AusDiagnostics

Multiplexed Diagnostics | Affordable Healthcare

ENTERIC VIRUSES (8-WELL)
REF 25037

FOR THE *HIGH*-PLEX 24 SYSTEM

INSTRUCTIONS FOR USE

IVD ARTG IVD CE

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

NOTICE OF CHANGE: APRIL 2018

Step 1 tubes now come in quantities of 12 x 8-well strips assembled in a 96-well frame, and will be foiled sealed in the future.
IMPORTANT: The foiled sealed Step 1 tubes require a hinged cycler cover to be installed before they can be used.

Please contact AusDiagnostics if your system has not been upgraded from the old cycler lid (see Section 12. Technical Enquiries).

Please see *High*-Plex 24 System IFU (Document 9150r10) for further instructions.

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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 kit 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 product must only be used with the *High*-Plex 24 System.
- Good laboratory practice is essential for the intended performance of this product. For further safety information, please consult the relevant Safety Data Sheets (SDS). **Note**: No AusDiagnostics reagents contain hazardous substances, as listed in Regulation (EC) No 1272/2008 and according to the Globally Harmonised System (GHS) classification. AusDiagnostics SDS's can be accessed online at http://www.ausdiagnostics.com/regulatory.html
- This kit 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.

2. FURTHER INSTRUCTIONS REQUIRED

The Instructions for Use (IFU) for Enteric Viruses (8-well) includes product-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).

This IFU must be read in conjunction with:

- *High*-Plex 24 System IFU (Document 9150r10).
- Mastermix IFU (Document 40000r03)

and if applicable, must also be read with:

- Synthetic Positive Controls IFU (Document 91001r05; See **Section 9. Controls**)

3. NAME AND INTENDED USE

Enteric Viruses (8-well) is intended for *in vitro* diagnostic (IVD) use by suitably trained personnel in qualified laboratories using the *High*-Plex 24 System (REF 9150).

These tests utilise a multiplex-tandem polymerase chain reaction (MT-PCR)[1] 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**.

Enteric Viruses (8-well) is intended as a semi-automated qualitative 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

ENTERIC VIRUSES (8-WELL) REF 25037 VER 07

ARTG Identifier: 235623

Assay	Target
Rotavirus	Rotavirus A (includes all strains)
noro-1	Norovirus Genogroup I (includes G1.1, 1.3, 1.6, 1.8, 1.9; excludes G1.2)
noro-2	Norovirus Genogroup II (multiple genotypes including 2.4)
EV	Enterovirus (includes types A, B, C and D)
hAdv F,G	Adenovirus Group F (includes AdV40 and 41) and G (includes AdV52)
Sapovirus	Sapovirus (includes genogroups 2, 4 and some 1 including 1.1)
Astrovirus	Astrovirus (includes serotypes 1 - 8)
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 235623) and the European Union (CE-mark).

These tests utilise a multiplex-tandem polymerase chain reaction (MT-PCR)[1] 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. Summary and Explanation of the Test**.

The Enteric Viruses (8-well) panel is intended to detect the following viruses that have been associated with gastrointestinal infection:

4.1 TARGET DESCRIPTIONS

Adenoviruses (hAdv) are associated with a range of clinical presentations, including respiratory and gastrointestinal infections, and are comprised of six different subgenera (A-F)[2,3]. The predominant serotypes responsible for gastroenteritis are AdV40 and AdV41 from the subgenus F[2,3], with a recently described AdV52 from subgenus G[4] also found in the gastrointestinal tract. The hAdv F,G assay is designed to detect Adenovirus F and G.

Astrovirus infections cause 5 - 9% of gastroenteritis in young children[5], with an estimated 90% of children having HAstV-1 antibodies[6]. There are eight described serotypes, with HAstV-1 being the most prevalent. The Astrovirus assay is designed to detect all known human Astrovirus serotypes.

Enterovirus (EV) is a member of the picornaviruses which are regarded as the most common cause of viral infection worldwide[7]. The EV assay is designed to detect human Enterovirus groups Coxsackie, Echovirus, and Enterovirus.

Noroviruses are the leading cause of epidemic gastroenteritis[2]. A low infectious dosage (~18-1000 particles) and the ability of the virus to withstand a wide range of temperatures (0°C - 60°C) are some of its characteristics that help facilitate widespread infections[8]. Noroviruses are classified into five distinct genogroups (GI-GV), where GI, GII and GIV are known to infect humans. GII type 4 is the most predominant genotype worldwide[8]. The noro-1 and noro-2 assays are designed to respectively detect Norovirus GI and GII types.

Rotavirus is the leading cause of severe diarrhoea in infants and children. Infection occurs through the faecal-oral route or through mucous membranes such as inhalation of airborne droplets containing the virus[9]. Rotavirus A causes more than 90% of all Rotavirus infections worldwide. The Rotavirus assay is designed to detect all strains.

Sapovirus infections are recognised as a significant cause of non-norovirus viral gastroenteritis in adults and children[10,11]. There are currently seven genogroups described, of which GI, GII, GIV and GV are known to infect humans[11]. The Sapovirus assay is designed to detect all four human Sapovirus genogroups.

