PHARMALINE

ONCOLOGY | MICROBIOLOGY | MEDICAL GENETICS

MOLECULAR BIOLOGY RESEARCH AND LABORATORY REAGENTS

PRODUCT CATALOG

2026

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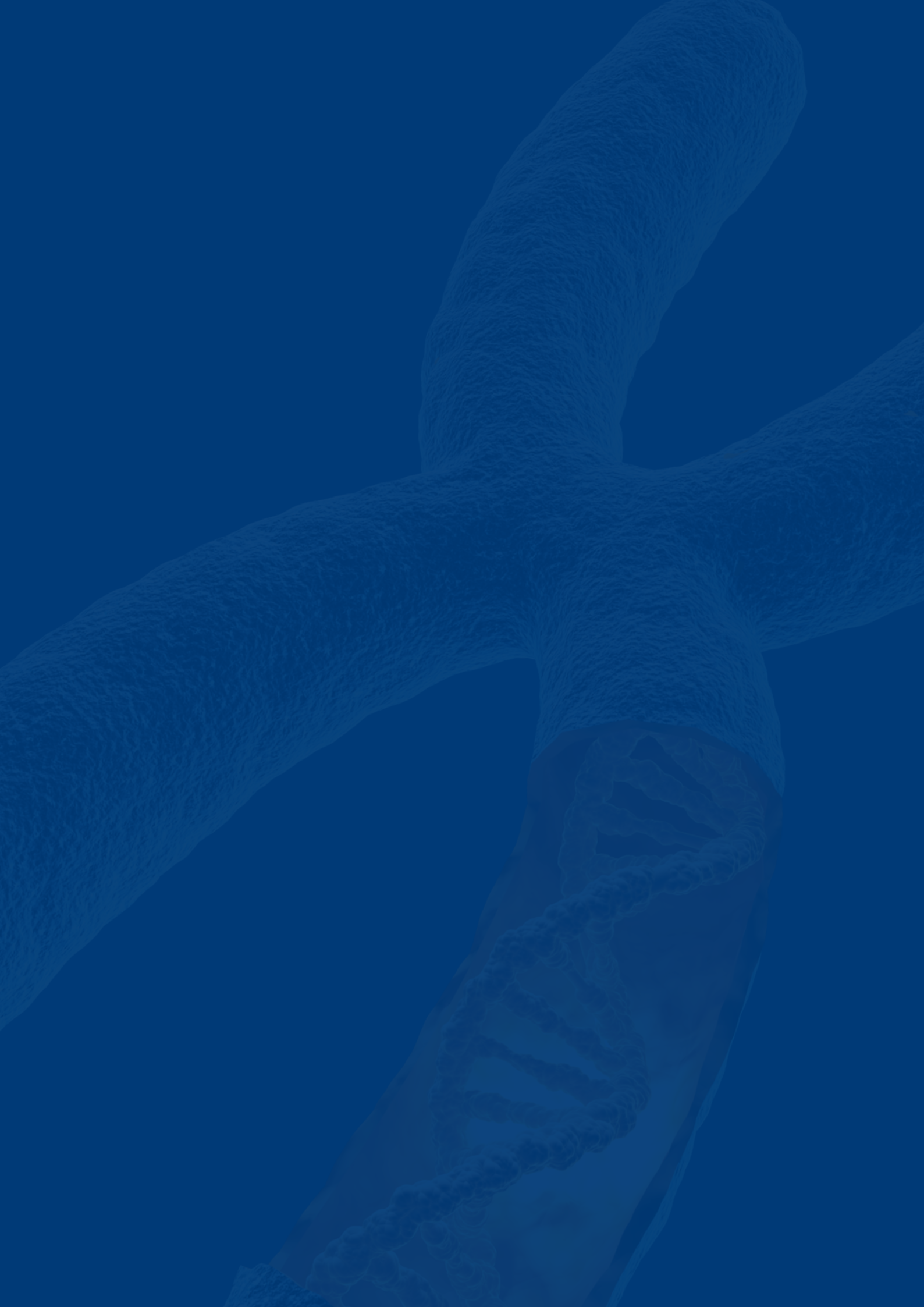


PHARMALINE MOLECULAR BIOLOGY REAGENTS

PharmaLine Healthcare Services Industry and Trade Inc.

PHARMALINE offers solutions that meet global standards in the field of molecular biology, in vitro diagnostics (IVD), and high-purity chemical reagents.
All our products are manufactured in cGMP certified facilities and in accordance with ISO 9001/ISO 13485 guidelines to guarantee the highest purity and consistency, from disease diagnosis to scientific project executions and clinical research.
Our manufacturing philosophy is to ensure the reliability and reproducible results that form the foundation of your laboratory work.

About Us

Our vision is to generate value in the field of molecular diagnostics through innovative products. As PharmaLine Healthcare Services Industry and Trade Inc., we are a reliable partner in your research, having completed our quality standard-based certifications.
Our Core Commitment:

- cGMP Manufacturing Standards: We manufacture products developed in our own R&D laboratory using robotic production lines, in compliance with international quality standards, and distribute them.
- Focus and Speed: Our focus is on the needs of patients and healthcare professionals. Thanks to our dynamic structure, we act agilely to achieve business goals and provide quick solutions.

Our goal is to ensure that our products contribute to solving patients' health problems.
problems and make the lives of their relatives easier.

PRODUCT CATALOG

Reagents for Molecular Biology Research

CONTENTS

PHARMALINE

ONCOLOGY | MICROBIOLOGY | MEDICAL GENETICS

PHARMALINE

ONCOLOGY | MICROBIOLOGY | MEDICAL GENETICS

01

Molecular Kits & IVD Products

MultiPatogen

CE IVD

MultiPatogen RespiroScan-4 RT-qPCR Kit Cat No: PHMP4-1000

Product Overview and Targets

The MultiPatogen RespiroScan-4 Kit is developed for the rapid and accurate diagnosis of viral agents in nucleic acid isolates obtained from clinical specimens (e.g., nasopharyngeal swabs, sputum). The kit operates via single-step RT-qPCR, targeting specific genomic RNA regions.

It simultaneously detects critical respiratory pathogens using **4-channel** instruments:

- SARS COV-2 ORF1ab (FAM)
- Influenza A&B (HEX)
- Respiratory Syncytial Virus (RSV) A/B (ROX)
- Internal Control (IC): Human RNaseP gene (CY5) for controlling specimen quality and inhibition.

Key Features

- Speed: Diagnosis can be completed in less than 1 hour (validated with Bio-Rad CFX96 Touch).
- Sensitivity: Provides excellent analytical performance, determined using synthetic pUC57 plasmid.
- Reliability: Includes Negative Control (NTC) and Positive Control (PC) for contamination and reagent stability control in every run.
- Certification: CE IVD marked and strictly for professional in vitro diagnostic use.

Storage

- Storage Temperature: Stable between (-15°C) and (-25°C)
- Shelf Life: 12 months.

MultiPatogen

CE IVD

MultiPatogen RespiroScan-4 RT-qPCR Kit **Cat No: PHMP4-1000**

Validation Data

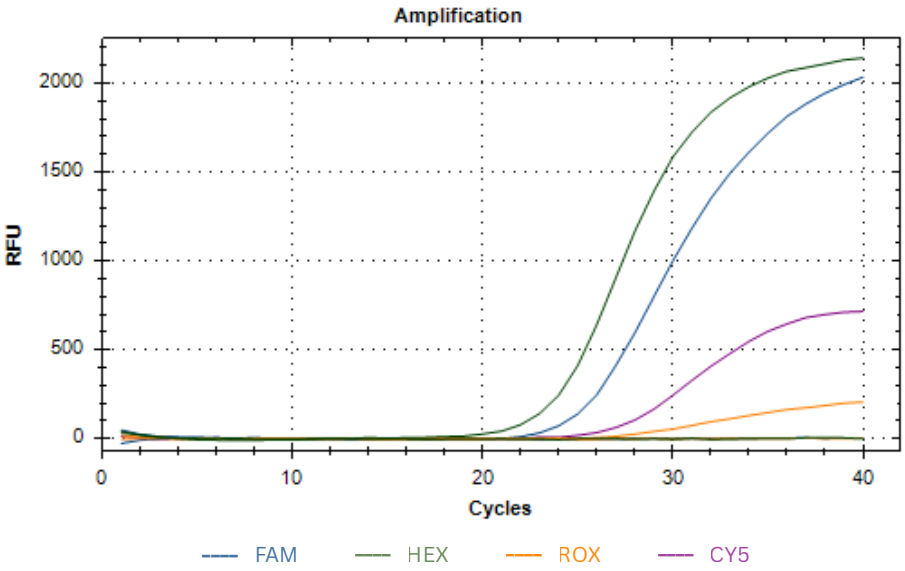


Figure 1. Positive Amplification Profile: The plot demonstrates specific signal accumulation exceeding the threshold in at least one of the target channels: FAM (SARS-CoV-2 ORF1ab), HEX (Influenza A&B), or ROX (RSV A/B). Detected positivity in target channels is diagnostically valid, regardless of the CY5 (Internal Control - RNase P) signal.

