

Appendix 1

**National Microbiology Framework Agreement
Order Form C163954
Hologic Laboratories Limited**

FROM

Authority:	UK Health Security Agency (the "Authority").
Invoice address:	Post: UKHSA Accounts Payable Team Manor Farm Road Porton Down Salisbury SP4 0JG United Kingdom E-mail: [REDACTED]
Contract Manager:	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
Secondary Contact: eg. business operational contact, project manager	N/A
Procurement lead	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
Name and address for notices:	Name: [REDACTED] Address: UK Health Security Agency Nobel House 17 Smith Square London SW1P 3HX
Internal reference (if applicable):	To be quoted on all correspondence relating to this Order Form: Contract Code: C163954

TO

Supplier:	Hologic Limited Heron House Oaks Business Park Crewe Road Wythenshawe
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National Microbiology Framework Schedule 7 - Ordering Procedure, Award Criteria and Order Form

	Manchester M23 9HZ Company Number: 02722343
Contract Manager:	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
Secondary Contact:	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
Account Manager:	Name: [REDACTED] Phone: [REDACTED] E-mail: [REDACTED]
Name and address for notices:	Name: [REDACTED] Address: Hologic Limited Heron House Oaks Business Park Crewe Road Wythenshawe Manchester M23 9HZ

Applicable terms and conditions

The following terms and conditions are applicable to the Contract for this Order:

Appendix A	Call-off Terms and Conditions for the Supply of Goods and the Provision of Services	Applicable to this Contract
Appendix B	Optional Additional Call-off Terms and Conditions for Installation and Commissioning Services	<input type="checkbox"/> (only applicable if this box is checked)
Appendix C	Optional Additional Call-off Terms and Conditions for Maintenance Services	<input type="checkbox"/> (only applicable if this box is checked)
Appendix D	Optional Additional Call-off Terms and Conditions for Bespoke Research, Development and Manufacturing Requirements	<input type="checkbox"/> (only applicable if this box is checked and to the extent the applicable terms are included in Annex A (Order Specific Key Provisions))
Appendix E	Optional Additional Call-off Terms and Conditions for Reagent Rental	<input type="checkbox"/> (only applicable if this box is checked)

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Appendix F	Optional Additional Call-off Terms and Conditions for Managed Equipment Services	<input type="checkbox"/> (only applicable if this box is checked)
Appendix G	Optional Additional Call-off Terms and Conditions for Clinical Laboratory Diagnostic Testing Services	<input type="checkbox"/> (only applicable if this box is checked and to the extent the applicable terms are included in Annex A (Order Specific Key Provisions))
Appendix H	<p>Further Optional Additional Call-off Terms and Conditions</p> <p>Each of the following clauses in Appendix H is only applicable to this Contract if the relevant box is checked:</p>	(only applicable if one or more boxes are checked)
	1. TUPE applies at the commencement of the provision of Services	<input type="checkbox"/>
	2. TUPE on exit	<input type="checkbox"/>
	3. Different levels and/or types of insurance	<input type="checkbox"/>
	4. Induction training for Services	<input type="checkbox"/>
	5. Further Authority obligations	<input type="checkbox"/>
	6. Assignment of Intellectual Property Rights in deliverables, materials and outputs of the Services	<input type="checkbox"/>
	7. Inclusion of a Change Control Process	<input type="checkbox"/>
	8. Authority step-in rights	<input type="checkbox"/>
	9. Guarantee	<input type="checkbox"/>
	10. Termination for convenience	<input checked="" type="checkbox"/>
	11. Pre-Acquisition Questionnaire	<input type="checkbox"/>
	12. Time of the essence (Goods)	<input type="checkbox"/>
	13. Time of the essence (Services)	<input type="checkbox"/>
	14. Specific time periods for inspection	<input type="checkbox"/>
	15. Specific time periods for rights and remedies under Clause 3.6 of Schedule 2 of Appendix A	<input type="checkbox"/>
	16. Right to terminate following a specified number of material breaches	<input type="checkbox"/>
	17. Expert Determination	<input checked="" type="checkbox"/>
	18. Consigned Goods	<input type="checkbox"/>

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	19. Improving visibility of Sub-contract opportunities available to Small and Medium Size Enterprises and Voluntary, Community and Social Enterprises	<input type="checkbox"/>	
	20. Management Charges and Information	<input type="checkbox"/>	
	21. COVID-19 related enhanced business continuity provisions	<input type="checkbox"/>	
	22. Buffer stock requirements	<input type="checkbox"/>	
	23. Modern slavery	<input checked="" type="checkbox"/>	
The additional Order Specific Key Provisions set out at Annex A (Order Specific Key Provisions) to this Order Form shall also apply to this Contract.			<input checked="" type="checkbox"/> (only applicable if this box is checked)

1. CONTRACT DETAILS
<p>(1.1) Commencement Date: The date this Order Form is signed by both Parties (the Authority and the Supplier).</p>
<p>(1.2) Services Commencement Date (if applicable): N/A</p>
<p>(1.3) Contract Price ((i) breakdown and (ii) payment profile):</p> <p>1.3.1. The maximum value of this Contract shall be eight million, three hundred thousand pound and zero pence (£8,300,000) (the “Contract Price”).</p> <p>1.3.2. For the avoidance of doubt, the Authority is not committed to pay the full Contract Price.</p> <p>1.3.3. The Contract Price excludes VAT at the applicable rate</p> <p>1.3.4. Only orders placed directly by the Authority are binding under this Contract (“POs”).</p> <p>1.3.5. See Appendix 1 - Goods Information and Pricing for the breakdown of pricing.</p> <p>1.3.6. Payment terms are net 30 days in arrears from the date the Authority receives valid invoices in accordance with this Contract.</p> <p>1.3.7. POs issued by the Authority in respect of this Agreement do not form part of this Agreement.</p>
<p>(1.4) Term of Contract:</p> <p>1.4.1. This Contract shall commence on the date the Order Form is signed by both Parties (the “Commencement Date”) and shall, unless terminated earlier, or extended, in accordance with its terms, expire on 31 March 2024 (the “Term”).</p> <p>1.4.2. The Authority may terminate the Contract for convenience at any time pursuant to Clause 10 (Termination for convenience) of Appendix H (Further Optional Additional Call-off Terms and Conditions) of this Contract provided the Authority gives the Supplier no less than 3 (three) months written notice.</p>
<p>(1.5) Term extension options:</p> <p>1.5.1. The Authority, at its sole discretion, shall be able to extend this Contract for 1 (one) period of up to 12 (twelve) months, (the “Extension Period”), in accordance with Clause 15.2 of the Call Off Terms and Conditions.</p> <p>1.5.2. The Authority may request a quote for the Extension Period as early as 30th November 2023.</p>

2. GOODS AND/OR SERVICES REQUIREMENTS**(2.1) Description of the Goods / Services:**

2.1.1. The Supplier shall provide and deliver to the Authority Panther reagents and consumables as listed in Appendix 1 – Goods Information and Pricing (the “**Goods**”).

(2.2) Premises and Location(s) at which the Goods / Services are to be delivered / provided:

2.2.1. The Supplier shall deliver the Goods to the sites detailed in Appendix 2 – Premises and Locations (“**Premises and Locations**”) or such other location as the Authority reasonably specifies from time to time.

2.2.2. The Supplier shall ensure that all Goods are labelled with product description, part number, volume, batch number, storage requirements and barcode.

2.2.3. All planned deliveries shall be pre-advised by the Supplier to the Authority's primary delivery contact stated below (individually or collectively be known as the “**Delivery Contact**” at least 2 (two) Business Days prior to attendance.

2.2.4. Delivery Contact: Detailed by site in Appendix 2.

2.2.5. The Supplier shall provide the following data when notifying the Delivery Contact:

- a. Supplier name
- b. Authority's PO Number
- c. Item reference, Supplier's part code, description and quantity
- d. Any special instructions originally entered on the Authority's PO.

2.2.6. The Delivery Contact will confirm:

- a. Booking reference number;
- b. Date and time of delivery of Goods (where applicable); and
- c. Delivery address.

2.2.7. Delivery of the Goods shall be considered to have occurred when the Delivery Contact or other authorised representative of the Authority at the Authority's nominated Premises and Location(s) has signed the Supplier's delivery note.

2.2.8. The Supplier shall carry out deliveries within the ordinary working hours at the Premises and Location(s) on the date specified on the PO unless otherwise agreed with the relevant Delivery Contact as stated in Annex A – Order Specific Key Provisions, Clause 1.3.

2.2.9. The Authority may refuse unscheduled deliveries of Goods. In such event, the Supplier shall rearrange such delivery of Goods utilising the delivery process set out in this Clause 2.2.

(2.3) Key personnel of the Supplier to be involved in the Goods / Services:

Name: [REDACTED]

Phone: [REDACTED]

E-mail: [REDACTED]

(2.4) Performance standards:

2.4.1. The Supplier shall ensure the goods are fit for purpose.

2.4.2. Timely delivery of the Goods in accordance with section 2.6 below.

2.4.3. Proof of delivery of the Goods to be supplied.

(2.5) Quality standards:

2.5.1. Unless expressly agreed otherwise the Supplier shall ensure that the Goods have an expiry date of at least 6 (six) months following the date of delivery by the Supplier, to allow the laboratories sufficient time to use the Goods.

2.5.2. If Goods are deemed to be Defective Goods by the Authority, the Authority, at its sole discretion, shall provide a written notice to the Supplier in accordance with Schedule 2, Clause 3 of the Call-Off Terms and Conditions.

2.5.3. Return Conditions:

2.5.3.1. For Rejected Goods:

- a) The Supplier is responsible for collecting the Rejected Goods.
- b) The Supplier is responsible for the costs of returning/collecting the Rejected Goods.

2.5.3.2. Return Conditions shall be in accordance with Schedule 2 - Clause 3 (Inspection, rejection, return and recall of the Goods) of the Call Off Terms and Conditions.

(2.6) Contract monitoring arrangements:

- 2.6.1. The Authority's Contract Manager (or their delegate) and the Supplier's Contract Manager shall meet quarterly (or such other frequency as reasonably requested by the Authority) to discuss the Supplier's performance and other matters connected to the delivery of the Contract.
- 2.6.2. The Supplier shall provide management information, using the template provided by the Authority in Appendix 3 – Example Management Information Report, on a quarterly basis to include, but not limited to:
- 2.6.2.1. Performance against below key performance indicators ("KPIs"), delivery expectations, demand/call-off plan.
 - 2.6.2.2. Compliance to processes: Delivery and invoicing processes as stated in Annex 1 of this Order Form.
 - 2.6.2.3. Quantity of Goods delivered against the relevant PO (including deliveries in excess and shortfall of the quantity ordered).
 - 2.6.2.4. Quality of delivery of the Goods in accordance with the Call Off Terms and Conditions and this Contract (including delivery presentation, presented in such a way that it can be unloaded safely and in a ready for use condition, and damaged Goods).
 - 2.6.2.5. Timely and accurate administration (including booking/amending delivery times, POs and invoices, delivery advice notes and labels being in accordance with the Call Off Terms and Conditions and this Contract).

