

COMPATIBILITY BETWEEN AmpliRun® Total CONTROLS AND ALLPLEX™ KITS (SEEGENE).

Molecular diagnostics has become one of the dominant platforms in clinical laboratories, offering the added value of improving the management of infectious diseases through increased speed, accuracy and sensitivity.

Quality assurance and quality control issues have often remained underdeveloped but are still critical. To relate patient results to prior results or to absolute values in clinical practice guidelines, those results need to be comparable across time and methods. The establishment of international standards and reference materials is thus of paramount importance.

Different guidelines as well as recommendations from professional organizations (CLIA, CLSI, NATA, CAP, ISO) reinforce the use of **third-party quality controls**. In this sense, clinical laboratories are now requested to implement a best-in-class quality assurance program by using **third-party quality controls** to meet their customers' needs and expectations for consistent, accurate, and timely test results.

AmpliRun® Total Controls are manufactured as **third-party quality controls**, to monitor the accuracy and precision of the complete analytical process: from extraction to results. These non-infectious lyophilized positive Controls include the complete inactivated microorganism in a matrix that mimics human specimens.

AmpliRun® Total Controls are quantified (copies/vial) and have been formulated to detect low level positive results with clinical relevance.

AmpliRun® Total Controls helps your laboratories to:

- **Ensure accuracy, precision and reproducibility of lab test results.**
- **Ensure integrity and confidence in test results.**
- **Review QC failures by identifying deficiencies and taking corrective actions on time.**
- **Comply with lab accreditation requirements.**
- **Maintain the laboratory's reputation.**

Prior to routine use, it is recommended that each laboratory tests the use of the **AmpliRun® Total Controls** with each specific PCR assay and instrument.

Several **AmpliRun® Total Controls** have been tested for compatibility with different Allplex™ kits from Seegene company.

Compatibility (*) is shown below:

Allplex™ STI Essential Assay (Ref. cat. SD9801X, SD10245Z)

AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB) - MBTC024 - RUO

Allplex™ SARS-CoV-2 Assay (Ref. cat. RV10248X)

AMPLIRUN® TOTAL SARS-COV-2 CONTROL (SWAB) - MBTC030 - CE IVD

AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB) - MBTC031 - CE IVD

Allplex™ Respiratory panel 1 (Ref. cat. RP9801X)

AMPLIRUN® TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB) - MBTC020 - CE IVD

AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB) - MBTC031 - CE IVD

Allplex™ Respiratory panel 2 (Ref. cat. RP9802X)

AMPLIRUN® TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB) - MBTC020 - CE IVD

() For a more detailed information go to Annex A of this document.*

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Annex A.

The detailed data for each AmpliRun® Total Control are shown in the following tables:

		Allplex™ STI Essential Assay (Ref. cat. SD9801X, SD10245Z)							
		CT	NG	TV	MGE	MHO	UU	UP	IC
AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB) MBTC024-R	CT	Detected							Detected
	NG		Detected						Detected
	TV			Detected					Detected
	MGE				Detected				Detected

Chlamydia trachomatis (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas vaginalis* (TV), *Mycoplasma genitalium* (MG), *Mycoplasma hominis* (MHO) *Ureaplasma urealyticum* (UU), *Ureaplasma parvum* (UP) and Internal Control (IC)

		Allplex™ SARS-CoV-2 Assay (Ref. cat. RV10248X)			
		E gene	RdRP/S gene	N gene	IC
AMPLIRUN® TOTAL SARS-COV-2 CONTROL (SWAB) MBTC030	SARS-COV-2	Detected			Detected
	SARS-COV-2		Detected		Detected
	SARS-COV-2			Detected	Detected

		Allplex™ SARS-CoV-2 Assay (Ref. cat. RV10248X)			
		E gene	RdRP / S gene	N gene	IC
AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB) MBTC031	SARS-COV-2	Detected			Detected
	SARS-COV-2		Detected		Detected
	SARS-COV-2			Detected	Detected
	Influenza A H3N2				
	Influenza B				
	RSV (B)				

Respiratory Syncytial Virus (RSV), Internal Control (IC)

		Allplex™ Respiratory panel 1 (Ref. cat. RP9801X)							
		Influenza A virus (Flu A)	Influenza A-H1 (Flu A-H1)	Influenza A-H1pdm09 (Flu A-H1pdm09)	Influenza A-H3 (Flu A-H3)	Influenza B virus (Flu B)	RSV (A)	RSV (B)	IC
AMPLIRUN® TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB) MBTC020	Adenovirus 4								Detected
	Coronavirus								Detected
	Influenza A H3N2	Detected			Detected				Detected
	Influenza B					Detected			Detected
	Novel Flu A H1N1			Detected					Detected
	Parainfluenza 1								Detected
	Parainfluenza 2								Detected
	Parainfluenza 3								Detected
	RSV (A)						Detected		Detected
	RSV (B)							Detected	Detected

Respiratory Syncytial Virus (RSV), Internal Control (IC)

		Allplex™ Respiratory panel 1 (Ref. cat. RP9801X)							
		Influenza A virus (Flu A)	Influenza A-H1 (Flu A-H1)	Influenza A-H1pdm09 (Flu A-H1pdm09)	Influenza A-H3 (Flu A-H3)	Influenza B virus (Flu B)	RSV (A)	RSV (B)	IC
AMPLIRUN® TOTAL SARS-CoV-2/FluA/FluB/RSV CONTROL (SWAB) MBTC031	SARS-COV-2								Detected
	Influenza A H3N2	Detected			Detected				Detected
	Influenza B					Detected			Detected
	RSV (B)							Detected	Detected

Respiratory Syncytial Virus (RSV), Internal Control (IC)



		<i>Allplex™ Respiratory panel 2 (Ref. cat. RP9802X)</i>							
		PIV4	MPV	PIV2	PIV1	AdV	HEV	PIV3	IC
AMPLIRUN® TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB) MBTC020	Adenovirus 4					Detected			Detected
	Coronavirus								
	Influenza A H3N2								
	Influenza B								
	Novel Flu A H1N1								
	Parainfluenza 1				Detected				Detected
	Parainfluenza 2			Detected					Detected
	Parainfluenza 3							Detected	Detected
	RSV (A)								
	RSV (B)								

Respiratory Syncytial Virus (RSV), Parainfluenza Virus (PIV), Adenovirus AdV, Human Enterovirus (HEV), Internal Control (IC)

AmpliRun® Total Controls were processed according the manufacturer’s instructions using the STARMag Universal extraction kit (Seegene, Seoul, South Korea) on the STARlet platform (Hamilton, Reno, Nevada, USA).

AmpliRun® Total Controls were reconstituted in compliance with the corresponding IFU with the exception of AMPLIRUN® TOTAL RESPIRATORY VIRAL PANEL CONTROL (SWAB), MBTC020, where 300µL were used rather than the advised 200µL (minimum required STARlet platform).