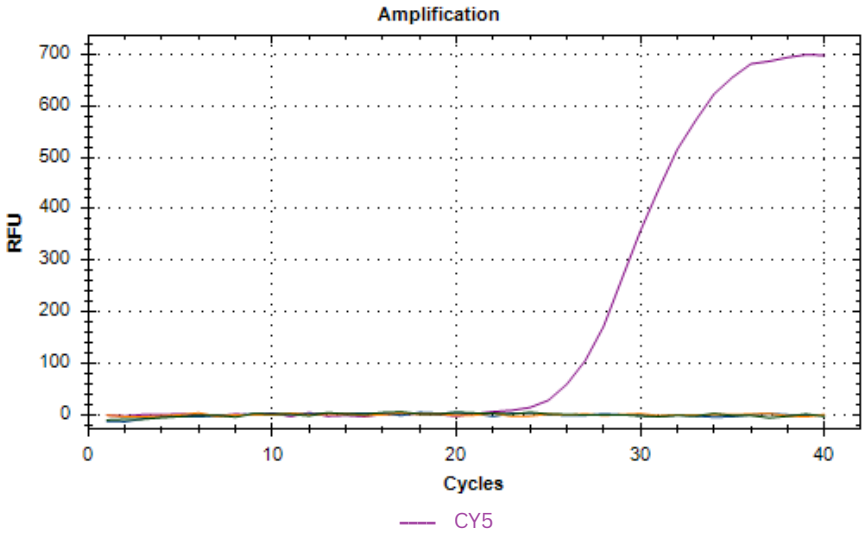


Figure 2. Negative Amplification Profile: No specific amplification was detected across the FAM, HEX, or ROX target channels. Analytical validity and sample integrity are confirmed by the positive signal in the CY5 (Internal Control - RNase P) channel. If all channels remain negative, the test is considered invalid and must be repeated.

UniPatogen

CE IVD

UniPatogen CerviDX12 HPV Genotyping Kit Cat No: PHCDX12-250

Product Overview and Targets

The CerviDX12 HPV Genotyping Kit is developed for the rapid and accurate diagnosis of viral agents in nucleic acid isolates obtained from clinical specimens such as cervical, penis, and vaginal swabs. The kit targets specific genomic DNA regions of the pathogen using real-time PCR (qPCR).

This kit simultaneously detects **12 high-risk HPV types** using **4-channel** qPCR instruments. The kit uses a proprietary mix structure to assign the following high-risk types to specific channels:

- FAM Channel Targets: HPV 39, HPV 33, HPV 51, HPV 66
- HEX Channel Targets: HPV 52, HPV 6/11, HPV 56, HPV 58
- ROX Channel Targets: HPV 35, HPV 68, HPV 31, HPV 59
- Internal Control (IC): Human RNase P gene (CY5 Channel) for controlling specimen quality and inhibition.

Key Features

- Speed: Diagnosis can be completed in less than 1 hour using validated instruments like the Bio-Rad CFX96 Touch.
- Multiplex Genotyping: Offers simultaneous detection and genotyping of 12 distinct HPV types, essential for clinical risk assessment.
- Analytical Performance: Pre-clinical optimization and validation were performed using positive control clones from the Karolinska Institute's International Human Papillomavirus Reference center, ensuring high specificity and reliability.
- Reliability: Includes Negative Control (NTC) and Positive Control (PC) for contamination and reagent stability control in every run.
- Certification: CE IVD marked and strictly for professional in vitro diagnostic use only.

Technical Details and Storage

- Kit Components: The kit consists of a 2X Master Mix (containing DNA polymerase, dNTP mix, reaction buffer) and four distinct Primer Mixes.
- Storage Temperature: Stable between (-15°C) and (-25°C)
- Shelf Life: 12 months.

UniPatogen

CE IVD

UniPatogen CerviDX12 HPV Genotyping Kit **Cat No: PHCDX12-250**

Validation Data

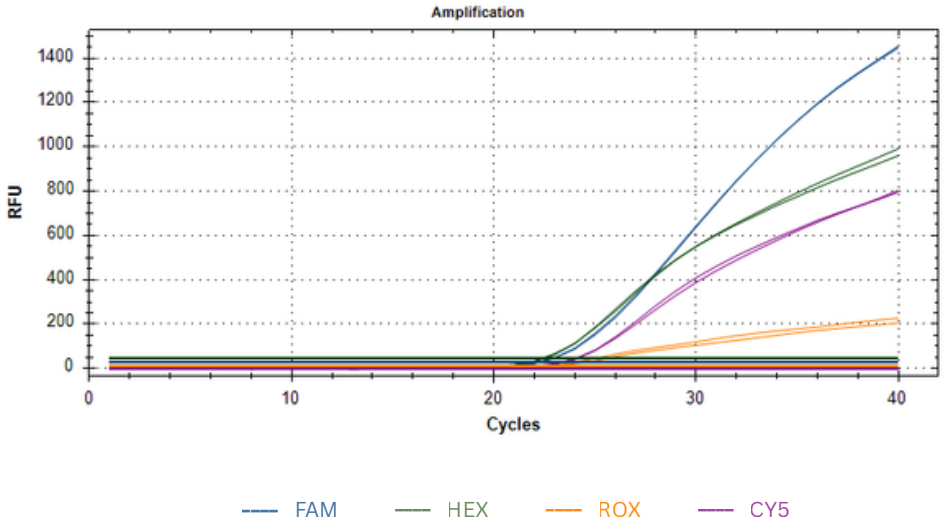


Figure 1. Positive Amplification Profile: The plot demonstrates specific signal accumulation exceeding the threshold in at least one of the target channels (FAM: 39, 33, 51, 66; HEX: 52, 6/11, 56, 58; ROX: 35, 68, 31, 59). Detected positivity in the target channels is considered diagnostically valid, independent of the CY5 (RNase P) internal control signal.

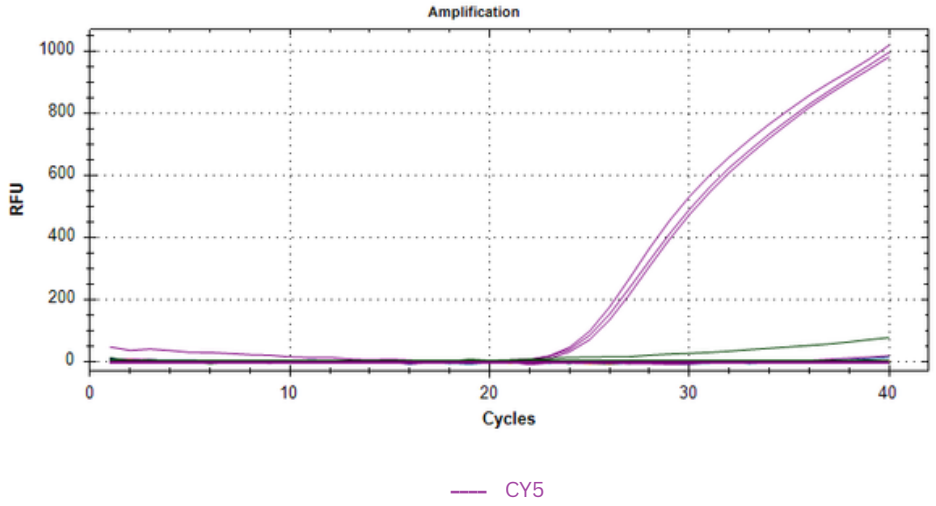


Figure 2. Negative Amplification Profile: No signal increase was detected in the target channels (FAM, HEX, ROX). The extraction quality and PCR performance are confirmed by the positive signal in the CY5 (RNase P) internal control channel. Instances where all channels are negative are considered invalid, and the test must be repeated.

UniPatogen

CE IVD

UniPatogen CerviDX15 HPV Genotyping Kit Cat No: PHCDX15-250

Product Overview and Targets

The CerviDX15 HPV Genotyping Kit is an in vitro diagnostic tool designed for the rapid and accurate diagnosis of viral agents in nucleic acid isolates obtained from cervical, penis, and vaginal swab specimens. The kit operates on the principle of real-time PCR (qPCR), targeting specific genomic DNA regions.

This kit performs simultaneous detection and genotyping of 15 high-risk HPV types using 4-channel qPCR instruments. The kit uses a proprietary primer-probe mix structure to assign the following high-risk types to specific channels:

- FAM Channel Targets: HPV 39, HPV 33, HPV 51, HPV 66, **HPV 16**
- HEX Channel Targets: HPV 52, HPV 6/11, HPV 56, HPV 58, **HPV 18**
- ROX Channel Targets: HPV 35, HPV 68, HPV 31, HPV 59, **HPV 45**
- Internal Control (IC): Human RNase P gene (CY5 Channel) for controlling specimen quality and inhibition.

Key Features

- Speed: Diagnosis can be completed in less than 1 hour (validated with Bio-Rad CFX96 Touch).
- Comprehensive Genotyping: Offers simultaneous detection and genotyping of 15 distinct high-risk HPV types.
- Analytical Performance: Pre-clinical optimization and validation were performed using positive control clones from the Karolinska Institute's International Human Papillomavirus Reference center , confirming high sensitivity, specificity, and linearity.
- Reliability: Includes Negative Control (NTC) and Positive Control (PC) for contamination and reagent stability control.
- Certification: CE IVD marked and strictly for professional in vitro diagnostic use only.

Technical Details and Storage

- Sample Type: Nucleic acid isolates from cervical, penis, and vaginal swabs.
- Storage Temperature: Stable between (-15°C) and (-25°C)
- Shelf Life: 12 months.