(2.7) Management information and meetings:

- 2.7.1. At the Authority's request, within 5 (five) Business Days of such request, the Supplier shall provide such management information to the Authority as the Authority may reasonably request from time to time.
- 2.7.2. The Supplier shall provide to the Authority, on a quarterly basis, two (2) Business Days prior to each meeting, a management report in the same or similar format as shown in Appendix 3.
- 2.7.3. Performance and key performance indicators to be reported by the Supplier on a quarterly basis include:
- a. Overall contract operational performance

- b. Delivery failures and root cause analysis
- c. Invoicing and billing
- d. Establish any improvement action plans required
- e. Process improvements / best industry practice
- f. Review and discussion of a continuous improvement plan
- g. Review of risks
- h. Objective reviews and scope for delivery of Goods
- i. Any other business.

2.7.4. The Supplier shall provide quarterly performance updates on the Social Value 'Fighting Climate Change' in relation, but not limited to, company annual sustainability targets, new and ongoing climate change initiatives, and environmental strategies.

3. CONFIDENTIAL INFORMATION (if applicable)

(3.1) The following information shall be deemed Confidential Information:

- a. Supplier pricing.
- b. Contact details including, but not limited to, email addresses, landline / mobile phone numbers, etc. of Supplier representatives.
- c. Contact details including, but not limited to, email addresses, landline / mobile phone numbers, etc. of Authority's representatives.

(3.2) Duration that the information shall be deemed Confidential Information:

3.2.1. For a period of 3 (three) years after the expiry or earlier termination of this Contract unless otherwise agreed in writing by the Parties.

4. DATA PROCESSING (if applicable)

(4.1) Personal Data to be processed by the Supplier:

N/A

5. LEASE / LICENSE (if applicable)

(5.1) The Authority is granting the following lease or licence to the Supplier:

N/A

For and on behalf of the Authority

DocuSigned by:



Full Name:



Job Title/Role: Deputy Commercial Director

Date Signed: 12/05/2023

For and on behalf of the Supplier

DocuSigned by:



Full Name:



Job Title/Role:



Date Signed: 11 May 2023

Annex A

Order Specific Key Provisions

1. Ordering Procedure

- 1.1. The Authority may, but shall not be obliged to, provide the Supplier with POs for reagents and consumables up to, but not cumulatively exceeding the Contract Price.
- 1.2. The Parties agree that where the Authority issues a Purchase Order whereby the delivery date required is at least 5 (five) Business Days after the date of the PO then Supplier shall fulfil such PO in its entirety. the period of one (1) week is adequate notice.
- 1.3. Where the Authority issues a PO whereby the delivery date required is less than 5 (five) Business Days after the date of the PO then the Supplier shall use its reasonable endeavours to fulfil such Purchase Order in its entirety. Where the Supplier is not able to fulfil such PO the Parties the Supplier shall advise the relevant Delivery Contact within 1 (one) Business Day as to when the PO can be fulfilled in its entirety and whether part shipment is possible. The Delivery Contact, in its sole discretion, shall agree any part shipment
- 1.4. The Supplier shall as part and parcel of the delivery of the Goods contain provide to the Authority any relevant technical information, quality standard, testing and validation information, and any handling and storage information.
- 1.5. The Supplier warrants that any Goods that are shown to fail the Specification (Appendix 4), within the expiry date required for the goods, are either replaced or full credit given.

2 Invoicing Terms

- 2.1 Payment terms are net 30 days from receipt of a valid invoice.
- 2.2. Following receipt of the Supplier's countersigned copy of the Contract, the Authority will send a unique PO number in accordance with clause 1.2 above. The Supplier must be in receipt of a valid PO number before submitting an invoice.

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- 2.3. The Supplier shall provide an invoice to the Authority for all Goods delivered to the Authority.
- 2.4. All invoices must be sent for approval and shall include the proof of delivery to the Authority's designated finance mailbox e-mail: payables@ukhsa.gov.uk and their agreed representative before being submitted for payment.
- 2.5. All invoices must be sent quoting a valid purchase order number. The Supplier shall provide a current statement of accounts on a quarterly basis; this is a standard commercial process and should show all invoices raised and amounts outstanding.
- 2.6. The Supplier shall provide compliant invoices that include, as a minimum, a valid PO number, PO line item number (if applicable), PO line description, and the details (name and telephone number) of the Authority's authorised representative. Non-compliant invoices will be sent back to the Supplier, which may lead to a delay in a payment.
- 2.7. In support of Goods delivered, the Supplier shall provide to the Authority a signed delivery note confirming receipt of the Goods at the Authority's nominated Premises and Locations.
- 2.8. Supplier queries regarding payment must be forwarded to the Authority's Accounts Payable section by email to: [REDACTED]

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Appendix 1 – Goods Information and Pricing

PRODUCT CODE	DESCRIPTION	ANNUAL EXPECTED USAGE	TERM		OFFER PRICE (EACH)
			START	END	
PRD-05576	APTIMA COMBO 2, 100-TEST KIT, PANTHER	AS REQUIRED	01/04/2023	31/03/2024	██████
PRD-05571	APTIMA COMBO 2, 250-TEST KIT, PANTHER	600			██████
302925	APTIMA CT, 100-TEST KIT, PANTHER	50			██████
302927	APTIMA GC, 100-TEST KIT, PANTHER	50			██████
303209	ATV V2, 100-TEST KIT, PANTHER, IVD	30			██████
303163	KIT, ATV (VER. 2), IVD 250, PANTHER	AS REQUIRED			██████
PRD-03919	M GEN ASSAY, APTIMA, 100T AS, (CALIBRATORS INCLUDED)	12			██████
301040	KIT, APTIMA CMB2URINE SPEC COLL	1000			██████
301041	KIT, APTIMA CMB2 SWAB SPEC COLL	1000			██████
PRD-03546	BOX OF SPECIMEN COLLECTION KITS, MULTITEST SWAB (IVD)(50 PK)	1000			██████
105575	APTIMA URINE COLLECTION TUBES	1000			██████
903031	TECAN TIPS	1000			██████
302807	KIT, CONTROLS, ATV, 250	AS REQUIRED			██████
PRD-04328	FLU REAGENT CARTRIDGES, 96-TEST, FUSION, CE IVD	100			██████

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PRD-04329	PARAFLU REAGENT CARTRIDGES, 96-TEST, FUSION, CE IVD	100			
PRD-04330	AMR REAGENT CARTRIDGES, 96-TEST, FUSION, CE IVD	100			
PRD-04868	BORDETELLA REAGENT CARTRIDGES, 96-TEST, FUSION, CE IVD	AS REQUIRED			
PRD-04303	OPEN ACCESS CARTRIDGES, 96-TEST, RNA/DNA ENZ	20			
PRD-04336*	FLU CONTROLS, FUSION, CE IVD	3			
PRD-04338*	ADV/HMPV/RV CONTROLS, FUSION, CE IVD	3			
PRD-04337*	PARAFLU CONTROLS, FUSION, CE VD	3			
PRD-04869*	BORDETELLA CONTROLS, FUSION, CE IVD	3	01/04/2023	31/03/2024	
PRD-04339	SPECIMEN LYSIS, FUSION, CE IVD	100			
PRD-04306	DNA, IC PRIMERS (ASR)	1			
PRD-04308	DNA, IC PROBE (ASR)	1			
PRD-04307	RNA, IC PRIMERS (ASR)	1			
PRD-04309	RNA, IC PROBE (ASR)	1			
PRD-06419	SARS-CoV-2 ASSAY. APTIMA. 250-TEST. CE-IVD	100			
PRD-07400	KIT, SARS/FLU A/B/RSV REAGENT CARTRIDGES, 96-TEST, FUSION, IVD (Assay and Controls)	100			

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PRD-06420	SARS-CoV-2 ASSAY CONTROLS. APTIMA. CE-IVD	AS REQUIRED			██████
PRD-07401*	KIT, SARS/FLU A/B/RSV Controls, FUSION, IVD (Assay and Controls)	3	01/04/2023	31/03/2024	██████
PRD-05074	Aptima CMV Quant Assay Kit – 100 tests	AS REQUIRED			██████0
PRD-07157	Panther Fusion EBV quant Assay - Cartridges	AS REQUIRED			██████
PRD-07232	Panther Fusion BKV quant Assay - Cartridges	AS REQUIRED			██████
PRD-07158*	Panther Fusion EBV/BKV controls Kit	3			██████
PRD-07159*	Panther Fusion EBV Calibrators (1-5)	3			██████
PRD-07234*	Panther Fusion BKV Calibrators (1-5)	3			██████
PRD-03478	SPECIMEN DILUENT, TUBES, AND CAPS	AS REQUIRED			██████
PRD-06783	Whole Blood Diluent Kit – 100 tubes	AS REQUIRED			██████

*Where indicated above, the Supplier shall provide ████████ to the Authority 3 units per annum per Premises and Location. The Parties agree that this shall be sufficient to perform the Supplier's IFU required QC for result generation. All additional units required by the Authority shall be chargeable by the Supplier as indicated above.

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Appendix 2 – Premises and Locations

Site	Address	Postcode	Delivery Contact	Email and Contact Number
Birmingham	UKHSA Birmingham Pathology Heartlands Hospital Bordesley Green East Birmingham	B9 5SS	[REDACTED]	[REDACTED] [REDACTED]
Bristol	UKHSA Pathology Building (Phase 2) Southmead Hospital Bristol	BS10 5NB	[REDACTED]	[REDACTED] [REDACTED]
Cambridge	UKHSA Cambridge Box 236 Cambridge University Hospitals NHS Foundation Trust Hills Road Cambridge	CB2 0QQ	[REDACTED]	[REDACTED] [REDACTED]

Appendix 3 – Example Management Information Report

Contract Ref	PO Number	Line Item	Delivered	Product Description	Qty Delivered	Date UK/ISA Req'd	Date Delivered	Quantity / Uppside	Location	Invoice Number	Invoice Date	Invoice Due Date	Invoice Due Date Check	Invoice Not Due / Overdue No. of Days	Invoice Paid / No
C148916													30/01/2000	0	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No
C148916								0.00				30/01/2000	30/01/2000	3012	No

Contract Ref	PO Number	Line Item	Product Description	Qty Scheduled	Product Description	Qty Scheduled	of Scheduled Del	Location	
			SCHEDULED DELIVERIES						
C148916									
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Appendix 4 – Specifications**4a. Aptima Chlamydia Trachomatis Assay (502184EN Rev. 010)****Aptima™****Panther System****Panther System**

Reagents for the Aptima CT assay are listed below for the Panther system. Reagent Identification Symbols are also listed next to the reagent name.

