AusDiagnostics

Multiplexed Diagnostics | Affordable Healthcare

SARS-COV-2, INFLUENZA AND RSV 8-WELL REF 20081

PANEL OF ASSAYS

CONSISTING OF THE IVD COMPONENTS:
STEP 1 TUBES FOR SARS-COV-2, INFLUENZA AND RSV 8-WELL REF 20081S
STEP 2 PLATES FOR SARS-COV-2, INFLUENZA AND RSV 8-WELL REF 20081P

FOR THE HIGH-PLEX 24 SYSTEM

INSTRUCTIONS FOR USE

IVD ARTG IVD CE

IMPORTANT NOTICE:

The **SARS-CoV-2 a** and **SARS-CoV-2 b** assays are now validated and suitable for IVD use.

If either of the SARS-CoV-2 assays calls positive, the sample can be treated as positive.

These Instructions for Use (IFU) must be read in conjunction with the High-Plex 24 System IFU.

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1. WARNINGS AND LIMITATIONS

- **IMPORTANT**: IVD performance claims are only applicable when the instructions provided are followed.
- **IMPORTANT**: Do not use if product or packaging is compromised in any way.
- **IMPORTANT**: Do not use Step 1 or Step 2 panel components with different catalogue and/or version numbers.
- **IMPORTANT**: Do not use expired products.
- Always handle and dispose of specimens potentially containing human pathogens according to relevant safety procedures.
- This panel of assays must only be used with the High-Plex 24 System.
- Good laboratory practice is essential for the intended performance of this panel of assays. For further safety information, please consult the relevant Safety Data Sheets (SDS). **Note**: No AusDiagnostics reagents contain hazardous substances, as listed in CLP Regulation (EC) No 1272/2008[1] and according to the Globally Harmonised System (GHS) classification. AusDiagnostics SDS's can be accessed online at http://www.ausdiagnostics.com/regulatory.html
- This panel of assays is designed to measure specific nucleic acid sequences. Therefore, a negative result does not exclude the possibility that an unusual sequence variant is present. The results obtained with this panel of assays should be used in conjunction with information available from clinical evaluations and other diagnostic procedures. A negative result cannot be relied upon for a definitive diagnosis. Failure or delay in treatment of an infected patient may lead to death, with immunocompromised patients being at highest risk.

2. FURTHER INSTRUCTIONS REQUIRED

The Instructions for Use (IFU) for SARS-CoV-2, Influenza and RSV 8-well includes panel-specific information not provided in other IFUs.The document ID of the IFU for this product is provided on the outer box label next to the IFU symbol and in the footer of this document. The IFU for this product and other IFUs can be accessed online at http://www.ausdiagnostics.com. Additionally, a paper copy is available upon request by contacting customer service via phone, email, or mail (see **Section 12. Technical Enquiries**).

These Instructions for Use must be read in conjunction with:

- High-Plex 24 System IFU (Document 91501-r13).
- Reagent Cassette IFU (Document 40001-r02)

and if applicable, must also be read with:

- Synthetic Positive Controls IFU (Document ID 91001-r08; See **Section 9. Controls**)
- Swab Elution Tubes (buffer) IFU (Document ID 90200r05; See **Section 6.3**)

3. NAME AND INTENDED USE

The SARS-CoV-2, Influenza and RSV 8-well panel of assays is intended for *in vitro* diagnostic (IVD) use by suitably trained personnel in qualified laboratories using the High-Plex 24 System (REF 91501).

These tests utilise a multiplex-tandem polymerase chain reaction (MT-PCR)[2] for the enrichment of targets and then amplification of targeted DNA and/or RNA. For the full description of the principle of the method, see the High-Plex 24 System IFU, **Section 5. Principle of Method**.

The SARS-CoV-2, Influenza and RSV 8-well panel of assays is intended as a semi-automated IVD test for the identification of pathogens in nucleic acid extracts from appropriate specimen types. For specimen and sample types that may be used, please see **Section 6. Specimen Requirements**.