UniPatogen

CE IVD

UniPatogen CerviDX15 HPV Genotyping Kit **Cat No: PHCDX15-250**

Validation Data

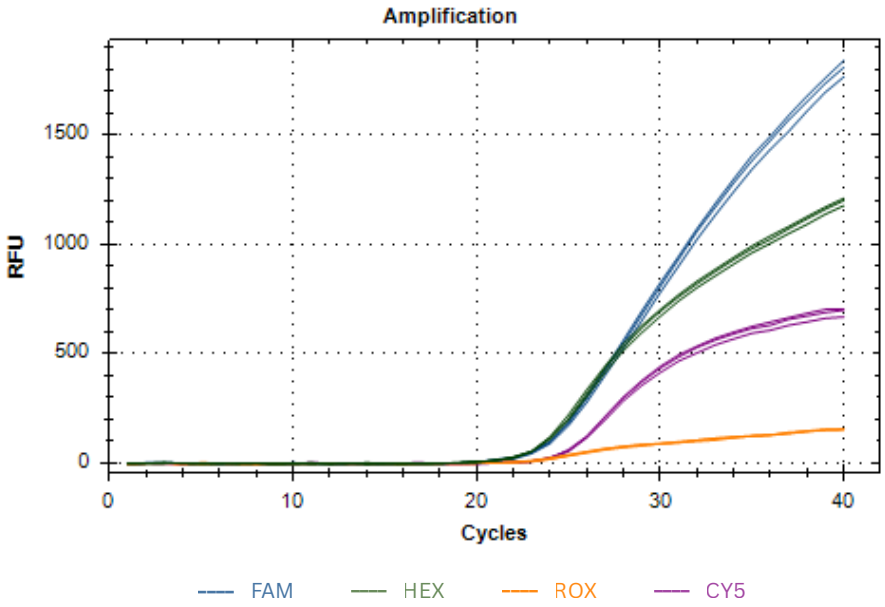


Figure 1. Positive Amplification Profile: The plot demonstrates specific signal accumulation exceeding the threshold in at least one of the target channels (FAM: 39, 33, 51, 66, 16; HEX: 52, 6/11, 56, 58, 18; ROX: 35, 68, 31, 59, 45). Detected positivity in the target channels is considered diagnostically valid, independent of the CY5 (RNase P) internal control signal.

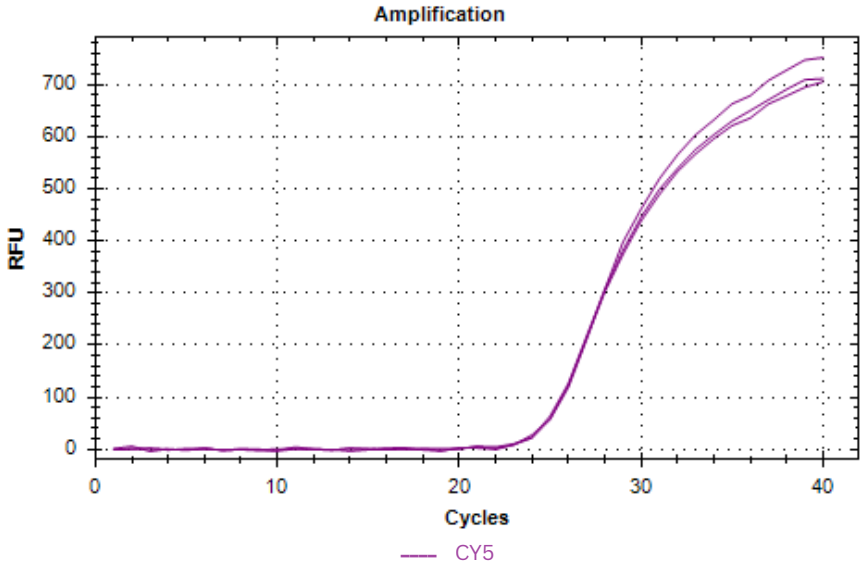


Figure 2. Negative Amplification Profile: No signal increase was detected in the target channels (FAM, HEX, ROX). The extraction quality and PCR performance are confirmed by the positive signal in the CY5 (RNase P) internal control channel. Instances where all channels are negative are considered invalid, and the test must be repeated.

Xplogen

CE IVD

Xplogen SMA qPCR Screening Kit **Cat No: PHSMA2024-100/1000**

Product Overview and Targets

The Xplogen SMA qPCR Screening Kit is an in vitro diagnostic tool designed for the detection of Spinal Muscular Atrophy (SMA). SMA is an autosomal recessive disease caused by mutations in the SMN1 (Survival Motor Neuron) gene. Approximately 95% of SMA patients lack both copies of SMN1 exon 7.

This kit utilizes Quantitative Real Time PCR (qPCR) to detect the C/T change at the 840th nucleotide of SMN1 Exon 7, distinguishing it from the SMN2 gene. It works on the principle of Copy Number Variation (CNV) analysis using the ΔΔCt method.

Detected Targets and Genotyping

This kit performs the detection of autosomal recessive SMA disease using 4-channel qPCR instruments, utilizing two primary channels for analysis:

- FAM Channel Target: SMN1 Exon 7 (Target Gene for Deletion Status detection)
- HEX Channel Target: Human Actin-β gene (Internal Reference Gene for normalization)

The kit determines copy number variation (CNV) based on the ΔΔCt method to classify the genotype:

- Healthy: ΔΔCt> 0.5 (2 copies Exon 7)
- Carrier/Heterozygous: 0.01-0.5 (1 copy Exon 7)
- Patient/Homozygous Deletion: 0-0.01 (0 copies Exon 7)

Key Features

- Dedicated Analysis **Software**: The kit is supported by **proprietary software** for automated ΔΔCt calculation and highly accurate result interpretation.
- High Performance: Designed to achieve a minimum of 98% specificity and 98% sensitivity.
- Sample Type: Applied to genomic DNA isolated from Whole Blood samples of individuals suspected of being carriers.
- CNV Analysis: Provides quantitative copy number determination of the SMN1 Exon 7 deletion.
- Reliability: Includes Negative Control (NTC) and Positive Control (PC) for contamination and reagent stability control.
- Certification: CE IVD marked and strictly for professional in vitro diagnostic use only.

Technical Details and Storage

- Kit Components: Contains 2X Master Mix (DNA polymerase, dNTP mix, ribonuclease inhibitor) and Primer Mix (SMN1 Exon 7 and Human Actin-β specific probes).
- Storage Temperature: Stable between (-15°C) and (-25°C)
- Shelf Life: 12 months.

Xplogen

CE IVD

Xplogen SMA qPCR Screening Kit **Cat No: PHSMA2024-100/1000**

Validation Data

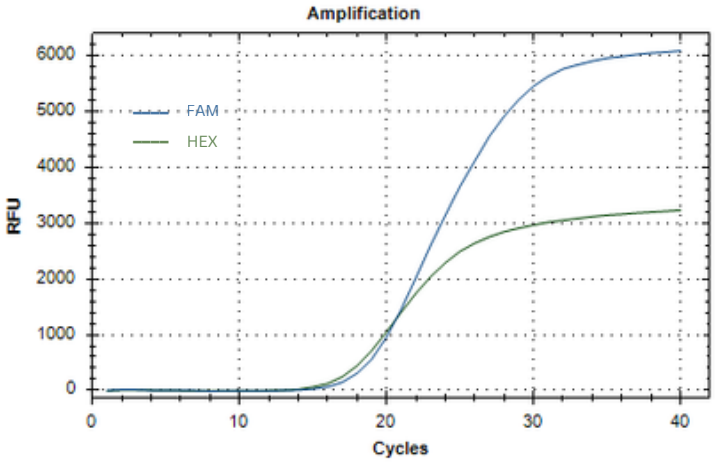


Figure 1. Healthy Genotype Profile: The plot demonstrates strong amplification in both the FAM (SMN1 Exon 7) and HEX (Actin-β) channels. A ΔΔCt Ct > 0.5 confirms the presence of two SMN1 copies, indicating a healthy genotype.

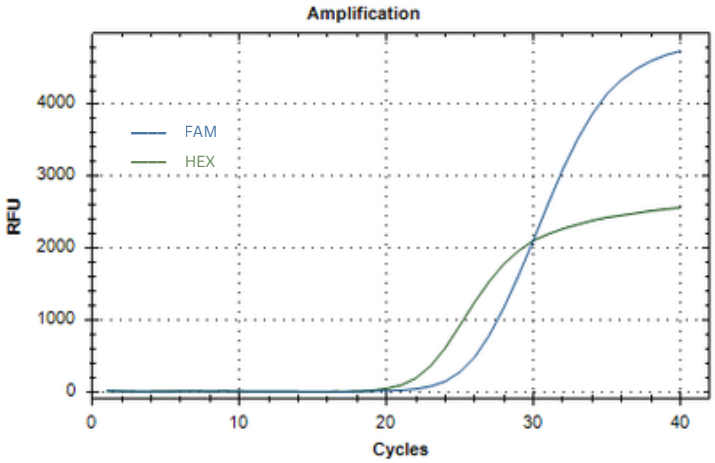


Figure 2. Carrier (Heterozygous) Profile: The plot reflects a single-copy deletion of SMN1. While the HEX (Actin-β) channel amplifies normally, the FAM channel shows a delayed signal. A ΔΔCt value between 0.01 and 0.5 classifies the individual as an SMA carrier.