Reagents and Materials Provided

Aptima Chlamydia trachomatis Assay Kit, 100 tests (2 boxes and 1 Controls kit)
(Cat. No. 302925)

Aptima Chlamydia trachomatis Assay Refrigerated Box (Box 1 of 2)
(store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity
A	Aptima Amplification Reagent CT <i>Non-infectious nucleic acids dried in buffered solution containing < 5% bulking agent.</i>	1 vial
E	Aptima Enzyme Reagent CT <i>Reverse transcriptase and RNA polymerase dried in HEPES buffered solution containing < 10% bulking reagent.</i>	1 vial
P	Aptima Probe Reagent CT <i>Non-infectious chemiluminescent DNA probes dried in succinate buffered solution containing < 5% detergent.</i>	1 vial
TCR-B	Aptima Target Capture Reagent B CT <i>Non-infectious nucleic acids in a buffered solution containing < 5% detergent.</i>	1 x 0.30 mL

Aptima Chlamydia trachomatis Assay Room Temperature Box (Box 2 of 2)
(store at 15°C to 30°C upon receipt)

Symbol	Component	Quantity
AR	Aptima Amplification Reconstitution Solution CT <i>Aqueous solution containing preservatives.</i>	1 x 11.9 mL
ER	Aptima Enzyme Reconstitution Solution CT <i>HEPES buffered solution containing a surfactant and glycerol.</i>	1 x 6.3 mL
PR	Aptima Probe Reconstitution Solution CT <i>Succinate buffered solution containing < 5% detergent.</i>	1 x 15.2 mL
S	Aptima Selection Reagent CT <i>600 mM borate buffered solution containing surfactant.</i>	1 x 43.0 mL
TCR	Aptima Target Capture Reagent CT <i>Buffered salt solution containing solid phase and capture oligomers.</i>	1 x 26.0 mL
	Reconstitution Collars	3
	Master Lot Barcode Sheet	1 sheet

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Panther System

Aptima™

Aptima Controls Kit
(store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity
PCT/NGC	Aptima Positive Control, CT / Negative Control, GC <i>Non-infectious CT nucleic acid in a buffered solution containing < 5% detergent. Each 400 µL sample contains the estimated rRNA equivalent of 1 CT IFU (5 fg/assay*).</i>	5 x 1.7 mL
PGC/NCT	Aptima Positive Control, GC / Negative Control, CT <i>Non-infectious GC nucleic acid in a buffered solution containing < 5% detergent. Each 400 µL sample contains the estimated rRNA equivalent of 50 GC cells (250 fg/assay*).</i>	5 x 1.7 mL

*The rRNA equivalents were calculated based on the genome size and estimated DNA:RNA ratio/cell of each organism.

Materials Required But Available Separately

Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.

	<u>Cat. No.</u>
Panther System	303095
Aptima Assay Fluids Kit <i>(Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)</i>	303014 (1000 tests)
Aptima Auto Detect Kit	303013 (1000 tests)
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther Run Kit <i>contains MTUs, waste bags, waste bin covers, assay fluids, and auto detects</i>	303096 (5000 tests)
Tips, 1000 µL, filtered, conductive, liquid sensing, and disposable	901121 (10612513 Tecan) 903031 (10612513 Tecan)
<i>Not all products are available in all regions. Contact your representative for region-specific information.</i>	MME-04134 (30180117 Tecan) MME-04128
Aptima Specimen Transfer Kit <i>for use with specimens in PreservCyt Solution</i>	301154C
Aptima Specimen Transfer Kit — printable <i>for use with specimens in PreservCyt Solution</i>	PRD-05110
Aptima Multitest Swab Specimen Collection Kit	PRD-03546
Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens	301041
Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens	301040
Aptima Urine Specimen Transport Tubes for Male and Female Urine Specimens	105575
Bleach, 5% to 7% (0.7 M to 1.0 M) sodium hypochlorite solution	—
Disposable gloves	—
SysCheck calibration standard	301078

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Aptima™**Panther System**

Aptima penetrable caps	105668
Replacement non-penetrable caps	103036A
Replacement caps for the 100-test kits	—
<i>Amplification, Enzyme, and Probe reagent reconstitution solutionsCL0041</i>	
<i>(100 caps)</i>	
<i>TCR and Selection reagent</i>	<i>501604 (100 caps)</i>

Optional Materials

	<u>Cat. No.</u>
Aptima Controls Kit	301110
Hologic Bleach Enhancer for Cleaning	302101
<i>for routine cleaning of surfaces and equipment</i>	

4b. Aptima™ Neisseria Gonorrhoeae Assay (502185EN Rev. 009)

Panther System

Aptima™

Panther System

Reagents for the Aptima GC Assay are listed below for the Panther System. Reagent Identification Symbols are also listed next to the reagent name.

Reagents and Materials Provided

Note: For information on any hazard and precautionary statements that may be associated with reagents, refer to the Safety Data Sheet Library at www.hologic.com/sds.

Aptima Neisseria gonorrhoeae Assay Kit, 100 tests (2 boxes and 1 Controls kit) (Cat. No. 302927)

Aptima Neisseria gonorrhoeae Assay Refrigerated Box (Box 1 of 2)
(store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity
A	Aptima Amplification Reagent GC <i>Non-infectious nucleic acids dried in buffered solution containing < 5% bulking agent.</i>	1 vial
E	Aptima Enzyme Reagent GC <i>Reverse transcriptase and RNA polymerase dried in HEPES buffered solution containing < 10% bulking reagent.</i>	1 vial
P	Aptima Probe Reagent GC <i>Non-infectious chemiluminescent DNA probes dried in succinate buffered solution containing < 5% detergent.</i>	1 vial
TCR-B	Aptima Target Capture Reagent B GC <i>Non-infectious nucleic acids in a buffered solution containing < 5% detergent.</i>	1 x 0.30 mL

Aptima Neisseria gonorrhoeae Assay Room Temperature Box (Box 2 of 2)
(store at 15°C to 30°C upon receipt)

Symbol	Component	Quantity
AR	Aptima Amplification Reconstitution Solution GC <i>Aqueous solution containing preservatives.</i>	1 x 11.9 mL
ER	Aptima Enzyme Reconstitution Solution GC <i>HEPES buffered solution containing a surfactant and glycerol.</i>	1 x 6.3 mL
PR	Aptima Probe Reconstitution Solution GC <i>Succinate buffered solution containing < 5% detergent.</i>	1 x 15.2 mL
S	Aptima Selection Reagent GC <i>600 mM borate buffered solution containing surfactant.</i>	1 x 43.0 mL
TCR	Aptima Target Capture Reagent GC <i>Buffered salt solution containing solid phase and capture oligomers.</i>	1 x 26.0 mL
	Reconstitution Collars	3
	Master Lot Barcode Sheet	1 sheet

Aptima™**Panther System****Aptima Controls Kit**
(store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity
PGC/NCT	Aptima Positive Control, GC / Negative Control, CT <i>Non-infectious GC nucleic acid in a buffered solution containing < 5% detergent. Each 400 µL sample contains the estimated rRNA equivalent of 50 GC cells (250 fg/assay*).</i>	5 x 1.7 mL
PCT/NGC	Aptima Positive Control, CT/ Negative Control, GC <i>Non-infectious CT nucleic acid in a buffered solution containing < 5% detergent. Each 400 µL sample contains the estimated rRNA equivalent of 1 CT IFU (5 fg/assay*).</i>	5 x 1.7 mL

*The rRNA equivalents were calculated based on the genome size and estimated DNA:RNA ratio/cell of each organism.

Materials Required But Available Separately

Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.

	<u>Cat. No.</u>
Panther System	303095
Aptima Assay Fluids Kit <i>(Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)</i>	303014 (1000 tests)
Aptima Auto Detect Kit	303013 (1000 tests)
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther Run Kit <i>contains MTUs, waste bags, waste bin covers, assay fluids, and auto detects</i>	303096 (5000 tests)
Tips, 1000 µL conductive, liquid sensing	10612513 (Tecan)
Aptima Specimen Transfer Kit <i>for use with specimens in PreservCyt Solution</i>	301154C
Aptima Specimen Transfer Kit — printable <i>for use with specimens in PreservCyt Solution</i>	PRD-05110
Aptima Multitest Swab Specimen Collection Kit	PRD-03546
Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens	301041
Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens	301040
Aptima Urine Specimen Transport Tubes for Male and Female Urine Specimens	105575

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Bleach, 5% to 7% (0.7 M to 1.0 M) sodium hypochlorite solution —

Disposable gloves —

Panther System**Aptima™**

SysCheck calibration standard	301078
Aptima penetrable caps	105668
Replacement non-penetrable caps	103036A
Replacement caps for the 100-test kits	—
<i>Amplification, Enzyme, and Probe reagent reconstitution solutions</i>	
	<i>CL0041 (100 caps)</i>
<i>TCR and Selection reagent</i>	<i>501604 (100 caps)</i>

Optional Materials

	<u>Cat. No.</u>
Aptima Controls Kit	301110
Hologic Bleach Enhancer for Cleaning <i>for routine cleaning of surfaces and equipment</i>	302101

4c. Aptima® Trichomonas vaginalis Assay (502536EN Rev. 008)**Aptima®****Panther System****Panther System**

Reagents for the Aptima Trichomonas vaginalis Assay are listed below for the Panther System. Reagent Identification Symbols are also listed next to the reagent name.

Reagents and Materials Provided

Note: For information on any hazard and precautionary statements that may be associated with reagents, refer to the Safety Data Sheet Library at www.hologic.com/sds.

Aptima Trichomonas vaginalis Assay Kit

250 tests (2 boxes and 1 Controls kit) (Cat. No. 303163)

100 test (2 boxes and 1 Controls kit) (Cat. No. 303209)

Aptima Trichomonas vaginalis Refrigerated Box (Box 1 of 2)
(store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity	
		250-test kit	100-test kit
A	Aptima Trichomonas vaginalis Amplification Reagent <i>Primers and nucleotides dried in buffered solution containing < 5% bulking agent.</i>	1 vial	1 vial
E	Aptima Trichomonas vaginalis Enzyme Reagent <i>Reverse transcriptase and RNA polymerase dried in HEPES buffered solution containing < 10% bulking reagent.</i>	1 vial	1 vial
P	Aptima Trichomonas vaginalis Probe Reagent <i>Chemiluminescent DNA probes dried in succinate buffered solution containing < 5% detergent.</i>	1 vial	1 vial
TCR-B	Aptima Trichomonas vaginalis Assay Target Capture Reagent B <i>Buffered solution containing < 5% detergent.</i>	1 x 0.56 mL	1 x 0.30 mL

Aptima Trichomonas vaginalis Room Temperature Box (Box 2 of 2) (store at room temperature, 15°C to 30°C upon receipt)

Symbol	Component	250-test kit	100-test kit
AR	Aptima Trichomonas vaginalis Amplification Reconstitution Solution <i>Aqueous solution containing preservatives.</i>	1 x 27.7 mL	1 x 11.9 mL
ER	Aptima Trichomonas vaginalis Enzyme Reconstitution Solution <i>HEPES buffered solution containing a surfactant and glycerol.</i>	1 x 11.1 mL	1 x 6.3 mL

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Aptima Trichomonas vaginalis Room Temperature Box (Box 2 of 2)
(store at room temperature, 15°C to 30°C upon receipt) (continued)