The pathogens targeted in this panel are listed and described in **Section 4. Summary and Explanation of the Test.**

4. SUMMARY AND EXPLANATION OF THE TEST

SARS-COV-2, INFLUENZA AND RSV 8-WELL REF 20081 VER 08

ARTG Identifier: 235809

Assay	Target
Influenza A	Influenza virus A (includes H1, H3, H5 and H7)
Flu Typing	Influenza virus A serotypes pdH1N1 and H3 (including H3N2) are differentiated
Influenza B	Influenza virus B (Yamagata and Victoria lineages)
RSV	Respiratory Syncytial Virus (includes and differentiates types A and B)
SARS-CoV-2 a	Severe Acute Respiratory Syndrome Coronavirus 2 (ORF1 gene)
SARS-CoV-2 b	Severe Acute Respiratory Syndrome Coronavirus 2 (ORF8 gene)
Sample Adequacy	Human reference gene for sample adequacy control
SPIKE	Artificial sequence for assay control

This product complies with the regulatory requirements for IVD medical devices of the competent authorities in Australia (ARTG Identifier 235809) and the European Union (CE-marked).

These tests utilise a multiplex-tandem polymerase chain reaction (MT-PCR)[2] for the amplification of targeted DNA and/or RNA. For the full description of the principle of the method, see the High-Plex 24 System IFU, **Section 5. Principle of the Method**.

The SARS-CoV-2, Influenza and RSV 8-well panel is intended to detect the following viruses that have been associated with respiratory infections:

4.1 TARGET DESCRIPTIONS: VIRUSES

Influenza A

Influenza virus A is the most virulent influenza virus in humans, and is sub-typed depending on surface haemagglutinin (HA) and neuraminidase (NA). The most significant H1 subtype has been H1N1, causing the Spanish Flu in 1918[3]. A novel H1N1 strain emerged in 2009 (pdH1N1 or "swine flu") that contained viral segments from human, pig and avian influenza[4]. The most common H3 variant is H3N2, which had its first known outbreak in 1968 in Hong Kong[5]. H5 and H7 variants are hosted by birds with certain strains transmissible to humans (causing "avian influenza") where sporadic infections are a public health concern. H5N1 has a mortality rate of about 60% of all known cases, where most sources of infection were from infected birds or contaminated environments[6]. Several H7 subtype infections with high pathogenicity have been reported in recent years, however there have been limited reports of human-to-human transmission[6]. The **Flu Typing** assay is designed to detect pdH1N1 and H3.

IMPORTANT: If the Flu Typing assay calls positive and the Influenza A assay calls negative, it is safe to report the Flu Typing assay as correct.

Influenza B

Influenza virus B is less common than Influenza A but does cause outbreaks of influenza as immunity is overcome by viral mutations. The Influenza Virus B assay is designed to detect both Influenza B variants, Victoria and Yamagata[7].

Respiratory Syncytial Virus (RSV)

Respiratory syncytial virus is a leading cause of lower respiratory tract infections in young children and

accounts for 50 – 90% of bronchiolitis hospital admissions[3]. Out of the two strains in circulation, A and B, RSV A is the predominating strain. The RSV assay is designed to detect both RSV A and B, and the MT Analysis software will distinguish between the two strains.
IMPORTANT: Discrimination between RSV A and B strains is for information purposes only.

SARS-CoV-2
Coronaviruses are a large family of RNA viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The recently discovered coronavirus SARS-CoV-2 causes coronavirus disease COVID-19 and was first observed in Wuhan, China.
IMPORTANT: If either of the SARS-CoV-2 assays calls positive, the sample can be treated as positive.

5. PANEL COMPONENTS AND REAGENTS: MATERIALS AND STORAGE

Note: No AusDiagnostics reagents contain hazardous substances, as listed in Regulation (EC) No 1272/2008[1] and according to the Globally Harmonised System (GHS) classification.