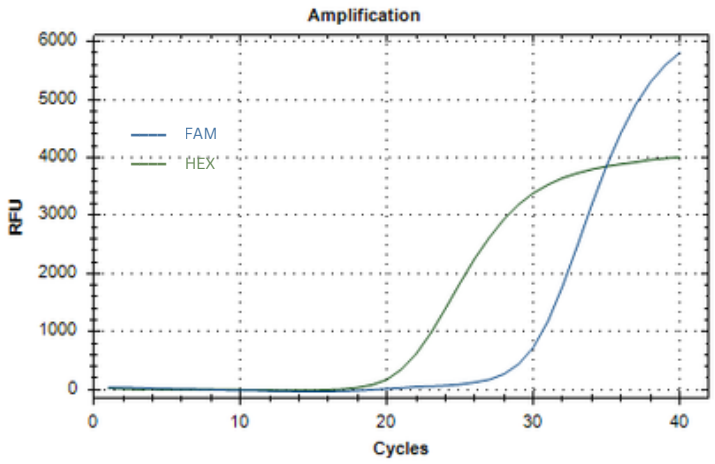


Figure 3. Patient (Homozygous Deletion) Profile: The plot shows a complete absence of SMN1 Exon 7 amplification in the FAM channel, while the HEX (Actin-β) channel remains positive for normalization. A ΔΔCt value between 0 and 0.01 confirms an SMA diagnosis.

UniPatogen

CE IVD

CerviPan HPV qPCR Screening Kit **Cat No:PHCPN50/100/250/500/1000**

Product Overview and Targets

The CerviPan HPV qPCR Screening Kit is an in vitro diagnostic tool designed for the rapid and accurate diagnosis of viral agents in nucleic acid isolates obtained from cervical swab specimens. The kit operates on the principle of real-time PCR (qPCR), targeting specific genomic DNA regions of the pathogen. It is applied to samples from women suspected of having an illness by healthcare providers.

This kit performs a comprehensive screening for high-risk HPV types using **4-channel** qPCR instruments, utilizing a two-mix structure (Primer Mix 1 and Primer Mix 2) to cover a broad spectrum of oncogenic risk:

- Primer Mix 1 utilizes four different channels (FAM, HEX, ROX, CY5) to detect HPV 16, HPV 18, and HPV 45, along with the Internal Control (IC).
- Primer Mix 2 utilizes the FAM and HEX channels to detect additional high-risk types, including HPV 31, 33, 35, 39, 51, 52, 56, 58, 59, 66, and 68. This mix also includes the Internal Control (IC).
- Internal Control (IC): Both mixes contain the Human RNase P gene to control for specimen quality.

Key Features

- Speed: Diagnosis can be completed in less than 1 hour (validated with Bio-Rad CFX96 Touch).
- Broad Screening: Provides wide coverage for critical high-risk HPV types across two mixes.
- Analytical Performance: Pre-clinical optimization and validation were performed using positive control clones from the Karolinska Institute's International Human Papillomavirus Reference Center, confirming high sensitivity, specificity, and linearity.
- Reliability: Includes Negative Control (NTC) and Positive Control (PC) for contamination and reagent stability control.
- Certification: CE IVD marked and strictly for professional in vitro diagnostic use only.

Technical Details and Storage

- Sample Type: Nucleic acid isolates from cervical swabs.
- Storage Temperature: Stable between (-15°C) and (-25°C)
- Shelf Life: 12 months.

UniPatogen

CE IVD

CerviPan HPV qPCR Screening Kit

Validation Data

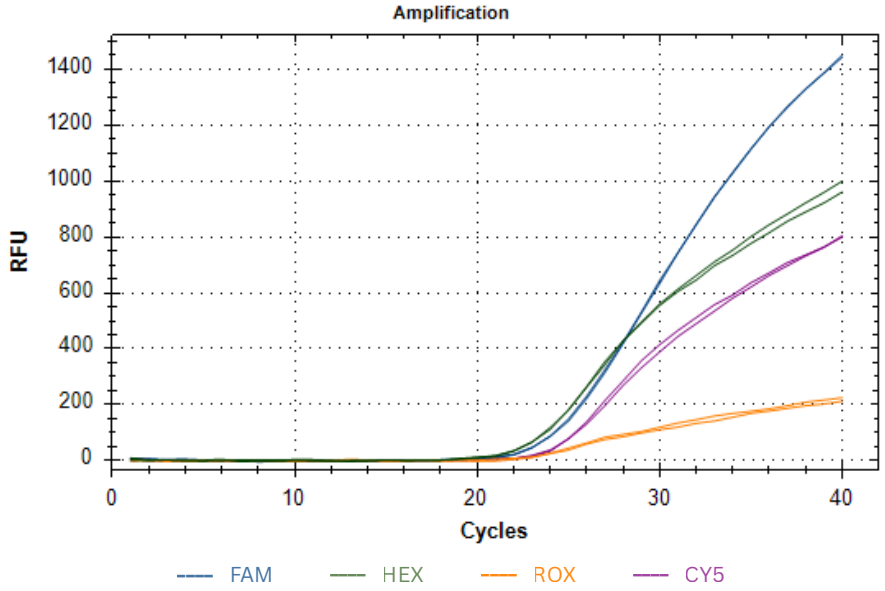


Figure 1. Primer Mix-1 (Types 16, 18, 45): Positive results are indicated by FAM (+) for HPV 16, HEX (+) for HPV 18, and ROX (+) for HPV 45. When all target channels are negative, Cy5 (Internal Control) must be positive; otherwise, the test is invalid. If any target channel is positive, the result is considered valid even if the IC is negative.

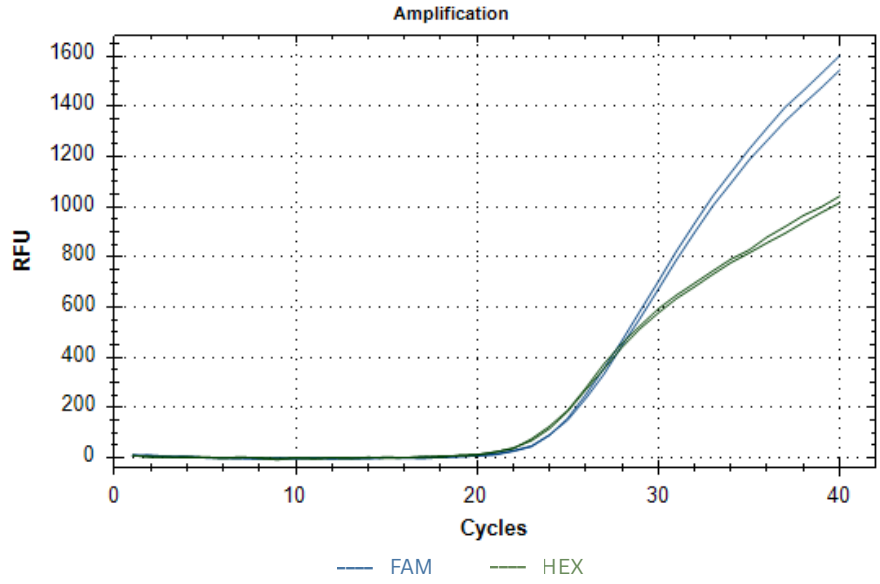


Figure 2. Primer Mix-2 (Other High-Risk Types): A FAM (+) result indicates positivity for at least one of the following HPV types: 31, 33, 35, 39, 51, 52, 54, 56, 58, 59, 66, and 68. When FAM is negative, HEX (Internal Control) must be positive. If both channels are negative, the test is considered invalid.

UniPatogen

CE IVD

UniPatogen CoviScope RT-qPCR Kit **Cat No: PHMCVSP-100/1000**

Product Overview and Targets

The Unipatogen CoviScope RT-qPCR Kit is an in vitro diagnostic tool designed for the qualitative detection of the genomic RNA of the SARS-CoV-2 coronavirus, the causative agent of COVID-19. It utilizes a specific Taqman probe system.

The kit is applied to nucleic acid isolates obtained from clinical specimens, including nasopharyngeal swabs, oropharyngeal swabs, bronchoalveolar lavage, nasopharyngeal aspirates, and sputum. The diagnosis is performed using a single-step Reverse Transcription (RT) and real-time PCR (qPCR) method (RT-qPCR) targeting specific genomic RNA regions.

This solution simultaneously targets the following genes using 2-channel qPCR instruments:

- SARS COV-2 (ORF1ab & N genes) (FAM)
- Internal Control (IC): Human RNaseP gene (HEX) for controlling specimen quality and potential qPCR inhibition.

Key Features

- Speed: Diagnosis can be completed in less than 1 hour (validated with Bio-Rad CFX96 Touch).
- Dual Target Detection: Targets two key regions of the SARS-CoV-2 genome (ORF1ab & N) for robust confirmation.
- Analytical Performance: Performance studies were carried out using synthetic SARS-CoV-2 RNA fragments, demonstrating high analytical quality ($R^2 = 0.9909$).
- Reliability: Includes Negative Control (NTC) and Positive Control (PC) for contamination and reagent stability control in every run.
- Certification: CE IVD marked and strictly for professional in vitro diagnostic use only.

Technical Details and Storage

- Sample Type: Includes 2X Master Mix (containing DNA polymerase, reverse transcriptase, dNTP mix, and inhibitor) and a Primer Mix.
- Storage Temperature: Stable between (-15°C) and (-25°C)
- Shelf Life: 12 months.