PR	Aptima Trichomonas vaginalis Probe Reconstitution Solution <i>Succinate buffered solution containing < 5% detergent.</i>	1 x 35.4 mL	1 x 15.2 mL
S	Aptima Trichomonas vaginalis Selection Reagent <i>600 mM borate buffered solution containing surfactant.</i>	1 x 108 mL	1 x 43.0 mL
TCR	Aptima Trichomonas vaginalis Target Capture Reagent <i>Buffered solution containing capture oligomers and magnetic particles.</i>	1 x 54.0 mL	1 x 26.0 mL
	Reconstitution Collars	3	3
	Master Lot Barcode Sheet	1 sheet	1 sheet

Aptima Trichomonas vaginalis Controls Kit
(store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity
NC	Aptima Trichomonas vaginalis Negative Control <i>Non-infectious non-target nucleic acid in a buffered solution containing < 5% detergent.</i>	5 x 1.7 mL
PC	Aptima Trichomonas vaginalis Positive Control <i>Non-infectious Trichomonas vaginalis organisms in buffered solution containing < 5% detergent.</i>	5 x 1.7 mL

Materials Required But Available Separately

Note: *Materials available from Hologic have catalog numbers listed, unless otherwise specified.*

	Cat. No.
Panther System	303095
Aptima Assay Fluids Kit <i>(Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)</i>	303014 (1000 tests)
Aptima Auto Detect Kit	303013 (1000 tests)
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther Run Kit <i>contains MTUs, waste bags, waste bin covers, assay fluids, and auto detects</i>	303096 (5000 tests)
Tips, 1000 µL conductive, liquid sensing	10612513 (Tecan)
Aptima Specimen Transfer Kit <i>for use with specimens in PreservCyt Solution</i>	301154C
Aptima Specimen Transfer Kit — printable <i>for use with specimens in PreservCyt Solution</i>	PRD-05110
Aptima Multitest Swab Specimen Collection Kit	PRD-03546
Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens	301041
Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens	301040
Aptima Urine Specimen Transport Tubes for Male and Female Urine Specimens	105575

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Bleach, 5% to 7% (0.7 M to 1.0 M) sodium hypochlorite solution	—
Disposable gloves	—
SysCheck calibration standard	301078
Aptima penetrable caps	105668
Replacement non-penetrable caps	103036A
Replacement Caps for the 250-test kits	—
<i>Amplification and Probe reagent reconstitution solutions</i>	
	<i>CL0041 (100 caps)</i>
<i>Enzyme Reagent reconstitution solution</i>	<i>501616 (100 caps)</i>
<i>TCR and Selection reagent</i>	<i>CL0040 (100 caps)</i>
Replacement Caps for 100-test kits	—
<i>Amplification, Enzyme, and Probe reagent reconstitution solutions</i>	
	<i>CL0041 (100 caps)</i>
<i>TCR and Selection reagent</i>	<i>501604 (100 caps)</i>

Optional Materials

	<u>Cat. No.</u>
Aptima Trichomonas vaginalis Controls Kit	302807
Hologic Bleach Enhancer for Cleaning <i>for routine cleaning of surfaces and equipment</i>	302101

4d. Aptima Mycoplasma genitalium Assay (AW-14170-001 Rev. 009)**Panther System**

Reagents for the Aptima Mycoplasma genitalium assay are listed below for the Panther system. Reagent Identification Symbols are also listed next to the reagent name.

Reagents and Materials**Aptima Mycoplasma genitalium Assay Kit**

100 tests (2 boxes) (Cat. No. PRD-03374)*

100 tests (2 boxes and 1 calibrators kit) (Cat. No. PRD-03919)

**Aptima Mycoplasma genitalium Refrigerated Box
(store at 2°C to 8°C upon receipt)**

Symbol	Component	Quantity
A	Aptima Mycoplasma genitalium Amplification Reagent <i>Non-infectious nucleic acids dried in buffered solution containing < 5% bulking agent.</i>	1 vial
E	Aptima Mycoplasma genitalium Enzyme Reagent <i>Reverse transcriptase and RNA polymerase dried in HEPES buffered solution containing < 10% bulking reagent.</i>	1 vial
P	Aptima Mycoplasma genitalium Probe Reagent <i>Chemiluminescent DNA probes dried in succinate buffered solution containing < 5% detergent.</i>	1 vial
IC	Aptima Mycoplasma genitalium Internal Control <i>Non-infectious RNA transcript in buffered solution containing < 5% detergent.</i>	1 vial

**Aptima Mycoplasma genitalium Room Temperature Box
(store at 15°C to 30°C upon receipt)**

Symbol	Component	Quantity
AR	Aptima Mycoplasma genitalium Amplification Reconstitution Solution <i>Aqueous solution containing preservatives.</i>	1 bottle
ER	Aptima Mycoplasma genitalium Enzyme Reconstitution Solution <i>HEPES buffered solution containing a surfactant and glycerol.</i>	1 bottle
PR	Aptima Mycoplasma genitalium Probe Reconstitution Solution <i>Succinate buffered solution containing < 5% detergent.</i>	1 bottle
S	Aptima Mycoplasma genitalium Selection Reagent <i>600 mM borate buffered solution containing surfactant.</i>	1 bottle

* Calibrator kits are sold separately. See individual catalog box number below.

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Aptima Mycoplasma genitalium Room Temperature Box (store at 15°C to 30°C upon receipt) (continued)

Symbol	Component	Quantity
TCR	Aptima Mycoplasma genitalium Target Capture Reagent <i>Buffered solution containing capture oligomers and magnetic particles.</i>	1 bottle
	Reconstitution Collars	3
	Master Lot Barcode Sheet	1 sheet

Aptima Mycoplasma genitalium Calibrators Kit (PRD-03393) (store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity
NCAL	Aptima Mycoplasma genitalium Negative Calibrator <i>Buffered solution containing < 5% detergent.</i>	5 vials
PCAL	Aptima Mycoplasma genitalium Positive Calibrator <i>Non-infectious Mycoplasma genitalium in vitro RNA transcript in buffered solution containing < 5% detergent.</i>	5 vials

Materials Required But Available Separately

Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.

	Cat. No.
Panther System	303095
Aptima Assay Fluids Kit <i>contains Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent</i>	303014 (1000 tests)
Aptima Auto Detect Kit	303013 (1000 tests)
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther System Run Kit <i>contains MTUs, waste bags, waste bin covers, assay fluids, and auto detects</i>	303096 (5000 tests)
Tips, 1000 µL, filtered, conductive, liquid sensing, and disposable	901121 (10612513 Tecan) 903031 (10612513 Tecan) MME- 04134 (30180117 Tecan) MME- 04128
<i>Not all products are available in all regions. Contact your representative for region-specific information.</i>	
Aptima Mycoplasma genitalium Calibrators Kit	PRD-03393
Aptima Specimen Transfer Kit <i>for use with specimens in PreservCyt™ solution</i>	301154C
Aptima Specimen Transfer Kit — printable <i>for use with specimens in PreservCyt™ solution</i>	PRD-05110

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Aptima Multitest Swab Specimen Collection Kit	PRD-03546
Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens	301041
Aptima Urine Specimen Collection Kit	301040
Or Aptima Urine Specimen Transport Tubes	105575
Bleach, 5% to 8.25% (0.7 M to 1.16 M) sodium hypochlorite solution	—
Disposable powderless gloves	—
Aptima penetrable caps	105668
Reagent replacement Caps for 100-test kits	
<i>Amplification, Enzyme, and Probe reagent reconstitution solutions</i>	CL0041 (100 caps)
<i>TCR and Selection reagent</i>	501604 (100 caps)
Plastic-backed laboratory bench covers	—
Centrifuge	—

Optional Materials

	Cat. No.
Hologic Bleach Enhancer for Cleaning <i>for routine cleaning of surfaces and equipment</i>	302101
Replacement non-penetrable caps	103036A

4e. AdV/hMPV/RV Assay (Panther Fusion™ System) (AW-16164-001 Rev. 005)**Panther Fusion System**

The Panther Fusion System is an integrated nucleic acid testing system that fully automates all steps necessary to perform various Panther Fusion assays from sample processing through amplification, detection, and data reduction.

Reagents and Materials Provided for Panther Fusion AdV/hMPV/RV Assay**Assay Packaging**

Components¹	Part No.	Storage
Panther Fusion AdV/hMPV/RV Assay Cartridges 96 Tests Panther Fusion AdV/hMPV/RV assay cartridge, 12 tests, 8 per box	PRD-04330	2°C to 8°C
Panther Fusion Internal Control-S 960 Tests Panther Fusion Internal Control-S tube, 4 per box	PRD-04332	2°C to 8°C
Panther Fusion AdV/hMPV/RV Assay Controls Panther Fusion AdV/hMPV/RV Positive Control tube, 5 per box Panther Fusion Negative Control tube, 5 per box	PRD-04338	2°C to 8°C
Panther Fusion Extraction Reagent-S 960 Tests Panther Fusion Capture Reagent-S bottle, 240 tests, 4 per box Panther Fusion Enhancer Reagent-S bottle, 240 tests, 4 per box	PRD-04331	15°C to 30°C
Panther Fusion Elution Buffer 2400 Tests Panther Fusion Elution Buffer pack, 1200 tests, 2 per box	PRD-04334	15°C to 30°C
Panther Fusion Reconstitution Buffer I 1920 Tests Panther Fusion Reconstitution Buffer I pack, 960 tests, 2 per box	PRD-04333	15°C to 30°C
Panther Fusion Oil Reagent 1920 Tests Panther Fusion Oil Reagent pack, 960 tests, 2 per box	PRD-04335	15°C to 30°C

¹ Components can also be ordered in the following bundles:

Panther Fusion Universal Fluids Kit, PRD-04430, contains 1 each Panther Fusion Oil and Panther Fusion Elution buffer.

Panther Fusion Assay Fluids I-S, PRD-04431, contains 2 Panther Fusion Extraction Reagents-S, 2 Panther Fusion Internal Control-S, and 1 Panther Fusion Reconstitution Buffer I.

Individually Packaged Items

Items	Part No.
Panther Fusion Specimen Lysis Tubes, 100 per bag	PRD-04339

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Materials Required and Available Separately

Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.

Material	Cat. No.
Panther System	303095
Panther Fusion Module	ASY-09600
Aptima Assay Fluids Kit (Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)	303014 (1000 tests)
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther System Run Kit for Real Time Assays contains MTUs, waste bags, waste bin covers, and assay fluids	PRD-03455 (5000 tests)
Or Panther System Run Kit (when running TMA assays in parallel with real time-TMA assays) contains MTUs, waste bags, waste bin covers, auto detect*, and assay fluids	303096 (5000 tests)
Panther Fusion Tube Trays, 1008 tests, 18 trays per box	PRD-04000
Liquid Handling (LiHa) Disposable Tips, 1000 µL	10612513 (Tecan)
Aptima penetrable caps (optional)	105668
Replacement non-penetrable caps (optional)	103036A
Replacement extraction reagent bottle caps	CL0040
P1000 pipettor and tips with hydrophobic plugs	-
Bleach, 5% to 7% (0.7 M to 1.0 M) sodium hypochlorite solution Note: Mix one part bleach with one part deionized water to make diluted working bleach solution 2.5% to 3.5% (0.35 M to 0.5 M) sodium hypochlorite solution.	-
Disposable powderless gloves	-

*Needed only for Panther Aptima TMA assays.