Panel Name	Panel components	REF	GTIN
SARS-CoV-2, Influenza and RSV 8-well	Step 1 Tubes for SARS-CoV-2, Influenza and RSV 8-well	20081S	9343044001598
	Step 2 Plates for SARS-CoV-2, Influenza and RSV 8-well	20081S	9343044001581
To be used with:	Demi RNA Reagent Cassette	40341RNA	9343044003110

5.1 STEP 1 TUBES
Step 1 Tubes for SARS-CoV-2, Influenza and RSV 8-well panels contain tubes for 96 samples.

Materials	Label	Description	Function	Qty.
Step 1 Tubes	**STEP 1 TUBES**	1 x individual sealed bag containing 12 x 8-well tube strips with dried oligonucleotides.	Receptacle for the Step 1 reaction	96

STORAGE AND HANDLING INSTRUCTIONS

The Step 1 Tubes must be stored between 14°C - 29°C.

Expiration of product is 6 months from manufacture and expiration date is provided on the label.

5.2 STEP 2 PLATES

The Step 2 Plates box for SARS-CoV-2, Influenza and RSV 8-well panels contains materials for 288 samples.

Materials	Label	Description	Function	Qty.
Step 2 Plates box	**STEP 2 PLATES**	Outer box	Outer packaging	1
Step 2 Plate	**STEP 2 PLATE**	Sealed bag containing 384-well plate with dried oligonucleotides	Receptacle for the Step 2 PCR reaction	12
Dilution plate	D	Empty, 96-well plate	Houses the dilution for Step 2	12
(Bleach) Container	C	Empty, white-capped 5.0 mL tube	To be loaded with bleach, which deactivates DNA/ RNA	6
Tip disposal bag	T	Zip-lock bags	Collects used tips for safe disposal	6

STORAGE AND HANDLING INSTRUCTIONS

The Step 2 Plates box must be stored between 14°C - 29°C.

IMPORTANT: Ensure desiccant is intact before removing product from pouch; do not use product if desiccant is compromised or missing

Expiration of product is 6 months from manufacture and expiration date is provided on the label.

5.3 DEMI RNA REAGENT CASSETTE

Outer box label	Materials	Description
DEMI RNA REAGENT CASSETTE REF 40341RNA ②	Step 1 RNA Enzymes	Enzymes for the Step 1 reaction including reverse transcriptase
	Step 1 Buffer	Buffer for the Step 1 reaction
	Step 2 Reagents	Enzymes in buffer for the Step 2 reaction
	Water	Used to dilute the Step 1 reaction products for Step 2
	Oil	Used to prevent evaporation of the Step 1 reaction

STORAGE AND HANDLING INSTRUCTIONS

Upon arrival, store the reagent cassettes below -20°C.

WARNING: Reagent cassettes may arrive thawed. This will not affect the performance of the reagent cassettes.

WARNING: A run must be started within 30 minutes of thawing the reagent cassette. Reagent cassettes are single-use only. Except for the initial freezing upon arrival (if necessary), do not re-freeze reagent cassettes.

Note: Take care to fully defrost reagent cassettes before **gently** inverting and spinning down as frozen reagents may pierce the foil seal.

Note: Do not re-use reagent cassettes. Dispose of them according to appropriate safety procedures.

Expiration of product is 6 months from manufacture and expiration date is provided on the label.

5.4 MATERIALS REQUIRED BUT NOT PROVIDED

Required reagents and equipment that are not provided by AusDiagnostics are:

- Personal protective equipment (PPE)
- Bleach with 0.4% available chlorine (4 mL required per run)
- Nuclease-free and adjustable pipettes
- Nuclease-free and sterile filtered tips

6. SPECIMEN REQUIREMENTS

6.1 SPECIMEN TYPES AND VOLUME

A nucleic acid extract that is suitable for PCR should be used with this product. Acceptable specimen types include nucleic acid extracts of nasal swabs, throat swabs, nasopharyngeal swabs, nasopharyngeal aspirate (NPA), tracheal aspirate, bronchial washing, or bronchoalveolar lavage (BAL).

Note: please store your nucleic acid extract in tubes free from PCR inhibitors and nucleases.

When working with RNA samples, standard precautions to minimise RNA degradation should be used.

IMPORTANT: Always handle and dispose of specimens potentially containing human pathogens according to relevant safety procedures.