UniPatogen

CE IVD

UniPatogen CoviScope RT-qPCR Kit **Cat No: PHMCVSP-100/1000**

Validation Data

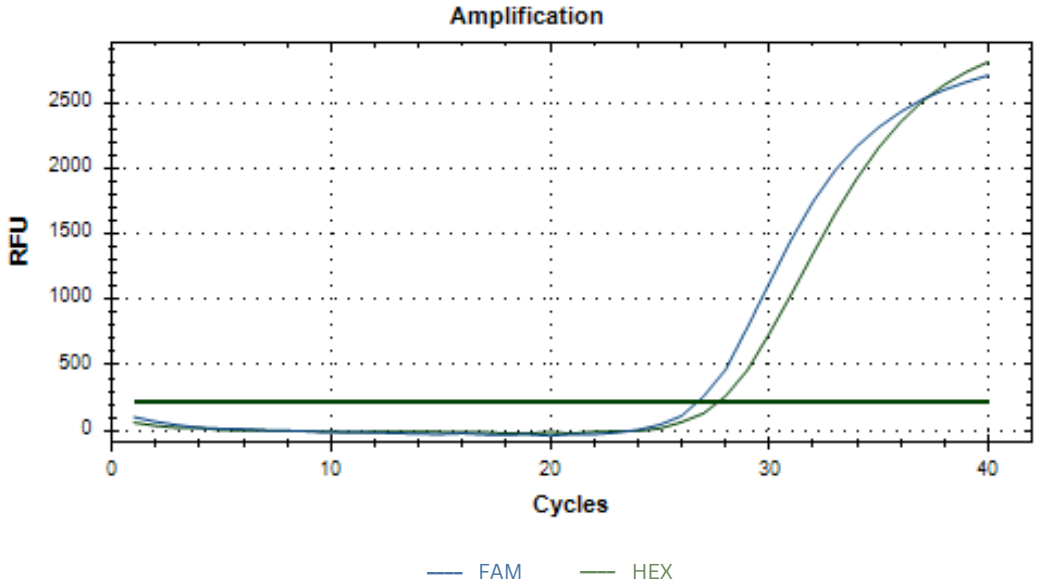


Figure 1. Positive Amplification Profile: The plot demonstrates a specific signal increase exceeding the threshold in the target channel (FAM: SARS-CoV-2 ORF1ab and N genes). Positivity detected in the target channel is diagnostically valid, regardless of the HEX (Internal Control - RNase P) signal.

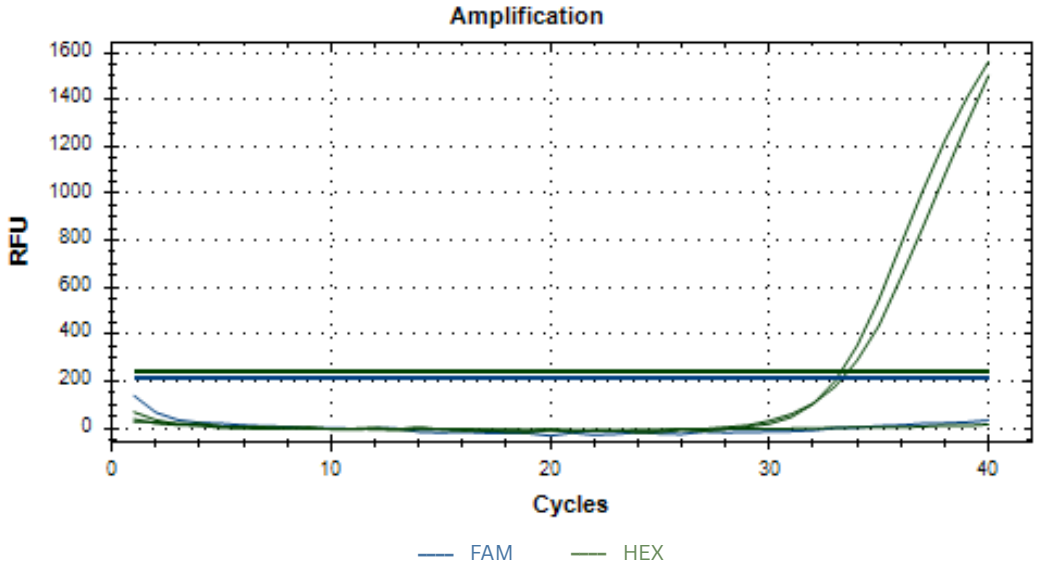


Figure 2. Negative Amplification Profile: No specific signal increase was detected in the target channel (FAM). Analytical validity and sample integrity are confirmed by the positive signal in the HEX (Internal Control - RNase P) channel. If both channels are negative, the test is considered invalid and must be repeated.

MultiPatogen

MultiPatogen TriPorter qPCR Kit **Cat No: PHMPPRT2024- 50/100/250**

Product Overview and Targets

The MultiPatogen TriPorter qPCR Kit is an in vitro diagnostic tool designed for the rapid and accurate diagnosis of bacterial agents. The kit is applied to nucleic acid isolates obtained from nasopharyngeal swabs and stool samples.

Diagnosis is performed using real-time PCR (qPCR), targeting specific genomic DNA regions of the pathogen

This solution simultaneously detects critical bacterial pathogens using 4-channel qPCR instruments, utilizing all four channels for comprehensive analysis:

- Methicillin-Resistant *Staphylococcus aureus* (MRSA) (FAM)
- *Salmonella typhi* (SAL) (HEX)
- Grup A *Streptococcus* (GAS) (ROX)
- Internal Control (IC): Human RNaseP (CY5)

Key Features

- Speed: Diagnosis can be completed in less than 1 hour (validated with Bio-Rad CFX96 Touch).
- Multiplex Detection: Simultaneous detection of three critical bacterial pathogens (MRSA, *Salmonella typhi,* GAS) in a single run.
- Sample Versatility: Validated for use with both respiratory (nasopharyngeal swab) and gastrointestinal (stool) samples.
- Reliability: Includes Negative Control (NTC) and Positive Control (PC) for contamination and reagent stability control in every run.

Storage

- Kit Components: Includes 2X Master Mix and Primer Mix (containing probes for MRSA, SAL, GAS, and IC).
- Storage Temperature: Stable between (-15°C) and (-25°C).
- Shelf Life: 12 months.
- Stool Sample Preparation: Requires the use of PharmaSEP buffer (PHSP2024-50/100) for proper sample extraction.

MultiPatogen

MultiPatogen TriPorter qPCR Kit **Cat No: PHMPPRT2024- 50/100/250**

Validation Data

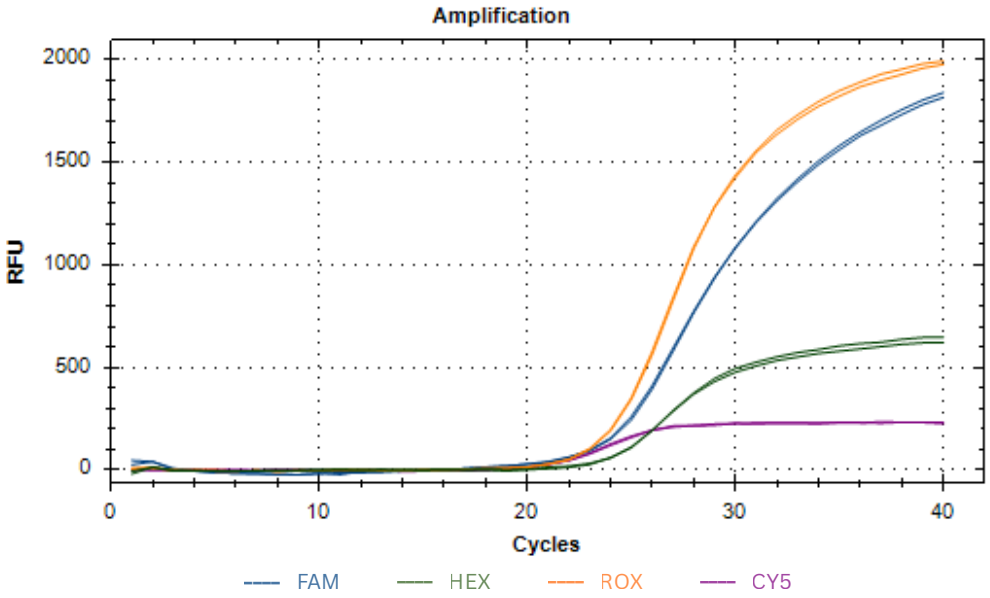


Figure 1. Positive Amplification Profile: The plot demonstrates specific fluorescence accumulation exceeding the threshold in at least one of the target channels: FAM (MRSA), HEX (Salmonella typhi), or ROX (GAS). Detected positivity in target channels is diagnostically valid, regardless of the CY5 (Internal Control - RNase P) signal.