4f. Bordetella Assay (Panther Fusion™ System) (AW-18637-001 Rev. 001)**Reagents and Materials Provided****Assay Packaging**

Components^a	Cat. No.	Storage
Panther Fusion Bordetella Assay Cartridges 96 Tests Panther Fusion Bordetella Assay cartridge, 12 tests, 8 per box	PRD-04868	2°C to 8°C
Panther Fusion Bordetella Assay Controls Panther Fusion Bordetella Positive Control tube, 5 per box Panther Fusion Negative Control tube, 5 per box	PRD-04869	2°C to 8°C
Panther Fusion Internal Control-S 960 Tests Panther Fusion Internal Control-S tube, 4 per box	PRD-04332	2°C to 8°C
Panther Fusion Extraction Reagent-S 960 Tests Panther Fusion Capture Reagent-S bottle, 240 tests, 4 per box Panther Fusion Enhancer Reagent-S bottle, 240 tests, 4 per box	PRD-04331	15°C to 30°C
Panther Fusion Elution Buffer 2400 Tests Panther Fusion Elution Buffer pack, 1200 tests, 2 per box	PRD-04334	15°C to 30°C
Panther Fusion Reconstitution Buffer I 1920 Tests Panther Fusion Reconstitution Buffer I pack, 960 tests, 2 per box	PRD-04333	15°C to 30°C
Panther Fusion Oil Reagent 1920 Tests Panther Fusion Oil Reagent pack, 960 tests, 2 per box	PRD-04335	15°C to 30°C

^a Components can also be ordered in the following bundles:

Panther Fusion Universal Fluids Kit, PRD-04430, contains 1 each Panther Fusion Oil and Panther Fusion Elution Buffer.
Panther Fusion Assay Fluids I-S, PRD-04431, contains 2 Panther Fusion Extraction Reagents-S, 2 Panther Fusion Internal Control-S, and 1 Panther Fusion Reconstitution Buffer I.

Individually Packaged Items

Items	Cat. No.
Panther Fusion Specimen Lysis Tubes, 100 per bag	PRD-04339

Materials Required and Available Separately**Note:** Materials available from Hologic have catalog numbers listed, unless otherwise specified.

Material	Cat. No.
Panther System	303095
Panther Fusion Module	PRD-04173
Panther Fusion System	PRD-04172
Aptima Assay Fluids Kit (Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)	303014 (1000 tests)
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther System Run Kit for Real Time Assays contains MTUs, waste bags, waste bin covers, and assay fluids	PRD-03455 (5000 tests)
Or Panther System Run Kit (when running TMA assays in parallel with real-time TMA assays) contains MTUs, waste bags, waste bin covers, auto detect ^a , and assay	303096 (5000 tests)
Panther Fusion Tube Trays, 1008 tests, 18 trays per box	PRD-04000
Liquid Handling (LiHa) Disposable Tips, 1000 µL	10612513 (Tecan)
Aptima penetrable caps (optional)	105668
Replacement non-penetrable caps (optional)	103036A
Replacement extraction reagent bottle caps	CL0040
P1000 pipettor and tips with hydrophobic plugs	–
Bleach, 5% to 7% (0.7 M to 1.0 M) sodium hypochlorite solution	–
Disposable powderless gloves	–

^a Needed only for Panther Aptima TMA assays.

4g. Aptima Combo 2™ Assay (AW-19693-001 Rev. 001)**Aptima Combo 2™**

Panther System

Panther System

Reagents for the Aptima Combo 2 assay for CT and GC are listed below for the Panther system. Reagent Identification Symbols are also listed next to the reagent name.

Reagents and Materials Provided**Aptima Combo 2 Assay Kit**

100 tests (2 boxes and 1 Controls kit) (Cat. No. PRD-05576)

250 tests (2 boxes and 1 Controls kit) (Cat. No. PRD-05571)

Aptima Combo 2 Refrigerated Box (Box 1 of 2)
(store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity 250 test kit	Quantity 100 test kit
A	Aptima Combo 2 Amplification Reagent <i>Non-infectious nucleic acids dried in buffered solution containing < 5% bulking agent.</i>	1 vial	1 vial
E	Aptima Combo 2 Enzyme Reagent <i>Reverse transcriptase and RNA polymerase dried in HEPES buffered solution containing < 10% bulking reagent.</i>	1 vial	1 vial
P	Aptima Combo 2 Probe Reagent <i>Non-infectious chemiluminescent DNA probes dried in succinate buffered solution containing < 5% detergent.</i>	1 vial	1 vial
TCR-B	Aptima Combo Target Capture Reagent B <i>Non-infectious nucleic acids in a buffered solution containing < 5% detergent.</i>	1 x 0.61 mL	1 x 0.30 mL

Aptima Combo 2 Room Temperature Box (Box 2 of 2)
(store at 15°C to 30°C upon receipt)

Symbol	Component	Quantity 250 test kit	Quantity 100 test kit
AR	Aptima Combo 2 Amplification Reconstitution Solution <i>Aqueous solution containing preservatives.</i>	1 x 27.7 mL	1 x 11.9 mL
ER	Aptima Combo 2 Enzyme Reconstitution Solution <i>HEPES buffered solution containing a surfactant and glycerol.</i>	1 x 11.1 mL	1 x 6.3 mL
PR	Aptima Combo 2 Probe Reconstitution Solution <i>Succinate buffered solution containing < 5% detergent.</i>	1 x 35.4 mL	1 x 15.2 mL
S	Aptima Combo 2 Selection Reagent <i>600 mM borate buffered solution containing surfactant.</i>	1 x 108 mL	1 x 43.0 mL

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Panther System

Aptima Combo 2™

Aptima Combo 2 Room Temperature Box (Box 2 of 2)
(store at 15°C to 30°C upon receipt)

Symbol	Component	Quantity	Quantity
		250 test kit	100 test kit
TCR	Aptima Combo 2 Target Capture Reagent <i>Buffered salt solution containing solid phase and capture oligomers.</i>	1 x 54 mL	1 x 26.0 mL
	Reconstitution Collars	3	3
	Master Lot Barcode Sheet	1 sheet	1 sheet

Aptima Controls Kit
(store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity
PCT/NGC	Aptima Positive Control, CT / Negative Control, GC <i>Non-infectious CT nucleic acid in a buffered solution containing < 5% detergent. Each 400 µL sample contains the estimated rRNA equivalent of 1 CT IFU (5 fg/assay*).</i>	5 x 1.7 mL
PGC/NCT	Aptima Positive Control, GC / Negative Control, CT <i>Non-infectious GC nucleic acid in a buffered solution containing < 5% detergent. Each 400 µL sample contains the estimated rRNA equivalent of 50 GC cells (250 fg/assay*).</i>	5 x 1.7 mL

*The rRNA equivalents were calculated based on the genome size and estimated DNA:RNA ratio/cell of each organism.

Materials Required but Available Separately

Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.

	<u>Cat. No.</u>
Panther System	303095
Aptima Assay Fluids Kit <i>(Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)</i>	303014 (1000 tests)
Aptima Auto Detect Kit	303013 (1000 tests)
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther Run Kit <i>contains MTUs, waste bags, waste bin covers, assay fluids, and auto detects</i>	303096 (5000 tests)
Tips, 1000 µL conductive, liquid sensing	10612513 (Tecan)

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Aptima Specimen Transfer Kit <i>for use with specimens in PreservCyt Solution</i>	301154C
Aptima Specimen Transfer Kit — printable <i>for use with specimens in PreservCyt Solution</i>	PRD-05110

Aptima Combo 2™**Panther System**

Aptima Multitest Swab Specimen Collection Kit	PRD-03546
Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens	301041
Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens	301040
Aptima Urine Specimen Transport Tubes for Male and Female Urine Specimens	105575
Bleach, 5% to 7% (0.7 M to 1.0 M) sodium hypochlorite solution	—
Disposable gloves	—
SysCheck calibration standard	301078
Aptima penetrable caps	105668
Replacement non-penetrable caps	103036A
Replacement caps for the 250-test kits <i>Amplification and Probe reagent reconstitution solutions</i>	—
	CL0041 (100 caps)
<i>Enzyme Reagent reconstitution solution</i>	501616 (100 caps)
<i>TCR and Selection reagent</i>	CL0040 (100 caps)
Replacement caps for the 100-test kits <i>Amplification, Enzyme, and Probe reagent reconstitution solutions</i>	—
	CL0041(100 caps)
<i>TCR and Selection reagent</i>	501604 (100 caps)

Optional Materials

	<u>Cat. No.</u>
Aptima Controls Kit	301110
Hologic Bleach Enhancer for Cleaning <i>for routine cleaning of surfaces and equipment</i>	302101

4h. Flu A/B/RSV Assay (Panther Fusion™ System) (AW-23081-001 Rev. 001)**Panther Fusion System**

The Panther Fusion system is an integrated nucleic acid testing system that fully automates all steps necessary to perform various Panther Fusion assays from sample processing through amplification, detection, and data reduction.

Reagents and Materials Provided for the Panther Fusion Flu A/B/RSV Assay**Assay Packaging**

Components¹	Part No.	Storage
Panther Fusion Flu A/B/RSV Assay Cartridges 96 Tests Panther Fusion Flu A/B/RSV assay cartridge, 12 tests, 8 per box	PRD-04328	2°C to 8°C
Panther Fusion Internal Control-S 960 Tests Panther Fusion Internal Control-S tube, 4 per box	PRD-04332	2°C to 8°C
Panther Fusion Flu A/B/RSV Assay Controls Panther Fusion Flu A/B/RSV Positive Control tube, 5 per box Panther Fusion Negative Control tube, 5 per box	PRD-04336	2°C to 8°C
Panther Fusion Extraction Reagent-S 960 Tests Panther Fusion Capture Reagent-S bottle, 240 tests, 4 per box Panther Fusion Enhancer Reagent-S bottle, 240 tests, 4 per box	PRD-04331	15°C to 30°C
Panther Fusion Elution Buffer 2400 Tests Panther Fusion Elution Buffer pack, 1200 tests, 2 per box	PRD-04334	15°C to 30°C
Panther Fusion Reconstitution Buffer I 1920 Tests Panther Fusion Reconstitution Buffer I pack, 960 tests, 2 per box	PRD-04333	15°C to 30°C
Panther Fusion Oil Reagent 1920 Tests Panther Fusion Oil Reagent pack, 960 tests, 2 per box	PRD-04335	15°C to 30°C

¹ Components can also be ordered in the following bundles:

Panther Fusion Universal Fluids Kit, PRD-04430, contains 1 each Panther Fusion Oil and Panther Fusion Elution buffer.