Volume of sample to be added to Step 1 Tube must be 10 µL.

6.2 SUITABLE NUCLEIC ACID EXTRACTION METHODS

Manual extraction and pipetting of nucleic acid extracts into Step 1 Tubes is best performed in a biological safety cabinet or PCR setup area.

The following manual and automated nucleic acid extraction methods have been validated by AusDiagnostics customers, and have been deemed suitable to produce nucleic acid extracts compatible with the SARS-CoV-2, Influenza and RSV 8-well panel.

Extraction System	Type
AusDiagnostics MT-Prep Extractor	Automated
bioMerieux, NucliSENS easyMAG	Automated
PerkinElmer Chemagic Prepito-D	Automated
Qiagen EZ1 Advanced	Automated
Qiagen QIAamp	Manual
Qiagen QIAsymphony	Automated
Roche High Pure series	Manual
Roche MagNA Pure series	Automated

7. FURTHER MT ASSAY SET UP OPTIONS

This section is intended to be read in conjunction with the High-Plex 24 System IFU, **Section 7.3 Run the Processor**.

Additional MT Assay Setup software options are as follows:

Sampling: The table below explains the options provided for robotic sampling:

Sampling options	Applicable situation
Manual pipetting into tube strip	Nucleic acid extracts have been manually transferred to the Step 1 Tubes prior to starting the run (therefore no robotic sampling required).
Robot sampling from 2 mL tubes	Nucleic acid extracts stored in 2 mL tubes are loaded on the Autosampling block for robotic sampling. Minimum volume 40 µL
Robot sampling from 1.5 mL flip-cap tubes	Nucleic acid extracts are stored in 1.5 mL flip-cap tubes are loaded on the Autosampling block for robotic sampling. Minimum volume 40 µL
Robot sampling from non-sequential 96 well plate locations	Nucleic acid extracts are stored in a 96-well plate are placed in the Autosampling block section for robotic sampling of non-sequential wells on the plate. Minimum volume 40 µL
Robot sampling from 96 well plate samples 1-24	Nucleic acid extracts are stored in a 96-well plate are placed in the Autosampling block section for robotic sampling of wells 1 - 24. Minimum volume 40 µL
Robot sampling from 96 well plate samples 25-48	Nucleic acid extracts are stored in a 96-well plate are placed in the Autosampling block section for robotic sampling of wells 25 - 48. Minimum volume 40 µL
Robot sampling from 96 well plate samples 49-72	Nucleic acid extracts are stored in a 96-well plate are placed in the Autosampling block section for robotic sampling of wells 49 - 72. Minimum volume 40 µL
Robot sampling from 96 well plate samples 73-96	Nucleic acid extracts are stored in a 96-well plate are placed on the Autosampling block section for robotic sampling of wells 73 - 96. Minimum volume 40 µL

8. INTERPRETATION OF RESULTS

WARNING: IVD performance claims do not extend to any changes made by the user to a result (i.e. "Reject" or "Confirm" a result). Any user changes will be clearly indicated in the Analysis Report.

The cycling curves and the melt curves of a run are displayed in the MT Analysis Software. Based on predefined parameters, the software will call the target as 'Present', 'Check' or blank (not detected). Note that multiple infections are possible. Molecular target concentrations, expressed as arbitrary units, are calculated relative to the internal control SPIKE, which amplifies a known amount of target molecules. As the concentration of SPIKE is not measured these values are in arbitrary units. Furthermore, in some panels the relative concentration of each target may be inferred from the normalised percent (displayed in parentheses after the 'Present' call.

For further details on analysis of results, please refer to the High-Plex 24 System IFU (**Section 11. Interpreting Software Results**).

IMPORTANT: Please report results to state or local public health departments, if applicable.

9. CONTROLS

9.1 POSITIVE CONTROL

It is recommended that positive controls be included in every run. Please refer to individual laboratory procedures. The failure of a positive control should lead to the reassessment of any negative result obtained since the last control was run.

