our best services at all times.

Yours faithfully,
For **Siemens Healthcare Pvt. Ltd.,**

Nandi
Subhash
Subhash Nandi
Manager Sales Support – East

Digitally signed by
Nandi Subhash
Date: 2021.03.01
17:51:29 +05'30'

c.c.to:-Mr.R.Banerjee/Mr.R.Ghosh/Mr.K.Sahoo/Mr.C.Bose/Mr.D.Kumar/Mr.M.Khan

Unrestricted

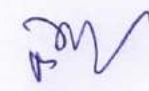
Siemens Healthcare Pvt. Ltd.

43, Shantipally, ,
R.B.Connector, Kolkata-700 042
West Bengal India

Tel: +91 33 24449010
Fax: +91 33 24449000
Email: hc_contact.india@siemens.com
www.siemens.co.in/healthcare

Registered Office: No. Unit.9A, 9th Floor, North Tower, Godrej One, Pirojshanagar, Eastern Express Highway, Vikhroli East, Mumbai – 400 079
Sales Office: Ahmedabad, Bangalore, Chandigarh, Chennai, Coimbatore, Hyderabad, Kharghar, Kolkata, Lucknow, Mumbai, Nagpur, New Delhi, Pune, Vadodara.

Dr. Bhagirathi Dwibedi
Additional Professor
Department of Paediatric
AIIMS, Bhubaneswar, Odisha



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

Manufacturer's Authorization

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

We, M/s. Fast Track Diagnostics, Luxembourg S.a.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.a.r.l

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



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



FTLyo Bacterial gastroenteritis (RUO)	FTlyo-14.1-64-H-RUO	11412008
FTLyo Bacterial gastroenteritis (RUO)	FTlyo-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)	FTlyo-21.1-32-H-RUO	11414111
FTLyo Flu (RUO)	FTlyo-21.1-32-L-RUO	11414113
FTLyo Flu (RUO)	FTlyo-21.1-64-H-RUO	11414112
FTLyo Flu (RUO)	FTlyo-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)	FTlyo-23-32-H-RUO	11412019
FTLyo EPA (RUO)	FTlyo-23-32-L-RUO	11412021
FTLyo EPA (RUO)	FTlyo-23-64-H-RUO	11412020
FTLyo EPA (RUO)	FTlyo-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)	FTlyo-28-32-H-RUO	11412013
FTLyo Bacterial meningitis (RUO)	FTlyo-28-32-L-RUO	11412015
FTLyo Bacterial meningitis (RUO)	FTlyo-28-64-H-RUO	11412014
FTLyo Bacterial meningitis (RUO)	FTlyo-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)	FTlyo-33.1-32-H-RUO	11412181
FTLyo Urethritis basic (RUO)	FTlyo-33.1-32-L-RUO	11412183
FTLyo Urethritis basic (RUO)	FTlyo-33.1-64-H-RUO	11412182
FTLyo Urethritis basic (RUO)	FTlyo-33.1-64-L-RUO	11412184

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

1. Identification of the manufacturer

Fast Track Diagnostics Luxembourg SARL
29, rue Henri Koch
L-4354 Esch-sur-Alzette
Tel.: +352 281098-1
Fax: +352 281098-214
info@ftd-ltd.com

2. Identification of the product

FTD Neuro9 (RUO)

Category: Multiplex Real-Time PCR reagents to identify pathogens causing meningitis.
Reference: 32 reactions: FTD-60.4-32-RUO (SMN: 11374019); 64 reactions: FTD-60.4-64-RUO (SMN: 11374020)
Indication: Research use only (RUO). Not for use in diagnostic procedures.

3. General information

FTD Neuro9 (RUO) contains reagents to identify human adenovirus (HAdV), human cytomegalovirus (HCMV), Epstein-Barr virus (EBV), herpes simplex viruses (HSV) 1 & 2, varicella zoster virus (VZV), enterovirus (EV), human parechovirus (HpeV), human herpesviruses (HHV) 6 and 7, human parvovirus B19 (B19V), brome mosaic virus (BMV) and murine cytomegalovirus (MCMV) which both serve as an internal control (IC).

Table 1: FTD Neuro9 (RUO) components (PP = primer and probe, IC = internal control, PC = positive control, NC = negative control).

Components		Contents	FTD-60.4-32-RUO SMN: 11374019	FTD-60.4-64-RUO SMN: 11374020
1	ACE PP	Primer/probe mix for HAdV, HCMV, EBV & IC (MCMV)	1 x 48 µl	2 x 48 µl
2	Vesic PP	Primer/probe mix for HSV-1, HSV-2, VZV & IC (MCMV)	1 x 48 µl	2 x 48 µl
3	EPA PP	Primer/probe mix for EV, HPeV & IC (BMV)	1 x 48 µl	2 x 48 µl
4	HHV/B19 PP	Primer/probe mix for HHV-6, HHV-7 & B19V	1 x 48 µl	2 x 48 µl
NEU PC1		Positive control (plasmid pool) for the identification of HAdV, HCMV & EBV. To be used with PPmix 1.	1 x 150 µl	2 x 150 µl
NEU PC2		Positive control (plasmid pool) for the identification of HSV-1, HSV-2, VZV, EV, HPeV, HHV-6, HHV-7 & B19V. To be used with PPmixes 2-4.	1 x 450 µl	2 x 450 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 128 µl	2 x 128 µl
Buffer		2x RT-PCR Buffer (Fast-track mastermix)	1 x 1600 µl	2 x 1600 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 40 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.

Fast Track

DIAGNOSTICS

A Siemens Healthineers Company

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 cycler 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						
Pathogen	Master Mix				Dye	Detection Wave Length (nm) ^(a)
	ACE	Vesic	EPA	HHV/B19		
	EBV	HSV-1	EV	HHV-6	green	520
	HCMV	HSV-2	HPeV	/	yellow	550
	IC (MCMV)	IC (MCMV)	IC (BMV)	B19V	orange	610
	HAdV	VZV	/	HHV-7	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. 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.