Panther Fusion Assay Fluids I-S, PRD-04431, contains 2 Panther Fusion Extraction Reagents-S, 2 Panther Fusion Internal Control-S, and 1 Panther Fusion Reconstitution Buffer.

Individually Packaged Items

Items	Part No.
Panther Fusion Specimen Lysis Tubes, 100 per bag	PRD-04339

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Materials Required and Available Separately*Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.*

Material	Cat. No.
Panther System	303095
Panther Fusion Module	PRD-04173
Aptima Assay Fluids Kit (Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)	303014 (1000 tests)
Panther Fusion System	PRD-04172
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther System Run Kit for Real Time Assays contains MTUs, waste bags, waste bin covers, and assay fluids	PRD-03455 (5000 tests)
Or Panther System Run Kit (when running TMA assays in parallel with real time-TMA assays) contains MTUs, waste bags, waste bin covers, auto detect*, and assay fluids	303096 (5000 tests)
Panther Fusion Tube Trays, 1008 tests, 18 trays per box	PRD-04000
Tips, 1000 µL filtered, conductive, liquid sensing, and disposable. Not all products are available in all regions. Contact your representative for region-specific information	901121 (10612513 Tecan) 903031 (10612513 Tecan) MME-04134 (30180117 Tecan) MME-04128
Aptima penetrable caps (optional)	105668
Replacement non-penetrable caps (optional)	103036A
Replacement extraction reagent bottle caps	CL0040
P1000 pipettor and tips with hydrophobic plugs	-
Bleach, 5% to 8.25% (0.7 M to 1.16 M) sodium hypochlorite solution	-
Disposable powderless gloves	-
Plastic-back laboratory bench covers	-
Lint-free wipes	-
Pipettor	-

*Needed only for Panther Aptima TMA assays.

4i. Paraflu Assay (Panther Fusion™ System) (AW-23708-001 Rev. 001)**Panther Fusion System**

The Panther Fusion system is an integrated nucleic acid testing system that fully automates all steps necessary to perform various Panther Fusion assays from sample processing through amplification, detection, and data reduction.

Reagents and Materials Provided for the Panther Fusion Paraflu Assay**Assay Packaging**

Components¹	Part No.	Storage
Panther Fusion Paraflu Assay Cartridges 96 Tests Panther Fusion Paraflu assay cartridge, 12 tests, 8 per box	PRD-04329	2°C to 8°C
Panther Fusion Internal Control-S 960 Tests Panther Fusion Internal Control-S tube, 4 per box	PRD-04332	2°C to 8°C
Panther Fusion Paraflu Assay Controls Panther Fusion Paraflu Positive Control tube, 5 per box Panther Fusion Negative Control tube, 5 per box	PRD-04337	2°C to 8°C
Panther Fusion Extraction Reagent-S 960 Tests Panther Fusion Capture Reagent-S bottle, 240 tests, 4 per box Panther Fusion Enhancer Reagent-S bottle, 240 tests, 4 per box	PRD-04331	15°C to 30°C
Panther Fusion Elution Buffer 2400 Tests Panther Fusion Elution Buffer pack, 1200 tests, 2 per box	PRD-04334	15°C to 30°C
Panther Fusion Reconstitution Buffer I 1920 Tests Panther Fusion Reconstitution Buffer I, 960 Tests, 2 per box	PRD-04333	15°C to 30°C
Panther Fusion Oil Reagent 1920 Tests Panther Fusion Oil Reagent, 960 tests, 2 per box	PRD-04335	15°C to 30°C

¹Components can also be ordered in the following bundles:

Panther Fusion Universal Fluids Kit, PRD-04430, contains 1 each Panther Fusion Oil and Panther Fusion Elution buffer.

Panther Fusion Assay Fluids I-S, PRD-04431, contains 2 Panther Fusion Extraction Reagents-S, 2 Panther Fusion Internal Control-S, and 1 Panther Fusion Reconstitution Buffer I.

Individually Packaged Items

Items	Part No.
Panther Fusion Specimen Lysis Tubes, 100 per bag	PRD-04339

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Materials Required and Available Separately

Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.

Material	Cat. No.
Panther System	303095
Panther Fusion Module	PRD-04173
Panther Fusion System	PRD-04172
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther System Run Kit for Real Time Assays contains MTUs, waste bags, waste bin covers, and assay fluids	PRD-03455 (5000 tests)
Or Panther System Run Kit (when running TMA assays in parallel with real time-TMA assays) contains MTUs, waste bags, waste bin covers, auto detect*, and assay fluids	303096 (5000 tests)
Panther Fusion Tube Trays, 1008 tests, 18 trays per box	PRD-04000
Tips, 1000 µL filtered, conductive, liquid sensing, and disposable. <i>Not all products are available in all regions. Contact your representative for region-specific information</i>	901121 (10612513 Tecan) 903031 (10612513 Tecan) MME-04134 (30180117 Tecan) MME-04128
Aptima Assay Fluids Kit (Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)	303014 (1000 tests)
Aptima penetrable caps (optional)	105668
Replacement non-penetrable caps (optional)	103036A
Replacement extraction reagent bottle caps	CL0040
P1000 pipettor and tips with hydrophobic plugs	-
Bleach, 5% to 8.25% (0.7 M to 1.16 M) sodium hypochlorite solution	-
Disposable powderless gloves	-
Plastic-back laboratory bench covers	-
Lint-free wipes	-

*Needed only for Panther Aptima TMA assays.

4j. SARS-CoV-2/Flu A/B/RSV Assay (Panther Fusion™ System) (AW-25328-001 Rev. 001)

Panther Fusion System

Panther Fusion™ SARS-CoV-2/Flu A/B/RSV

Panther Fusion System

The Panther Fusion System is an integrated nucleic acid testing system that fully automates all steps necessary to perform various Panther Fusion assays from sample processing through amplification, detection, and data reduction.

Reagents and Materials Provided for Panther Fusion SARS-CoV-2/Flu A/B/RSV Assay**Assay Packaging**

Components¹	Part No.	Storage
Panther Fusion SARS-CoV-2/Flu A/B/RSV Assay Cartridges 96 Tests Panther Fusion SARS-CoV-2/Flu A/B/RSV assay cartridge, 12 tests, 8 per box	PRD-07400	2°C to 8°C
Panther Fusion Internal Control-S 960 Tests Panther Fusion Internal Control-S tube, 4 per box	PRD-04332	2°C to 8°C
Panther Fusion SARS-CoV-2/Flu A/B/RSV Controls Panther Fusion SARS-CoV-2/Flu A/B/RSV Positive Controls tube, 5 per box Panther Fusion Negative Control tube, 5 per box	PRD-07401	2°C to 8°C
Panther Fusion Extraction Reagent-S 960 Tests Panther Fusion Capture Reagent-S bottle, 240 tests, 4 per box Panther Fusion Enhancer Reagent-S bottle, 240 tests, 4 per box	PRD-04331	15°C to 30°C
Panther Fusion Elution Buffer 2400 Tests Panther Fusion Elution Buffer pack, 1200 tests, 2 per box	PRD-04334	15°C to 30°C
Panther Fusion Reconstitution Buffer I 1920 Tests Panther Fusion Reconstitution Buffer I pack, 960 tests, 2 per box	PRD-04333	15°C to 30°C
Panther Fusion Oil 1920 Tests Panther Fusion Oil pack, 960 tests, 2 per box	PRD-04335	15°C to 30°C

¹ Components can also be ordered in the following bundles:

Panther Fusion Universal Fluids Kit, PRD-04430, contains 1 each Panther Fusion Oil and Panther Fusion Elution buffer.

Panther Fusion Assay Fluids I-S, PRD-04431, contains 2 Panther Fusion Extraction Reagents-S, 2 Panther Fusion Internal Control-S, and 1 Panther Fusion Reconstitution Buffer I.

Individually Packaged Items

Items	Part No.
Panther Fusion Specimen Lysis Tubes, 100 per bag	PRD-04339

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Materials Required and Available Separately

Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.

Material	Cat. No.
Panther™ System	303095
Panther Fusion System	PRD-04172
Panther Fusion Module	PRD-04173
Aptima™ Assay Fluids Kit (Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)	303014 (1000 tests)
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther System Run Kit for Real Time Assays contains MTUs, waste bags, waste bin covers, and assay fluids	PRD-03455 (5000 tests)
Or Panther System Run Kit (when running TMA assays in parallel with real time-TMA assays) contains MTUs, waste bags, waste bin covers, auto detect*, and assay fluids	303096 (5000 tests)
Panther Fusion Tube Trays, 1008 tests, 18 trays per box	PRD-04000
Tips, µL, filtered, liquid-sensing, conductive, and disposable.	901121 (10612513 Tecan) 903031 (10612513 Tecan)
Not all products are available in all regions. Contact your representative for region-specific information.	MME-04134 (30180117 Tecan) MME-04128
Aptima penetrable caps (optional)	105668
Replacement non-penetrable caps (optional)	103036A
Replacement extraction reagent bottle caps	CL0040
P1000 pipettor and tips with hydrophobic plugs	-
Bleach, 5% to 8.25% (0.7 M to 1.16 M) sodium hypochlorite solution Note: Refer to the <i>Panther/Panther Fusion System Operator's Manual</i> for instructions on preparing diluted sodium hypochlorite solution.	-
Disposable powderless gloves	-

*Needed only for Panther Aptima TMA assays.

4k. Aptima™ CMV Quant Assay (AW-25509-001 Rev. 003)**Panther System**

Reagents for the Aptima CMV Quant assay are listed below for the Panther system. Reagent identification symbols are also listed next to the reagent name.