The Synthetic Positive Controls for Respiratory Pathogens (REF 91011 **VER 06**) contains all IVD targets for the SARS-CoV-2, Influenza and RSV 8-well panel except for SARS-CoV-2 b. A Synthetic Positive Control for the SARS-CoV-2 b assay is currently in development.

The Synthetic Positive Controls IFU must be read before using these controls.

9.2 NEGATIVE CONTROL

It is recommended that a negative control be run according to the individual laboratory procedures. Amplification of the negative control indicates contamination from the environment (e.g. from handling during set up or spillages of sample material on the MT Processor deck). In this case, the surface of the MT Processor deck (including the thermal cycler cover) should be wiped with a non-corrosive nucleic acid denaturing reagent (e.g. DNA-OFF™) and then UV treated. The relevant samples should be retested.
DO NOT USE BLEACH TO CLEAN THE INSTRUMENT.

9.3 SAMPLE ADEQUACY AND HUMAN DNA CONTROL

The Sample Adequacy Control assay targets a human reference gene as an indicator of the suitability of the nucleic acid extract, or direct sampling specimen. The Human DNA Control assay targets a human DNA reference gene, to indicate the presence of human DNA in the nucleic acid extract or direct sampling specimen.
IMPORTANT: If both the assay and sample adequacy control call negative, a new sample should be collected. If the assay calls positive and the sample adequacy calls negative, the sample is positive.

9.4 SUITABLE NUCLEIC ACID CONTROL

It is the user's responsibility to ensure a suitable nucleic acid extraction procedure is in place. It is recommended a known positive control be included per extraction run.

If the nucleic acid extraction control is not detected, the negative results cannot be relied upon. It is recommended that any sample with a negative nucleic acid extraction control should be re-collected and re-extracted if appropriate, and analysis repeated.

9.5 SAMPLE INHIBITION AND INSTRUMENT FUNCTION CONTROL

SPIKE is a completely artificial sequence that is present in Step 1 Tubes to monitor sample inhibition and instrument performance. SPIKE has been designed to have no cross-reactivity with diagnostic targets or assays. If SPIKE is shown to be inhibited, then this suggests that the sample contained inhibitory substances, or that the reaction conditions are suboptimal. In this case a negative result cannot be relied upon and it is recommended that the sample should be re-extracted if appropriate, and analysis repeated. For further details on analysis of SPIKE, please refer to the High-Plex 24 System IFU (**Section 9.2 Verification of Instrument Function and Sample Inhibition**).

10. PERFORMANCE CHARACTERISTICS

10.1 REPRODUCIBILITY AND REPEATABILITY

The reproducibility of the assays on the High-Plex 24 System was assessed by testing five samples on three batches across three days (with each batch tested once per day) and three systems with three operators. The coefficient of variation (c_V) for the resulting mean cycle take-off values (Ct values) for each of the samples were calculated. It was found that the Ct values for all samples at all concentrations were highly reproducible with c_V values ranging from 2.08% to 4.86%, averaging 3.40%.

The repeatability of the assays on the High-Plex 24 System was assessed by testing five samples on three batches with one batch tested three times each day on one system. It was found that the Ct values for all samples at all concentrations were highly repeatable with c_V values ranging from 2.26% to 5.11%, averaging 3.84%.

The low c_V from these studies provides evidence that the High-Plex 24 System is suitably precise for IVD use.

10.2 INTERFERING SUBSTANCES

A range of exogenous and endogenous substances including those expected to be found in the sample types for this panel were tested for potential PCR interference. Minimal or no interference was seen due to the presence of any one of the substances tested.

The presence of the internal control, SPIKE, in all AusDiagnostics panels controls for possible PCR interference in each sample.

For further details on interfering substances, please refer to the High-Plex 24 System IFU (**Section 13.1 Interfering Substances**).