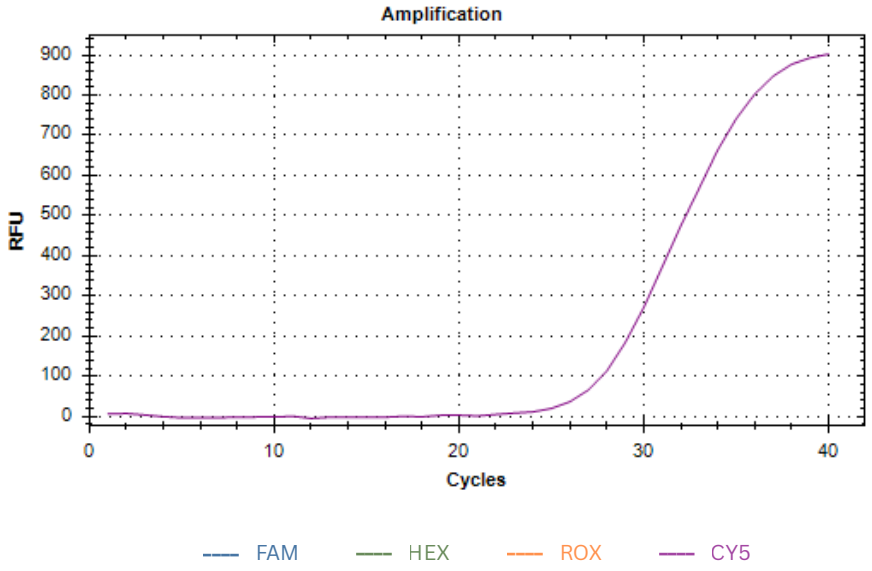


Figure 2. Negative Amplification Profile: No specific signal increase was detected in the FAM, HEX, or ROX target channels. Analytical validity and sample integrity are confirmed by the positive signal in the CY5 (Internal Control - RNase P) channel. If all channels remain negative, the test is considered invalid and must be repeated.

MultiPatogen

MultiPatogen Gastroenteritis qPCR Panel Cat No: PHMPGIS 2023-25/50/100

Product Overview and Targets

The MultiPatogen GIS Gastroenteritis qPCR Panel is an in vitro diagnostic tool designed for the rapid and accurate detection of viral, bacterial, and parasitic agents that cause gastrointestinal system infections. The kit is intended for use with nucleic acid isolates obtained from rectal swabs and stool samples.

Diagnosis is performed using one-step reverse transcription (RT) and Real-Time PCR (qPCR) targeting specific genomic RNA and DNA regions of the pathogens. This panel utilizes all four channels to simultaneously detect multiple pathogens:

- FAM Kanalı: *Astrovirus*, *Norovirus* GI/GII, *Entamoeba histolytica*, *Salmonella spp.*, *Vibrio cholerae*, *Plesiomonas shigelloides, Shigella*/EIEC, EPEC.
- HEX Kanalı: *Rotavirus, Sapovirus, Cryptosporidium sp., Campylobacter spp., Vibrio parahaemolyticus, Clostridium difficile* (Toxin A/B), EAEC, ETEC.
- ROX Kanalı: *Cyclospora cayetanensis, Vibrio vulnificus*, STEC (stx1/stx2), Human Actin (IC).
- CY5 Kanalı: *Adenovirus, Giardia lamblia, Yersinia enterocolitica*, Human RNaseP (IC).

Key Features

- Speed: Diagnosis can be completed in less than 1 hour using validated devices such as the Bio-Rad CFX96 Touch.
- Comprehensive Panel: Provides extensive screening for viral, bacterial, and parasitic gastroenteritis agents within a single kit.
- Flexibility: Optimized for both RT-qPCR and direct qPCR protocols depending on the target type.
- Reliability: Includes Negative Control (NTC) and Positive Control (PC) in every run to monitor contamination and reagent stability.

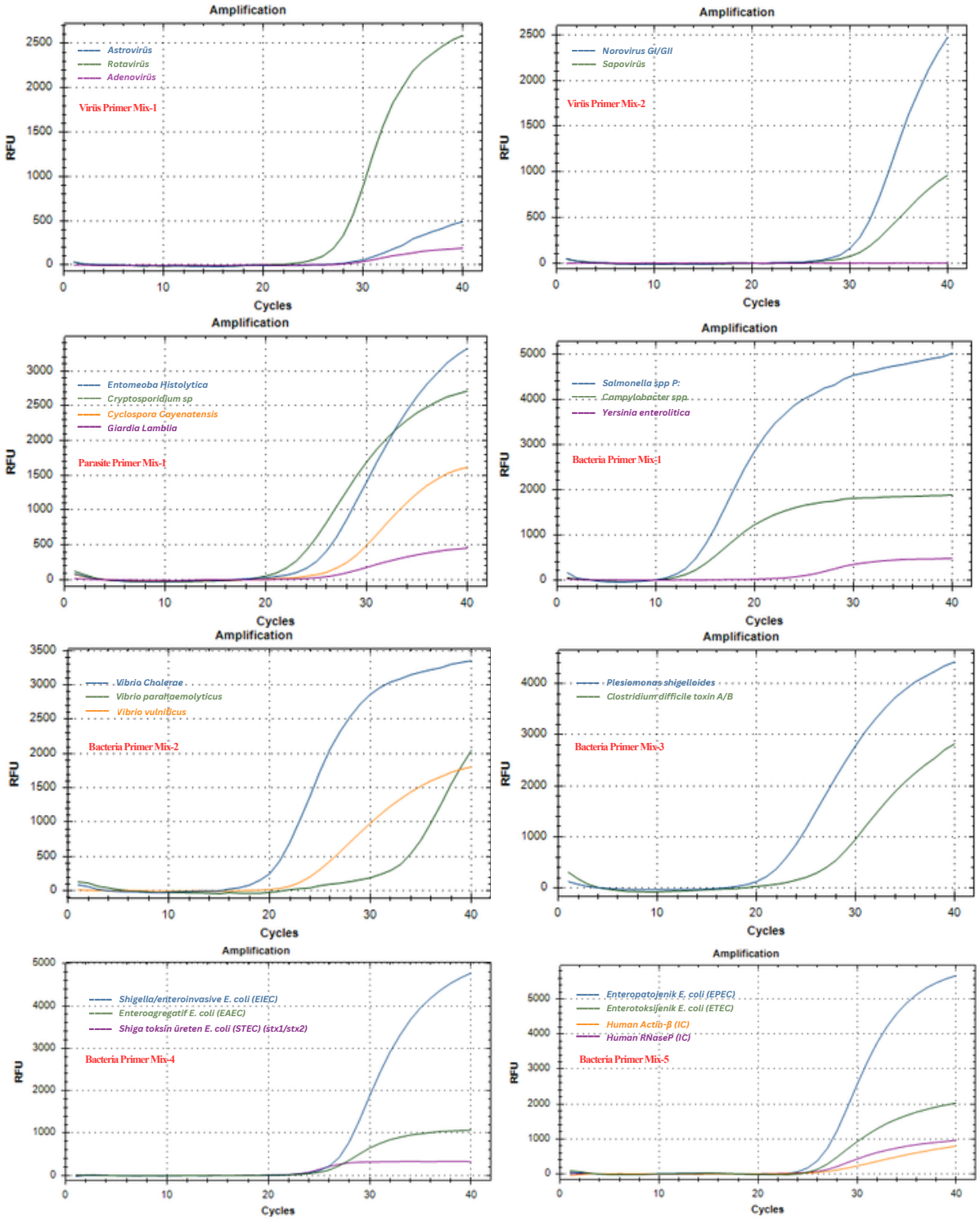
Storage

- Kit Components: Contains 2X Taq Mix, 2X RT Mix, target-specific Primer Mixes, and Control Reagents (PC, NTC).
- Storage Temperature: Stable between (-15°C) and (-25°C).
- Shelf Life: 12 months.
- Validated Devices: Validated for use with Bio-Rad CFX96, Qiagen Rotor-Gene Q, and Thermo Fisher QuantStudio systems.

MultiPatogen

MultiPatogen Gastroenteritis qPCR Panel **Cat No: PHMPGIS 2023-25/50/100**

Validation Data



PHARMALINE®

CE IVD

MonkeyPox qPCR Kit **Cat No: PHMNKY2022-100/500**

Product Overview and Targets

The Pharmaline MonkeyPox qPCR Kit is developed for the rapid and accurate diagnosis of viral agents in nucleic acid isolates obtained from clinical specimens, specifically using swab samples collected from skin lesions. Diagnosis is performed using real-time PCR (qPCR), targeting specific genomic DNA regions of the pathogen.

This solution enables the qualitative detection and genotyping of the MonkeyPox virus.

Detected Targets and Key Advantages

The kit utilizes 4-channel qPCR instruments and specific probes to detect and differentiate the two major MonkeyPox clades:

- Detects the MonkeyPox Generic (G2R) gene, providing general confirmation of the virus's presence. (FAM)
- Detects MonkeyPox Type-2 (Clade-II) (F3L), allowing for the differentiation of the West African Clade. (HEX)
- Detects MonkeyPox Type-1 (Clade-I) (F3L), allowing for the differentiation of the Central African Clade. (ROX)
- Detects the Internal Control (IC) (Human RNaseP gene), which controls for sample quality and PCR inhibition (CY5)

Key Features

- Genotyping Capability: Allows differentiation (genotyping) between the more severe Central African Clade-I and the West African Clade-II.
- Speed: Diagnosis can be completed in less than 1 hour (validated with Bio-Rad CFX96 Touch).
- Reliability: Includes Negative Control (NTC) and Positive Control (PC) for contamination and reagent stability control.
- Certification: CE IVD marked and strictly for professional in vitro diagnostic use only.

Technical Details and Storage

- Sample Type: Nucleic acid isolates from skin lesion swabs.
- Storage Temperature: Stable between (-15°C) and (-25°C)
- Shelf Life: 12 months.