Reagents and Materials Provided

Aptima CMV Quant Assay Kit, 100 tests (Cat. No. PRD-05074)

(1 assay box, 1 calibrator kit, 1 controls kit, and 1 target enhancer reagent box)

Aptima CMV Quant Assay Box

(store at 2°C to 8°C upon receipt)

Symbol	Component	Quantity
A	qCMV Amplification Reagent <i>Non-infectious nucleic acids dried in buffered solution.</i>	1 vial
E	qCMV Enzyme Reagent <i>Reverse transcriptase and RNA polymerase dried in HEPES buffered solution.</i>	1 vial
PRO	qCMV Promoter Reagent <i>Non-infectious nucleic acids dried in buffered solution.</i>	1 vial
AR	qCMV Amplification Reconstitution Solution <i>Aqueous solution containing glycerol and preservatives.</i>	1 x 7.2 mL
ER	qCMV Enzyme Reconstitution Solution <i>HEPES buffered solution containing a surfactant and glycerol.</i>	1 x 5.8 mL
PROR	qCMV Promoter Reconstitution Solution <i>Aqueous solution containing glycerol and preservatives.</i>	1 x 4.5 mL
TCR	qCMV Target Capture Reagent <i>Nucleic acids in a buffered salt solution containing solid phase, non-infectious nucleic acids, and Internal Calibrator.</i>	1 x 72.0 mL
	Reconstitution Collars	3
	Master Lot Barcode Sheet	1 sheet

Aptima CMV Quant Calibrator Kit (Cat. No. PRD-05075)

(store at -15°C to -35°C upon receipt)

Symbol	Component	Quantity
PCAL	qCMV Positive Calibrator <i>Plasmid DNA in buffered solution.</i>	5 x 2.5 mL
	Calibrator Barcode Label	—

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Aptima CMV Quant Controls Kit (Cat. No. PRD-05076)

(store at -15°C to -35°C upon receipt)

Symbol	Component	Quantity
NC	qCMV Negative Control <i>CMV negative defibrinated human plasma containing gentamicin and 0.2% sodium azide as preservatives.</i>	5 x 0.8 mL
LPC	qCMV Low Positive Control <i>Inactivated CMV in defibrinated human plasma containing gentamicin and 0.2% sodium azide as preservatives.</i>	5 x 0.8 mL
HPC	qCMV High Positive Control <i>Inactivated CMV in defibrinated human plasma containing gentamicin and 0.2% sodium azide as preservatives.</i>	5 x 0.8 mL
	Control Barcode Label	—

Aptima CMV Quant Target Enhancer Reagent Box

(store at 15°C to 30°C upon receipt)

Symbol	Component	Quantity
TER	qCMV Target Enhancer Reagent <i>A concentrated solution of lithium hydroxide.</i>	1 x 46.0 mL

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Materials Required but Available Separately

Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.

Material	Cat. No.
Panther™ System	—
Panther Run Kit for Real Time Assays (for real-time assays only)	PRD-03455 (5000 tests)
<i>Aptima™ Assay Fluids Kit (also known as Universal Fluids Kit) contains Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent</i>	303014 (1000 tests)
<i>Multi-tube units (MTUs)</i>	104772-02
<i>Panther Waste Bag Kit</i>	902731
<i>Panther Waste Bin Cover</i>	504405
Or, Panther System Run Kit <i>(when running non-real-time-TMA assays in parallel with real-time-TMA assays) contains MTUs, waste bags, waste bin covers, auto detect, and assay fluids</i>	303096 (5000 tests)
Whole Blood Diluent tubes (for processing whole blood specimens only)	PRD-06783 (100 pre-filled tubes per bag)
Tips, 1000 µL filtered, conductive, liquid sensing, and disposable	901121 (10612513 Tecan) 903031 (10612513 Tecan) MME-04128 MME-04134 (30180117 Tecan)
<i>Not all products are available in all regions. Contact your representative for region-specific information</i>	
Bleach, 5% to 8.25% (0.7 M to 1.16 M) sodium hypochlorite solution	—
Disposable, powderless gloves	—
Replacement non-penetrable caps	103036A
Replacement Hologic Solid Caps (single-use tube cap for whole blood processing)	PRD-06720
Reagent replacement caps	
<i>Amplification, Enzyme, and Promoter reagent reconstitution bottles</i>	<i>CL0041 (100 caps)</i>
<i>TCR bottle</i>	<i>CL0040 (100 caps)</i>
<i>TER bottle</i>	<i>903302 (100 caps)</i>
Plastic-backed laboratory bench covers	—
Lint-free wipes	—
Pipettor	—
Tips	—
Primary collection tubes (EDTA and PPT) options:	—
<i>13 mm x 100 mm</i>	
<i>13 mm x 75 mm</i>	
<i>16 mm x 100 mm</i>	
Centrifuge	—
Vortex mixer	—

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Optional Materials

Material	Cat. No.
Secondary tube options:	
12 mm x 75 mm	—
13 mm x 100 mm	—
16 mm x 100 mm	—
<i>Aptima Specimen Aliquot Tubes (SATs) (100 pack)</i>	503762
Transport tube cap (100 pack)	504415
<i>cap for SAT</i>	
Aptima Specimen Diluent	PRD-03003
Aptima Specimen Diluent Kit	PRD-03478
<i>contains Aptima Specimen Diluent, 100 SATs and 100 caps</i>	
Transfer pipets	—
Cotton-tipped swabs	—
Tube rocker	—

4I. EBV Quant Assay (Panther Fusion™) (AW-26019-001 Rev. 001)**Panther Fusion System**

The Panther Fusion system is an integrated nucleic acid testing system that fully automates all steps necessary to perform various Panther Fusion assays from sample processing through amplification, detection, and data reduction.

Reagents and Materials Provided**Assay Packaging**

Components	Part No.	Storage
Panther Fusion EBV Quant Assay Calibrators		
PCAL 1 qEBV, 3 per box		
PCAL 2 qEBV, 3 per box		
PCAL 3 qEBV, 3 per box		
PCAL 4 qEBV, 3 per box		
PCAL 5 qEBV, 3 per box		
Panther Fusion EBV–BKV Quant Assay Controls		
HPC High Positive Control tube, 5 per box		
LPC Low Positive Control tube, 5 per box		
NC III Transplant Negative Control tube, 5 per box		
Panther Fusion EBV Quant Assay Cartridge 96 Tests		
Panther Fusion qEBV assay cartridge, 12 tests, 8 per box		
Panther Fusion Internal Control-B 960 Tests		
Panther Fusion Internal Control-B tube, 4 per box		
Panther Fusion Extraction Reagent-B 960 Tests		
Panther Fusion Capture Reagent-B bottle, 240 tests, 4 per box		
Panther Fusion Enhancer Reagent-B bottle, 240 tests, 4 per box		
Panther Fusion Elution Buffer 2400 Tests		
Panther Fusion Elution Buffer pack, 1200 tests, 2 per box		
Panther Fusion Reconstitution Buffer I 1920 Tests		
Panther Fusion Reconstitution Buffer I, 960 Tests, 2 per box		
Panther Fusion Oil Reagent 1920 Tests		
Panther Fusion Oil Reagent, 960 tests, 2 per box		

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Materials Required and Available Separately

Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.

Material	Cat. No.
Panther System	303095
Panther Fusion Module	PRD-04173
Panther Fusion System	PRD-04172
Aptima Assay Fluids Kit (Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)	303014 (1000 tests)
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther System Run Kit contains MTUs, waste bags, waste bin covers, assay fluids, and auto detects*	303096 (5000 tests)
Tips, 1000 µL, filtered, liquid-sensing, conductive, and disposable: <i>Not all products are available in all regions. Contact your representative for region-specific information.</i>	901121 (10612513 Tecan) 903031(10612513 Tecan) MME-04134 (30180117 Tecan) MME-04128
Panther Fusion Tube Trays, 1008 Tests, 18 trays per box	PRD-04000
Whole Blood Diluent tubes (for processing whole blood specimens only)	PRD-06783 (100 pre-filled tubes per bag)
Replacement Hologic Solid Caps (single-use tube cap)	PRD-06720 (100 caps per bag)
Bleach, 5% to 8.25% (0.7 M to 1.16 M) sodium hypochlorite solution	—
Disposable powderless gloves	—
Plastic-backed laboratory bench covers	—
Lint-free wipes	—
Pipettor	—
Tips	—
Primary collection tubes (EDTA and PPT) options: 13 mm x 100 mm 12 mm x 75 mm 16 mm x 100 mm	—
Centrifuge	—
Vortex mixer	—

*Needed only for Panther Aptima TMA assays.

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Optional Materials

Material	Cat. No.
Secondary tube options:	
12 mm x 75 mm	—
13 mm x 100 mm	—
16 mm x 100 mm	—
Aptima Specimen Aliquot Tubes (SATs) (100 pack)	503762
Transport tube cap (100 pack) <i>cap for SAT</i>	504415
Aptima Specimen Diluent	PRD-03003
Aptima Specimen Diluent Kit <i>contains Aptima Specimen Diluent, 100 SATs and 100 caps</i>	PRD-03503
Transfer pipets	—
Tube rocker	—

4m. BKV Quant Assay (Panther Fusion™) (AW-26020-001 Rev. 001)**Panther Fusion System**

The Panther Fusion system is an integrated nucleic acid testing system that fully automates all steps necessary to perform various Panther Fusion assays from sample processing through amplification, detection, and data reduction.

Reagents and Materials Provided**Assay Packaging**

Components	Part No.	Storage
Panther Fusion BKV Quant Assay Calibrators		
PCAL 1 qBKV, 3 per box		
PCAL 2 qBKV, 3 per box		
PCAL 3 qBKV, 3 per box		
PCAL 4 qBKV, 3 per box		
PCAL 5 qBKV, 3 per box		
Panther Fusion EBV–BKV Quant Assay Controls		
HPC High Positive Control tube, 5 per box LPC Low Positive Control tube, 5 per box		
NC III Transplant Negative Control tube, 5 per box		
Panther Fusion BKV Quant Assay Cartridge 96 Tests		
Panther Fusion qBKV assay cartridge, 12 tests, 8 per box		
Panther Fusion Internal Control-B 960 Tests		
Panther Fusion Internal Control-B tube, 4 per box		
Panther Fusion Extraction Reagent-B 960 Tests		
Panther Fusion Capture Reagent-B bottle, 240 tests, 4 per box Panther Fusion Enhancer Reagent-B bottle, 240 tests, 4 per box		
Panther Fusion Elution Buffer 2400 Tests		
Panther Fusion Elution Buffer pack, 1200 tests, 2 per box		
Panther Fusion Reconstitution Buffer I 1920 Tests		
Panther Fusion Reconstitution Buffer I, 960 Tests, 2 per box		
Panther Fusion Oil Reagent 1920 Tests		
Panther Fusion Oil Reagent, 960 tests, 2 per box		

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Materials Required and Available Separately*Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.*

Material	Cat. No.
Panther System	303095
Panther Fusion Module	PRD-04173
Panther Fusion System	PRD-04172
Aptima Assay Fluids Kit (Aptima Wash Solution, Aptima Buffer for Deactivation Fluid, and Aptima Oil Reagent)	303014 (1000 tests)
Multi-tube units (MTUs)	104772-02
Panther Waste Bag Kit	902731
Panther Waste Bin Cover	504405
Or Panther System Run Kit contains MTUs, waste bags, waste bin covers, assay fluids, and auto detects*	303096 (5000 tests)
Tips, 1000 µL, filtered, liquid-sensing, conductive, and disposable: <i>Not all products are available in all regions. Contact your representative for region-specific information.</i>	901121 (10612513 Tecan) 903031(10612513 Tecan) MME-04134 (30180117 Tecan) MME-04128
Panther Fusion Tube Trays, 1008 Tests, 18 trays per box	PRD-04000
Aptima Urine Specimen Transport Tubes for processing urine specimens only	105575 (100 pre-filled tubes per bag)
Replacement Hologic Solid Caps (single-use tube cap)	PRD-06720 (100 caps per bag)
Bleach, 5% to 8.25% (0.7 M to 1.16 M) sodium hypochlorite solution	—
Disposable powderless gloves	—
Plastic-backed laboratory bench covers	—
Lint-free wipes	—
Pipettor	—
Tips	—
Primary collection tubes (EDTA and PPT) options: 13 mm x 100 mm 12 mm x 75 mm 16 mm x 100 mm	—
Centrifuge	—
Vortex mixer	—

*Needed only for Panther Aptima TMA assays.