10.3 ANALYTICAL SPECIFICITY

The MT-PCR technology achieves highly specific pathogen detection and is not to be confused with standard PCR or multiplex PCR. The step 1 amplification is limited to 18 cycles at which point very little of the starting materials (primers and dNTP) in the master mix have been converted into amplicon products. Each reaction therefore proceeds independently of the others in the multiplex thus preventing competition between the different assays. The second PCR step employs a set of individual PCR reactions with the primers nested inside the first step primers so that any mis-primed product in the first step cannot result in amplification in the second step. Furthermore the pre-amplification of the first step means that the second step PCR progresses easily to produce clean product in every case. Different conditions are employed for the two PCR steps which favour amplification of low concentration targets in the first step, but clean PCR in the second step. By using a two step reaction with a dilution between the steps, the effect of any inhibitory substances is also reduced.

A number of published studies have provided evidence that a positive result is only obtained for the gene targeted by the specific inner primers in the multiplex panels. For example, no cross-reactivity was detected in a 17 fungal pathogen multiplex using 200 blood culture specimens that contained bacteria including *Staphylococcus aureus*, *Staphylococcus epidermidis*, coagulase negative *Staphylococcus*, *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Streptococcus pneumoniae*, *Proteus mirabilis*, *Salmonella typhi*, *Bacteroides fragilis*, *Klebsiella oxytoca*, *Enterococcus faecalis*, *Pseudomonas aeruginosa*, *Streptococcus gordonii*, *Streptococcus pyogenes*, *Streptococcus constellatus*, *Streptococcus salivarius*, *Sphingobacterium spiritivorum*, *Corynebacterium jeikeium*, *Propionibacterium acnes* or in 30 blood cultures without micro-organisms.[8, 9]

10.4 ANALYTICAL SENSITIVITY

The limit of detection (LoD) was determined using serial dilutions of plasmids, with a multiplexed Step 1 amplification and 16 replicates per dilution tested. The LoD was determined to be the lowest concentration that showed 100% target amplification. Ranges are used when samples with higher concentrations were not detected, contrary to 100% amplification of samples with lower concentrations. The LoDs calculation is given as either copies per 10 µL sample or copies per mL of the original sample. The sample copies/mL calculation is based on 100% efficient nucleic acid extraction that concentrates a 200 µL sample into a 50 µL eluate.

Assay	LoD (copies/ 10 µL)	LoD (copies/ mL)
Influenza A	76-95	1,900-2,375
H1(2009)	18	450
HA-H3	52	1300
Influenza B	21	525
RSV-A	4-27	100-675
RSV-B	85	2125
SARS-CoV-2 a	86-173	2150-4325
SARS-CoV-2 b	In progress	In progress

10.5 CLINICAL PERFORMANCE USING NUCLEIC ACID EXTRACTS

The clinical performance for the targets used in this product were assessed by multiple clinical laboratories in Australia, New Zealand and the United Kingdom. Each institution's alternative method was considered the reference method for this assessment.

Assay	SENSITIVITY % (95% CI)	SPECIFICITY % (95% CI)
Influenza A	100.0 (88.6-100.0)	100 (96.7-100.0)
H1(2009)	100.0 (80.8-100.0)	100.0 (97.0-100.0)
HA-H3	100.0 (82.8-100.0)	100.0 (97.1-100.0)
Influenza B	100.0 (87.4-100.0)	100.0 (99.2-100.0)
RSV (RSV A & B)	100.0 (93.9-100.0)	100.0 (99.1-100.0)
SARS-CoV-2 a	100 (90.8-100.0)	100 (97.4-100.0)
SARS-CoV-2 b	97.7 (86.5-99.9)	99.4 (96.2-100.0)

