

Reliable quality controls

For your diagnostics



REDx™ (CE)

Ensuring the daily consistency of an analysis process. They serve as an aid to reliable patient results.

PROCEEDx™ (RUO)

For checking the prescribed device specifications in internal processes.

ONBOARDx™ (RUO)

Used for validation and verification of instrument, kit and assay qualifications as well as training of users. Consists of various PROCEEDx™ controls.

Quality controls from Microbix to support any laboratory

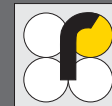
With the help of quality controls it is possible to find and correct errors in the analysis processes of a laboratory in time and thus to ensure the delivery of accurate results. The controls are included into the overall workflow in the same way as a patient sample, pass through all process steps, and thus indicate a possible deviation from the usual quality at an early stage if used regularly.

Microbix's Quality Assessment Products (QAPs) portfolio currently offers quality controls under the brands PROCEEDx™, ONBOARDx™ and REDx™, which can be used together with tests for molecular and immunological diagnosis of bacterial and viral diseases in the areas of respiratory infections, gastrointestinal infections and sexually transmitted diseases.

Product	Format	Test compatibility	Art. No.	
Respiratory infections			PROCEEDx™	REDx™ Controls
Adenovirus Positive	Vial (1.0 mL)	Nucleic acid*; Immunoassay	VP-15-01	
Adenovirus + Rotavirus Positive	Vial (1.0 mL)	Nucleic acid*; Immunoassay	VP-15-02	
Adenovirus + hMPV + Parainfluenza 2&3 Positive	Swab	Nucleic acid	VP-S-15-M1	
Influenza A Positive	Vial (1.0 mL)	Nucleic acid; Immunoassay	VP-13-01	
	Swab	Nucleic acid; Immunoassay	VP-S-13-01	
Influenza A + Adenovirus Positive	Vial (1.0 mL)	Nucleic acid; Immunoassay	VP-13-04	
Influenza A + Rotavirus Positive	Vial (1.0 mL)	Nucleic acid*; Immunoassay	VP-13-05	
Influenza A + RSV Positive	Vial (1.0 mL)	Nucleic acid; Immunoassay	VP-13-03	
Influenza A + B Positive	Vial (1.0 mL)	Nucleic acid; Immunoassay	VP-13-02	
Influenza B Positive	Vial (1.0 mL)	Nucleic acid; Immunoassay	VP-14-01	
	Swab	Nucleic acid; Immunoassay	VP-S-14-01	
Influenza B + Adenovirus Positive	Vial (1.0 mL)	Nucleic acid*; Immunoassay	VP-14-03	
Influenza B + Rotavirus Positive	Vial (1.0 mL)	Nucleic acid*; Immunoassay	VP-14-04	
Influenza B + RSV Positive	Vial (1.0 mL)	Nucleic acid; Immunoassay	VP-14-02	
Parainfluenza 3 Positive	Vial (1.0 mL)	Nucleic acid	VP-10-M1	
RSV Positive	Vial (1.0 mL)	Nucleic acid; Immunoassay	VP-07-01	
	Swab	Nucleic acid; Immunoassay	VP-S-07-01	
RSV + Adenovirus Positive	Vial (1.0 mL)	Nucleic acid*; Immunoassay	VP-07-02	
RSV + Rotavirus Positive	Vial (1.0 mL)	Nucleic acid*; Immunoassay	VP-07-03	
SARS-CoV-2 Negative	Vial (0.5 mL)	Nucleic acid	VP-99-M3	RED-99-M3
	Swab	Nucleic acid	VP-S-99-M4	RED-S-99-M4
SARS-CoV-2 Positive	Vial (0.5 mL)	Nucleic acid	VP-19-01	RED-19-01
	Swab	Nucleic acid	VP-S-19-01	RED-S-19-01
SARS-CoV-2 Positive Ag	Swab	Immunoassay	VP-S-19-02	RED-S-19-02
SARS-CoV-2 P.1 Swab Positive	Swab	Nucleic acid	VP-S-19-05	
SARS-CoV-2 B.1.1.7 Swab Positive	Swab	Nucleic acid	VP-S-19-03	
SARS-CoV-2 B.1.351 Swab Positive	Swab	Nucleic acid	VP-S-19-04	
SARS-CoV-2 B.1.617 Swab Positive	Swab	Nucleic acid	VP-S-19-06	
SARS-CoV-2 + Influenza A + Influenza B + RSV Positive	Swab	Nucleic acid	VP-S-19-M1	
HCoV + Rhinovirus + Enterovirus Positive	Swab	Nucleic acid	VP-S-20-M1	
Respiratory Swab Negative Control	Swab	Nucleic acid*; Immunoassay	VP-S-99-01	RED-S-99-01

* Products are compatible with nucleic acid tests by design and QC released only by immunological tests.

Product	Format	Test compatibility	Kit components	Art. No.
Compatible with immunological test systems				ONBOARDx™ Kit
SARS-CoV-2 Ag Swab Kit	Swab	Immunoassay	10x SARS-CoV-2 Ag Positive 2x Respiratory Negative	VP-SK-COV2AG-01
SARS-CoV-2 Ag Swab Kit B	Swab	Immunoassay	15x Sars-CoV-2 AG Positive 5x Respiratory Negative	VP-SK-COV2AG-02
Respiratory Swab Kit B	Swab	Immunoassay	5x SARS-CoV-2 Ag Positive 5x Influenza A Positive 5x Influenza B Positive 5x RSV Positive	VP-SK-RESPAG-02