Microbiology Framework Schedule 7 - Ordering Procedure, Award Criteria and Order Form

Optional Materials

Material	Cat. No.
Secondary tube options:	
12 mm x 75 mm	—
13 mm x 100 mm	—
16 mm x 100 mm	—
Aptima Specimen Aliquot Tubes (SATs) (100 pack)	503762
Transport tube cap (100 pack) <i>cap for SAT</i>	504415
Aptima Specimen Diluent	PRD-03003
Aptima Specimen Diluent Kit <i>contains Aptima Specimen Diluent, 100 SATs and 100 caps</i>	PRD-03503
Transfer pipets	—
Tube rocker	—

4n. Aptima™ Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens (AW-26249-001 Rev. 001)

Intended Use

The Aptima™ Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens is for use with Aptima assays. The Aptima Unisex Swab Specimen Collection Kit is intended to be used for the collection of female endocervical or male urethral swab specimens.

The Aptima Unisex Swab Specimen Collection Kit is also intended for use with other clinical specimen material for processing, extraction, and analysis with other Hologic products as specified in their labeling.

Materials Provided

50 Aptima Unisex Swab Specimen Collection Kits for Endocervical and Male Urethral Swab Specimens (Cat. No. 301041)

Each kit contains:

Component	Quantity	Description
Unisex collection swab	1	Swab for endocervical or male urethral swab specimens.
Cleaning swab	1	Female cleaning swab.
Transport tube	1	Tube containing swab transport medium (2.9 mL).

Warnings and Precautions

A. Do not apply the transport medium directly to skin or mucous membranes or take internally.

Note: Hazard Communication reflects the EU Safety Data Sheets (SDS) classifications. For hazard communication information specific to your region, refer to the region specific SDS on the Safety Data Sheet Library at www.hologicsds.com.

Kit Storage Requirements

Store collection kit at room temperature (15°C to 30°C).

Swab Specimen Performance

The assay performance characteristics of the female endocervical and male urethral swab specimens are provided in the appropriate Aptima assay package insert. The Aptima assay package inserts may be referenced online at www.hologic.com. The performance of the male urethral swab specimen has not been established for all Aptima assays.

4o. Aptima™ Urine Specimen Collection Kit for Male and Female Urine Specimens (AW-26251-001 Rev. 001)**Intended Use**

The Aptima™ Urine Specimen Collection Kit for Male and Female Urine Specimens is for use with Aptima assays. The Aptima Urine Specimen Collection Kit is intended to be used for the collection and transport of male or female urine specimens.

Materials Provided**50 Aptima Urine Specimen Collection Kits for Male and Female Urine Specimens (Cat. No. 301040)**

Each kit contains:

Component	Quantity	Description
Pipette	1	Disposable transfer pipette.
Specimen transport tube	1	Tube containing 2.0 mL Urine Transport Medium (UTM).

Warnings and Precautions

A. Do not apply the transport medium directly to skin or mucous membranes or take internally.

Note: Hazard Communication reflects the EU Safety Data Sheets (SDS) classifications. For hazard communication information specific to your region, refer to the region specific SDS on the Safety Data Sheet Library at www.hologicds.com.

Kit Storage Requirements

Store collection kit at room temperature (15°C to 30°C).

4p. Aptima® Multitest Swab Specimen Collection Kit (AW-26253-001 Rev. 001)**Intended Use**

The Aptima® Multitest Swab Specimen Collection Kit is intended to be used for collection of the following swab specimen types: vaginal, rectal, throat, penile meatal, and lesions. Refer to the appropriate assay package insert for appropriate specimen types.

Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated.

The Aptima Multitest Swab Specimen Collection Kit for Multitest Swab Specimens is also intended for use with other clinical specimen material for processing, extraction, and analysis with other Hologic products as specified in their labeling.

Materials Provided**50 Multitest Swab Specimen Collection Kits (Cat. No. PRD-03546)**

Each kit contains:

Component	Quantity	Description
Swab	1	Individually wrapped, sterile swab
Transport tube	1	Tube containing Specimen Transport Medium (STM), 2.9 mL

Kit Storage Requirements

Store collection kit at room temperature (15°C to 30°C).

Multitest Swab Specimen Performance

Assay performance characteristics using the Multitest swab specimens are provided in the appropriate Aptima assay package insert. The Aptima assay package inserts may be referenced online at www.hologic.com. The performance of the patient-collected vaginal swab specimen, patient-collected penile meatal swab specimen, rectal swab specimen, and throat swab specimen, has not been established for all Aptima assays.

When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification of each specimen.

4q. Specimen Lysis Tubes (AW-26255-001 Rev. 001)**Intended Use**

Specimen Lysis Tubes are intended to be used for processing specimens for use with Hologic® assays. Refer to the applicable assay package insert for appropriate Specimen Lysis Tubes and specimen types authorized for use with each assay.

Materials Provided**Available Products**

Component	Quantity	Description	Cat. No.
Panther Fusion® Specimen Lysis Tube	100 each	1 tube containing 0.71 mL of Specimen Transport Media (STM) with a penetrable cap	PRD-04339
Hologic® Specimen Lysis Tube	100 each	1 tube containing 0.71 mL of Specimen Transport Media (STM) with a solid cap	PRD-06554

Materials Required but not Provided

Note: Materials available from Hologic have catalog numbers listed, unless otherwise specified.

	<u>Cat. No.</u>
P1000 pipettor and tips with hydrophobic plugs for the transfer of specimen from the primary collection container to the Specimen Lysis Tube	—
Pipet or repeat pipettor capable of 0.78 mL ± 0.07 mL dispense for preparation of Custom Specimen Lysis Tubes only	—
Hologic Solid Cap for use with PRD-06554*, 100 caps per bag <i>*a single-use cover for the Hologic Specimen Lysis Tube (PRD-06554 only) after testing as part of the uncapped workflow</i>	PRD-06744
Fisherbrand VersaClosure Tube Closures*, 1000 per pack <i>*a single-use tube cover for the Hologic Specimen Lysis Tube (PRD-06554 only) after testing as part of the uncapped workflow</i>	02-707

Warnings and Precautions

Do not apply the transport medium directly to skin or mucous membranes or take internally. For information on any hazards and precautionary statements that may be associated with the specimen lysis tube, refer to the Safety Data Sheet Library at www.hologicsds.com.

Storage Requirements

Store Specimen Lysis Tubes prior to use at room temperature (15°C to 30°C).

Specimen Performance

The assay performance characteristics of the specimens are provided in the appropriate Hologic assay package insert. The Hologic assay package inserts may be referenced online at www.hologic.com.

4r. Aptima® Assay Fluids Kit (Panther® System) (AW-26509-001 Rev. 002)**Materials Provided****Aptima Assay Fluids Kit (Cat No. 303014)**

(Store at 15°C to 30°C upon receipt)

Symbol	Component	Quantity
W	Aptima Wash Solution <i>10 mM HEPES buffered solution containing less than 2% preservative.</i>	1 x 2.9 L
O	Aptima Oil Reagent <i>Silicone oil.</i>	1 x 260 mL
DF	Aptima Buffer for Deactivation Fluid <i>800 mM Bicarbonate buffered solution.</i>	1 x 1.4 L

Warnings and Precautions

- A. Use routine laboratory precautions.
- B. For professional use.
- C. Avoid microbial and ribonuclease contamination of Aptima Assay Fluids.

Storage and Handling Requirements

- A. Store unopened Aptima Assay Fluids at 15°C to 30°C.
- B. Once opened, Aptima Assay Fluids are stable for 60 days.
- C. Do not use after the expiration date.
- D. Some reagents of this kit are labeled with risk and safety symbols.

4s. Panther Fusion® Open Access™ RNA/DNA Enzyme Cartridge (AW-26511-001 Rev.001)**Materials Provided**

Note: Hazard Communication reflects the EU Safety Data Sheets (SDS) classifications. For hazard communication information specific to your region, refer to the region specific SDS on the Safety Data Sheet Library at www.hologicsds.com.

Catalog Number: PRD-04303

Open Access Refrigerated Reagents (2° to 8°C):

Open Access RNA/DNA Enzyme Cartridge (12 tests per cartridge) 12 x 0.024 mL
Reverse transcriptase and DNA polymerase dried in HEPES buffered lyophilized solution containing < 10% bulking reagent.

Storage and Handling Requirements

A. The following table provides storage and handling requirements for the cartridge.

Reagent	Unopened Storage	On-board/Open Stability¹	Opened Storage
Open Access RNA/DNA Enzyme Cartridge	2°C to 8°C	60 days	2°C to 8°C ²

When reagents are removed from the Panther Fusion System, return them immediately to their appropriate storage temperatures.

¹ On-board stability starts at the time the reagent is placed on the Panther Fusion System.

² If removed from the Panther Fusion System, store the cartridge in an air-tight container with desiccant at the recommended storage temperature.

- B. Discard any unused reagents that have surpassed their on-board stability.
- C. Avoid cross-contamination during reagent handling and storage.
- D. Do not freeze reagents.
- E. Do not use the cartridge if the storage pouch has lost its seal or if the enzyme cartridge foil is not intact.
- F. Do not use the reagents after the expiration date.

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4t. Panther Fusion® Open Access General Purpose Reagents (AW-26514-001 Rev. 001)**Materials Provided**

Note: Hazard communication information for labeling of globally marketed products reflects the US and EU Safety Data Sheets (SDS) classifications. For hazard communication information specific to your region, refer to the region specific SDS on the Safety Data Sheet Library at www.hologicsds.com.

Panther Fusion General Purpose Reagents

Specimen Transport Medium	1 x 80 mL	PRD-04423
Urine Transport Medium	1 x 80 mL	PRD-04943
Blood Transport Medium	1 x 80 mL	PRD-04944
Panther Fusion Open Access Diluent Additive	1 x 1 mL	PRD-04945
Panther Fusion Oil	2 x 38 mL	PRD-04335
Oil Reagent	1 x 24.6 mL	PRD-04304

Storage and Handling Requirements

- A. Store unopened Specimen Transport Medium, Urine Transport Medium, Blood Transport Medium, Panther Fusion Oil, and Oil Reagent at 15°C to 30°C. Store unopened Panther Fusion Open Access Diluent Additive at -85°C to -15°C.
- B. Once opened, Panther Fusion Oil, and Oil Reagent are stable for 60 days when capped and stored at their intended storage conditions. Testing of the prepared working diluents, i.e., STM, UTM, or BTM, combined with the Panther Fusion Open Access Diluent Additive has demonstrated stability at room temperature up to 30 days. Customers are recommended to determine stability in consideration of a specific assay performance and use case.
- C. Discard any unused reagents that have surpassed their stability.
- D. Avoid cross-contamination during reagent handling and storage.
- E. Do not freeze the Panther Fusion Open Access General Purpose Reagents, except for the Panther Fusion Open Access Diluent Additive that must be stored frozen.