11. LIMITATIONS OF THE PROCEDURE

- This product is only for use by suitably trained personnel in qualified laboratories.
- The performance of the SARS-CoV-2, Influenza and RSV 8-well panel has only been established on the AusDiagnostics High-Plex 24 systems.
- The assays in this product do not provide a quantitative value for the pathogen(s) in the sample.
- The performance of the test has been evaluated for use with human specimen material only.
- The performance of this test has only been validated with nucleic acid extracts from the following specimen types: nasal swab, throat swab, nasopharyngeal swab, nasopharyngeal aspirate (NPA), tracheal aspiration, bronchial washing, and bronchoalveolar lavage (BAL). It has not been validated for use with other sample types.
- The performance of this test has not been established for patients without symptoms of respiratory illness.
- The performance of this test has not been established for immunocompromised individuals.
- The SARS-CoV-2, Influenza and RSV 8-well panel is designed to measure specific nucleic acid sequences. Therefore, a negative result does not exclude the possibility that an unusual sequence variant is present. The results obtained with this product should be used in conjunction with information available from clinical evaluations and other diagnostic procedures. A negative result cannot be relied upon for a definitive diagnosis. Failure or delay in treatment of an infected patient may lead to death, with immunocompromised patients being at highest risk.
- The detection of nucleic acid is dependent upon proper specimen collection, handling, transportation, storage, and preparation (using manufacturer of specimen collection devices instructions). Failure to follow proper procedures can lead to incorrect results.
- Discrimination between RSV A and RSV B strains is for information purposes only.

12. TECHNICAL ENQUIRIES

Further instructions and troubleshooting can be found in the High-Plex 24 System IFU (**Section 14. Troubleshooting**).

For assistance or if any issues recur, please contact AusDiagnostics.
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13. ACKNOWLEDGEMENTS

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14. GLOSSARY

The following symbols can be found on AusDiagnostics SARS-CoV-2, Influenza and RSV 8-well Panel components or throughout these Instruction for Use (IFU). Use the definitions below as a guideline to interpret the symbols.

14.1 SYMBOLS

Where relevant, symbols are taken from ISO 15223-1:2016 Medical devices - Symbols to be used with medical devices labels, labelling and information to be supplied.

	Manufacturer
	Authorised representative in the European Union
 or REF	Catalogue Number
 or Ver	Version number
LOT	Lot/Batch code
GTIN	This product has been assigned a unique Global Trade Item Number.
	Indicates that the relevant product is intended for *in vitro* diagnostic use in Australia and is included on the Australian Register of Therapeutic Goods (ARTG).
	Indicates that the relevant product is intended for *in vitro* diagnostic use in the European Economic Area and is compliant with the European IVD Directive 98/79/EC.
	WARNING. Please read the indicated section carefully.
	Please consult the identified instructions for use before use
	Do not re-use
	Storage temperature range (upper and lower limit)
	Storage temperature range (upper limit only)
	Positive Control
	Expiry date (yyyy-mm-dd)
WARNING	Indicates a statement that alerts users about a situations that, if not avoided, could result in hazards or other serious adverse consequences from the use of the device
IMPORTANT	Indicates a statement that alerts the user to special care or special activities necessary for the safe and effectives use of the device
Note	Indicates additional information

14.2 DEFINITIONS

Panel of assays: A set of panel components that are intended to be used together to detect a specific group ("panel") of targets. Panel components include Step 1 Tubes and Step 2 Plates.

Panel-specific IFU: Instructions for Use (IFU) which contain information specific to a panel.

Operator: The individual who is interacting with the High-Plex 24 System.

Primers: Short synthetic oligonucleotides specifically designed to bind to and amplify specific gene sequences under conditions provided during PCR.

A Run: All steps from starting the MT Assay Setup Software (see **Section 7.3 Run the processor**) to generation of the MT Analysis file is considered "a run"

RUO: RESEARCH USE ONLY. This assay is not intended for IVD use and has not been validated.

Target: A gene or sequence that primers are designed to hybridise to.

15. DISCLAIMER

AusDiagnostics does not warrant or guarantee that its products are merchantable or satisfactory for any particular purpose, and there are no warranties, express or implied, to such effect. AusDiagnostics will not be liable for any incidental, consequential or contingent damages involving the use of its products. AusDiagnostics' responsibility is limited to replacement of items ordered only.

AusDiagnostics reserves the right to discontinue or change specifications, products, services, or models at any time without incurring obligations.

In no event shall AusDiagnostics be responsible for failures, errors, or other liabilities resulting from customers' noncompliance with the procedures and precautions outlined herein or as a result of pathogen variants which were not sequenced at the time of assay design.

16. REFERENCES

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17. DOCUMENT HISTORY

Document ID of IFU	Date of Change	Changes
20081-r01	20/03/2020	Original document.