MonkeyPox qPCR Kit **Cat No: PHMNKY2022-100/500**

Validation Data

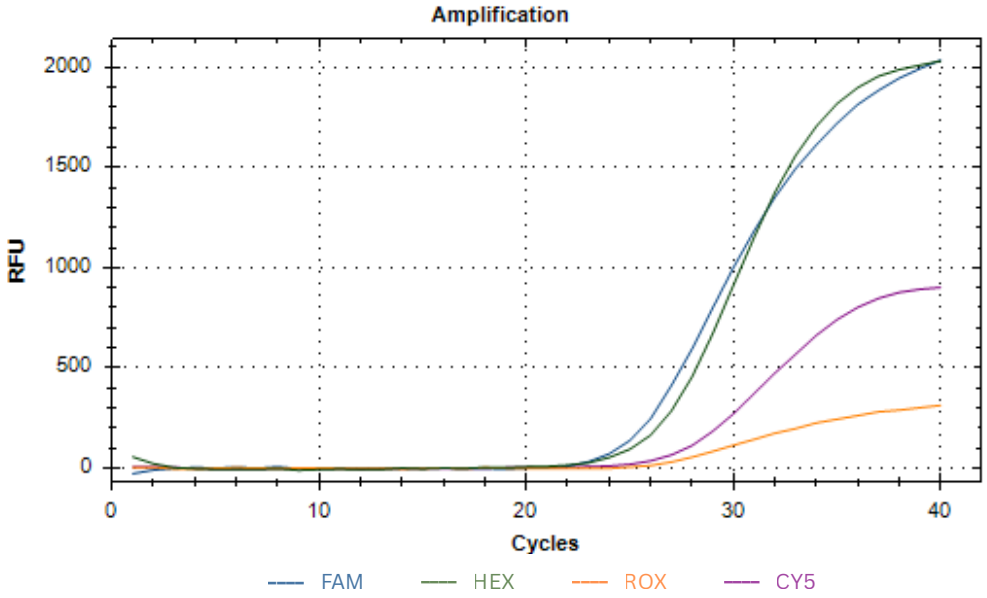


Figure 1. Positive Amplification Profile: The plot demonstrates specific fluorescence accumulation exceeding the threshold in at least one of the target channels: FAM (Mpox Generic - G2R), HEX (Clade-II / West African), or ROX (Clade-I / Central African). Detected positivity in target channels is diagnostically valid, regardless of the CY5 (Internal Control - RNase P) signal. Simultaneous detection in generic and clade-specific channels provides a definitive confirmation of virus presence and clade differentiation.

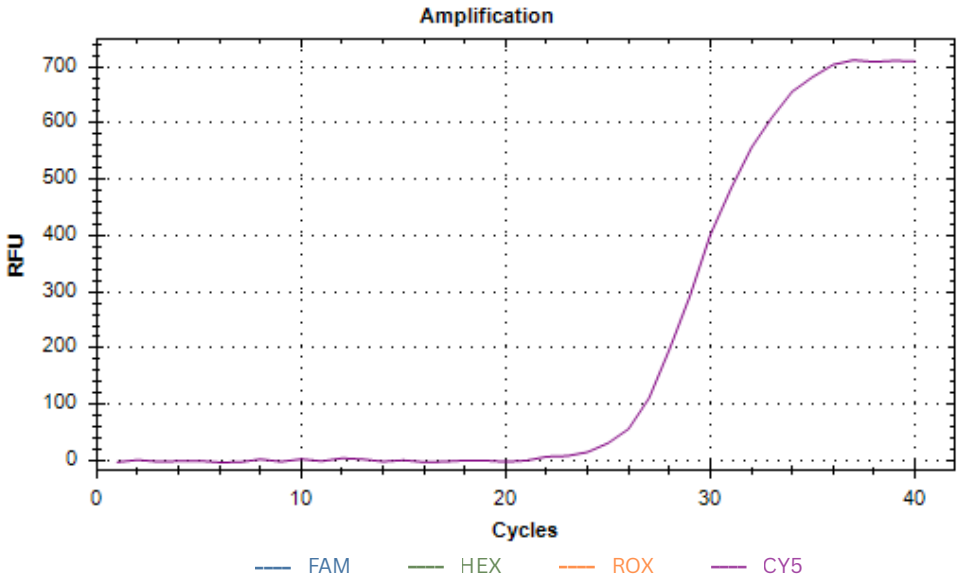


Figure 2. Negative Amplification Profile: No specific amplification was detected across the FAM, HEX, or ROX target channels. Analytical validity and sample integrity are confirmed by the positive signal in the CY5 (Internal Control - RNase P) channel. If all channels remain negative, the test is considered invalid and must be repeated.

PHARMALINE®

CE IVD

Malaria Detection Kit — Cat No: PHMLR2022-100

Product Overview and Targets

The Malaria Detection Kit is an in vitro diagnostic tool designed for the highly sensitive and specific detection of all five *Plasmodium* parasite species known to cause malaria. The kit works with Total DNA/Genomic DNA isolated from suspected blood.

Diagnosis is performed using Real-Time PCR (qPCR). The assay is based on a conserved region specific to the 18S rRNA genes of the five *Plasmodium* parasites, using a universal primer-probe design.

The Malaria Detection Kit performs its analysis using two primary fluorescent channels:

- FAM Channel: Used for the detection of *Plasmodium* spp. (all five species of malaria parasite).
- HEX Channel: Used for the Internal Control.

Key Features

- Broad Detection: Capable of detecting all five types of malaria parasites: *Plasmodium vivax, Plasmodium malaria, Plasmodium ovale, Plasmodium falciparum,* and *Plasmodium knowlesi*.
- High Sensitivity: qPCR analysis provides high sensitivity for detecting the parasite's genetic material.
- Compatibility: Fully compatible with Pharmaline Genomic DNA isolation kit (REF: PHDNA2021-100).
- Validated Instruments: Compatible with Biorad® CFX96, LightCycler480 (Roche), and RotorgeneQ (QiaGen).
- Certification: CE IVD marked and strictly for professional use.

Technical Details and Storage

- Sample Type: Total DNA/Genomic DNA isolated from whole blood.
- Shelf Life: 12 months.
- Storage Temperature: Stable between (-15°C) and (-25°C). PCR reagents are stored at -20°C for long-term storage.

Malaria Detection Kit **Cat No: PHMLR2022-100**

Validation Data

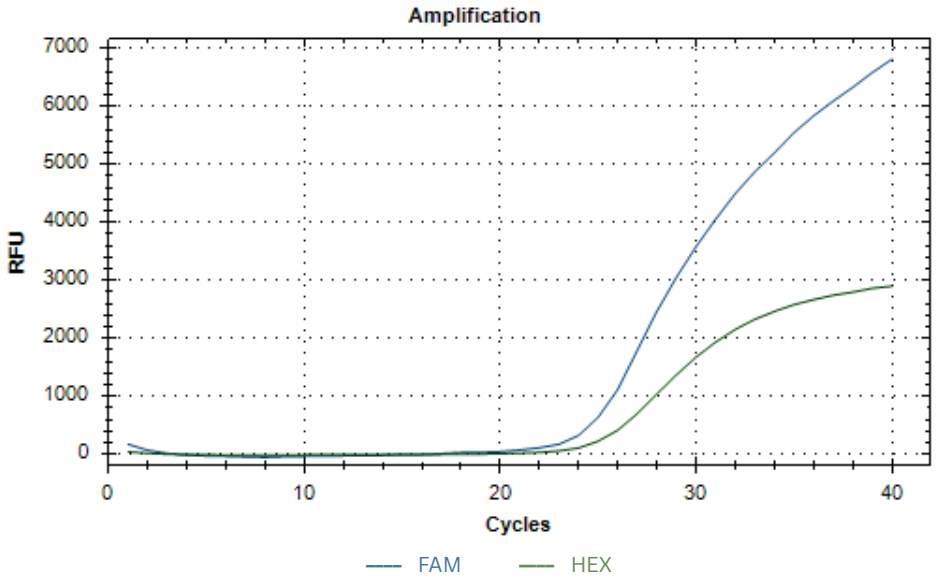


Figure 1. Positive Amplification Profile: The plot demonstrates a specific signal increase exceeding the threshold in the target channel (FAM: Plasmodium spp. - all species). Positivity detected in the target channel is diagnostically valid, regardless of the HEX (Internal Control) signal.

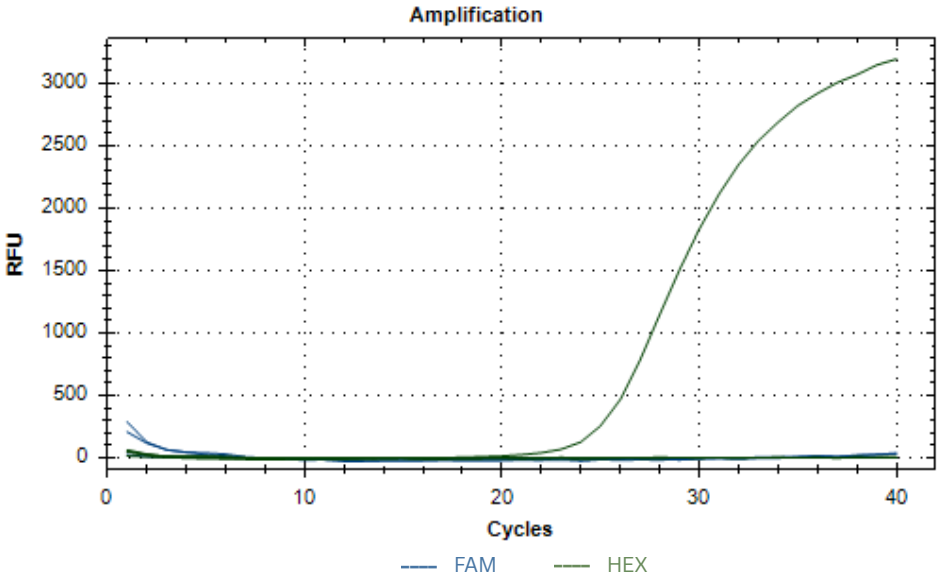


Figure 2. Negative Amplification Profile: No specific signal increase was detected in the target channel (FAM). Analytical validity and sample integrity are confirmed by the positive signal in the HEX (Internal Control) channel. If both channels remain negative, the test is considered invalid and must be repeated.