Product	Format	Test compatibility	Kit components	Art. No.
Compatible with molecular test systems				ONBOARDx™ Kit
SARS-CoV-2 Vial Kit 01	Vial (0.5mL)	Nucleic acid	8x SARS-CoV-2 Positive 4x SARS-CoV-2 Negative	VP-K-CoV2-01
SARS-CoV-2 Swab Kit 01	Swab	Nucleic acid	8x SARS-CoV-2 Positive 4x SARS-CoV-2 Negative	VP-SK-CoV2-01
Respiratory Vial Kit	Vial (0.5 mL*, 1.0 mL)	Nucleic acid	3x SARS-CoV-2 Positive Sample* 3x Influenza A Positive Sample 3x Influenza B Positive Sample 3x RSV Positive Sample	VP-K-RESP-01
Respiratory Swab Kit	Swab	Nucleic acid	3x SARS-CoV-2 Positive 3x Influenza A Positive 3x Influenza B Positive 3x RSV Positive	VP-SK-RESP-01
SARS-CoV-2 Variant Swab Kit	Swab	Nucleic acid	3x SARS-CoV-2 B.1.1.7 Positive 3x SARS-CoV-2 B.1.351 Positive 3x SARS-CoV-2 P.1 Positive 3x SARS-CoV-2 WT Positive	VP-SK-CVAR-01
SARS-CoV-2 Variant Swab Kit 2	Swab	Nucleic acid	3x SARS-CoV-2 B.1.1.7 Positive 3x SARS-CoV-2 B.1.351 Positive 3x SARS-CoV-2 P.1 Positive 3x SARS-CoV-2 B.1.617 Positive 3x SARS-CoV-2 WT Positive	VP-SK-CVAR-02

Product	Format	Test compatibility	Art. No.	
Sexually transmitted Infections			PROCEEDx™	REDx™ Controls
<i>Chlamydia trachomatis</i> Positive	Vial (1.0 mL)	Nucleic acid	VP-12-M1	
	Vial (1.0 mL)	Immunoassay	VP-12-01	
<i>Chlamydia trachomatis</i> + <i>Neisseria gonorrhoeae</i> Positive	Vial (1.0 mL)	Nucleic acid	VP-12-M2	
<i>Neisseria gonorrhoeae</i> Positive	Vial (1.0 mL)	Nucleic acid	VP-17-M1	
<i>Trichomonas vaginalis</i> Positive	Vial (1.0 mL)	Nucleic acid; Immunoassay	VP-61-01	
<i>Mycoplasma genitalium</i>	Vial (1.0 mL)	Nucleic acid	VP-63-01	RED-63-01
HPV 16 Positive	Vial (1.0 mL)	Nucleic acid	VP-62-16	RED-62-16
HPV 18 Positive	Vial (1.0 mL)	Nucleic acid	VP-62-18	RED-62-18
HPV 31 Positive	Vial (1.0 mL)	Nucleic acid	VP-62-31	
HPV 33 Positive	Vial (1.0 mL)	Nucleic acid	VP-62-33	
HPV 39 Positive	Vial (1.0 mL)	Nucleic acid	VP-62-39	
HPV 45 Positive	Vial (1.0 mL)	Nucleic acid	VP-62-45	RED-62-45
HPV 67 Positive (hr Negative)	Vial (1.0 mL)	Nucleic acid	VP-62-67	
HSV 1 Positive	Vial (1.0 mL)	Nucleic acid	VP-02-M1	
HSV 2 Positive	Vial (1.0 mL)	Nucleic acid	VP-23-M1	
HSV 1 & 2 Positive	Vial (1.0 mL)	Nucleic acid; Immunoassay	VP-02-M2	
MDx Negative ¹	Vial (1.0 mL)	Nucleic acid	VP-99-M1	
STI Negative Control ²	Vial (1.0 mL)	Nucleic acid		RED-99-M1

¹ Negative for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

² Negative for HPV, *Mycoplasma genitalium*, *Trichomonas vaginalis* and *Neisseria gonorrhoeae*.

Product	Format	Test compatibility	Art. No.	
Gastrointestinal Infections			PROCEEDx™	REDx™ Controls
<i>Cryptosporidium parvum</i> Positive	Vial (1.0 mL)	Nucleic acid*; Immunoassay	VP-37-01	
<i>Giardia lamblia</i> Positive	Vial (1.0 mL)	Nucleic acid*; Immunoassay	VP-38-01	
Rotavirus Positive	Vial (1.0 mL)	Nucleic acid*; Immunoassay	VP-35-01	
MDx Negative ³	Vial (1.0 mL)	Nucleic acid; Immunoassay	PT-99-01	

³ Negative for RSV, Influenza A/B, Adenovirus, Rotavirus, *Chlamydia trachomatis*.

* Products are compatible with nucleic acid tests by design and QC released only by immunological tests.

Summary information on the Microbix controls

What are the special features of the Microbix controls?

- In clinically relevant matrix
- Produced from native pathogens when possible
- Very similar to patient samples
- Not infectious
- Cross-assay and cross-instrument compatible
- Applicable in conjunction with nucleic acid based and immunodiagnostic assays
- Positive and negative controls available
- Room temperature stability with the swab based QAPs
- Point-of-Care-Testing compatibility

Important information on handling Microbix controls

- Stable for up to two years
- Swabs and/or liquid aliquots (ready to use)
- Stored at 2-8 °C (vial) and 2-30 °C (swab)

REDTM controls IVD Quality Control



Specifics:

- Ensure day-to-day consistency of an analytical process
- Assists in determining reliable patient test results

PROCEEDTM Verification/Validation RUO



Specifics:

- Verification of device specifications in internal processes
- Ensure customer needs include acceptance criteria for external users (validation)

ONBOARDTM kit Verification/Validation RUO



Specifics:

- All-encompassing validation and verification kit for instrument/kit/assay qualification and operator training
- Contains PROCEEDTM material