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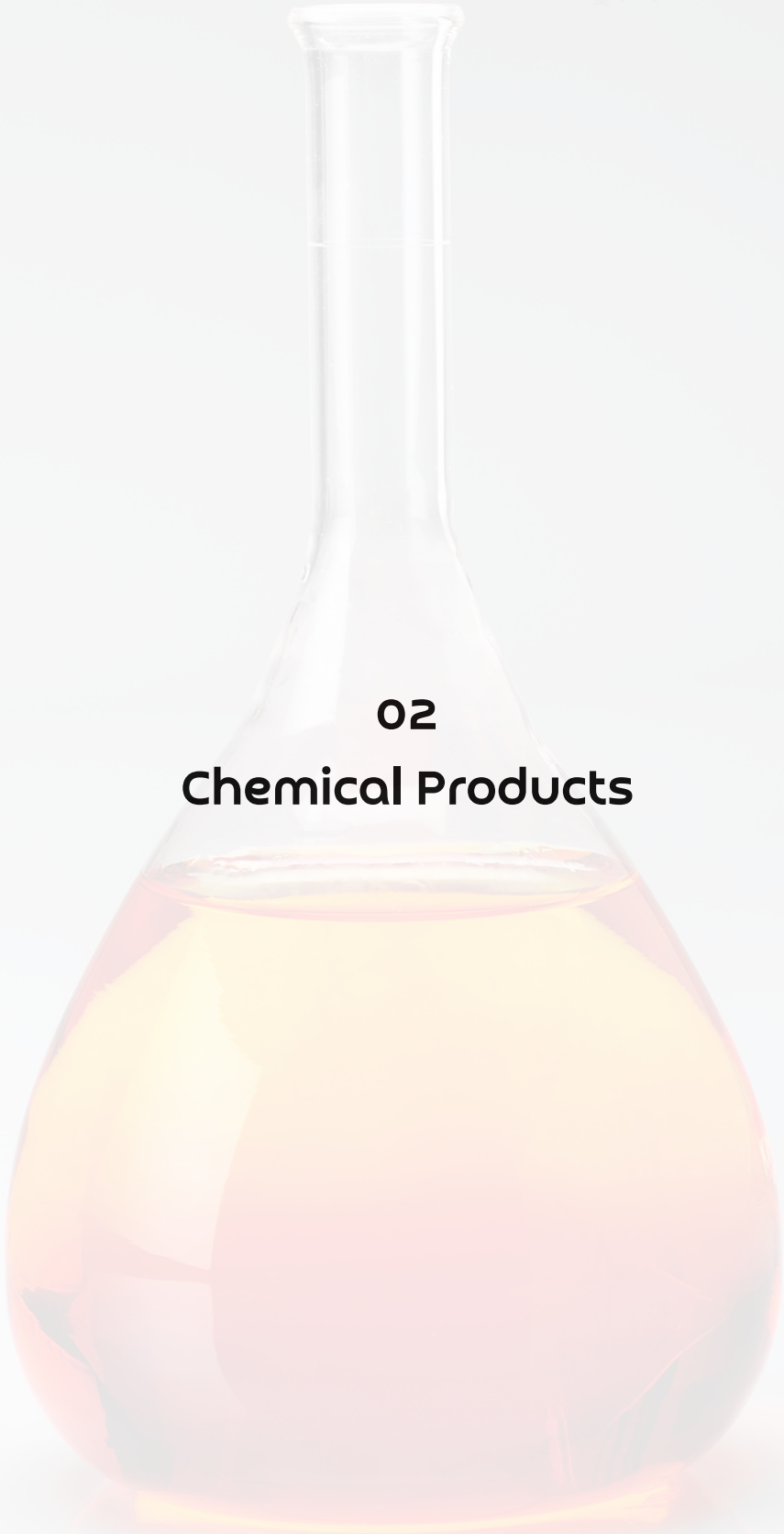


02

Chemical Products

PharmaSEP

CE IVD

Stool Extraction Preparation Buffer Cat No: PHSP2024-50/PHSP2024-100

Product Overview

PharmaSEP is a versatile buffer solution designed primarily as a Stool Extraction Preparation Buffer for in vitro diagnostic use. It has a wide range of uses in biological and biochemical research.

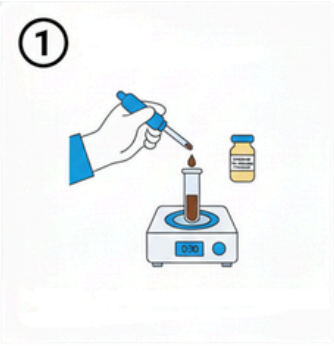
Key Features

- Versatile Use: A reliable tool for pH stabilization, providing an isotonic environment, cleaning nucleic acids during isolation, and the preparation/dilution of biological reagents.
- Reliable Sample Prep: Ensures reliable and standardized preparation of nucleic acid extracts from challenging stool sample.
- Convenient Storage: Can be stored and transported at room temperature, between 15°C and 25°C.
- Shelf Life: 12 months.

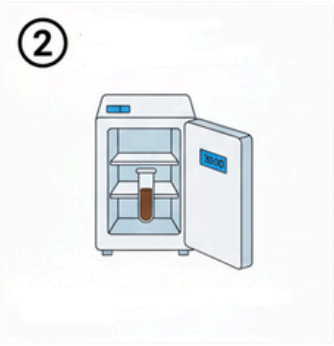
Stool Sample Preparation Protocol Highlights

The buffer facilitates a simple preparation process for extraction:

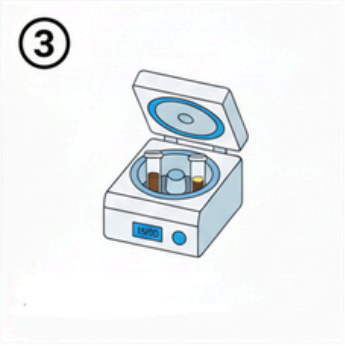
1. Mixing: The stool sample (100 mg solid or 100 µl liquid) is added to 900 µl of PharmaSEP and vortexed at the highest speed for 30 seconds.
2. Freezing: The mixture is frozen at -20°C for 30 minutes.
3. Centrifugation: After thawing, the sample is centrifuged at 5000g for 15 minutes.
4. Extraction Ready: The resulting supernatant is then ready for nucleic acid extraction.



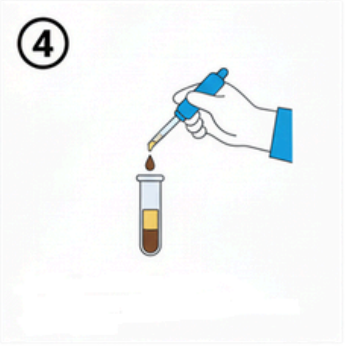
1. Mixing:
100 mg stool + 900 µl PharmaSEP, vortex for 30 sec.



2. Freezing:
The mixture is frozen at -20°C for 30 min.



3. Centrifugation:
5000 g for 15 minutes.



4. Extraction Ready:
Supernatant is ready for nucleic acid extraction.

PHARMALINE®

CE IVD

PharmaDirect qPCR Solüsyonu Cat No: PHDRCT2023-50/100/200

Product Overview and Targets

The PharmaDirect qPCR Solution is designed to allow clinical samples contained within Viral Transport Medium (VTM) to be used directly in qPCR assays without the need for any nucleic acid purification process.

Its special formulation ensures that viral pathogens present in the VTM are lysed (disrupted) during the pre-denaturation step of the PCR reaction, leading to the release of nucleic acid. The specialized chemicals stabilize the released nucleic acid, prevent non-specific binding during amplification, and enhance amplification efficiency.

Key Features

- Extraction-Free qPCR: Eliminates the nucleic acid extraction step, significantly reducing hands-on time and costs.
- Enhanced Efficiency: Special chemicals stabilize the nucleic acid and prevent non-specific binding, improving amplification yield.
- Compatibility: Optimized for use with Pharmaline brand qPCR kits for optimal results.
  - Note on Limitations: The solution is developed for DNA viruses and is not suitable for use with RNA viruses.
  - The elimination of the extraction step may increase the protein contamination rate in PCR wells, potentially reducing the sensitivity of the qPCR kit by 1–2%.
- Reaction Composition (Example): A typical 15 µl Direct qPCR Reaction Mix includes 7.5 µl of 2X Master Mix (resulting in a 1X final concentration), 2.5 µl of Primer Mix, 2.5 µl of PharmaDirect Solution, and 2.5 µl of VTM Sample.

Technical Details and Storage

- Storage Conditions: Store and transport at room temperature (below 25°C) with the lid tightly closed.
- pH Sensitive: The solution is pH-adjusted and can be affected by ambient gases; ensure the solution is not exposed to air during storage.
- Handling: Gently mix the master mix, primer mix, and PharmaDirect solution by inverting them (do not vortex) to homogenize the mixture before dispensing.
- UV Protection: Protect the solution from Ultraviolet (UV) light.

PharmaLine Healthcare Services Industry and Trade Inc.

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