5. KIT COMPONENTS: MATERIALS AND STORAGE

Note: No AusDiagnostics reagents contain hazardous substances, as listed in Regulation (EC) No 1272/2008[12] and according to the Globally Harmonised System (GHS) classification.

Kit name	Kit component	REF	GTIN
Enteric Viruses (8-well)	Step 1 Tubes: Enteric Viruses (8-well)	25037S	9343044002243
	Step 2 Plates: Enteric Viruses (8-well)	25037P	9343044002236
	Demi RNA Mastermix	40340RNA	9343044001758

5.1 STEP 1 TUBES

Step 1 Tubes for Enteric Viruses (8-well) 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.

IMPORTANT: The Step 1 tubes with foil seals require a hinged cycler cover to be installed before they can be used. Please contact AusDiagnostics if you have not been upgraded from the old cycler lid (see Section 12. Technical Enquiries).

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 Enteric Viruses (8-well) 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
Water tube		Blue-capped 2.0 ml tube containing 1.5 ml water	Dilution of mastermix and samples	36
Oil tube		Green-capped 2.0 ml tube containing 0.7 ml mineral oil	Prevents evaporation of the Step 1 reaction	36
Dilution plate		Empty, 96-well plate	Houses the dilution for Step 2	12
(Bleach) Container		Empty, white-capped 5.0 ml tube	To be loaded with bleach, which deactivates DNA/ RNA	6

Materials	Label	Description	Function	Qty.
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 MASTERMIX

Mastermix box label	Materials	Labels	Description	Vol.	Qty
DEMI RNA MASTERMIX REF 40340RNA	Step 1 Demi RNA	A	Yellow-capped 0.5 ml tube containing the enzymes in buffer for the Step 1 reaction	120 µl	10
	Step 2 Demi RNA	B	Red-capped 1.5 ml tube containing the enzymes in buffer for the Step 2 reaction	500 µl	10

STORAGE AND HANDLING INSTRUCTIONS

Upon arrival, store the Mastermix box below - 20°C.

WARNING: Mastermix is delivered frozen. If thawed upon arrival, please do not use and contact AusDiagnostics.

WARNING: A run must be started within 30 minutes of thawing the Mastermix. Mastermix is for single use only. Do not re-freeze Mastermixes.

WARNING: Do not re-use reagents and dispose of them according to appropriate safety procedures.

Expiration of product is 3 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 faecal samples and culture.

PCR inhibitors may be present in nucleic acid extracts from faecal samples and their level is dependent on the method used (see **Section 6.2**). Nucleic acid extracts should be free of particulate matter. **Note**: please store your nucleic acid extract in tubes free from PCR inhibitors and nucleases.

AusDiagnostics has validated the use of Roche S.T.A.R. buffer (according to its Instructions for Use) for the preparation of fresh, non-preserved faecal specimens to produce nucleic acid extracts suitable for use with AusDiagnostics Faecal panels:

- Take approximately 100 µl of fresh faecal sample into 1 ml of S.T.A.R. buffer, vortex thoroughly and freeze.
- Thaw the sample and heat to 95°C for 30 sec. After centrifuging for 3 - 5 minutes at 1000 x g, use 200 µl for nucleic acid extraction.

IMPORTANT: long term storage of un-extracted faecal samples in S.T.A.R buffer (even when stored frozen) may result in degradation of RNA. When working with RNA samples, standard precautions to minimise RNA degradation should be used.

Alternatively, Qiagen's Buffer ASL – stool lysis buffer (as per its Instructions for Use) has also been validated to produce nucleic acid extracts suitable for use with AusDiagnostics Faecal panels:

- Add between 100 – 200 µl faeces (or loop full of stool) into 1 mL aliquots of ASL buffer
- Use 400 µl for nucleic acid extraction.

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 automated nucleic acid extraction methods have been validated by AusDiagnostics customers, and have been deemed suitable to produce nucleic acid extracts compatible with the Enteric Viruses (8-well) kit. For further details on the extraction protocols used, please contact AusDiagnostics (see **Section 11. Technical Enquiries**)

Extraction System	Type
bioMerieux NucliSENS easyMAG	Automated
PerkinElmer chemagic prepito-D	Automated
Qiagen QIAsymphony	Automated
Qiagen EZ1	Automated
Qiagen Universal Biorobot system	Automated
Roche High Pure series	Manual
Roche MagNA Pure series	Automated
STRATEC Molecular InviGenius	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).

Sampling options	Applicable situation
Robot sampling from 2 mL tubes	Nucleic acid extracts stored in 2 mL tubes are loaded on the Autosampling block for robotic sampling.
Robot sampling from 1.5 mL flip-cap tubes	Nucleic acid extracts are stored in 1.5 mL flip-cap tubes and loaded on the Autosampling block for robotic sampling.
Robot sampling from 96 well plate samples 1-24	Nucleic acid extracts are stored in a 96-well plate and placed in the Autosampling block section for robotic sampling of wells 1 - 24.
Robot sampling from 96 well plate samples 25-48	Nucleic acid extracts are stored in a 96-well plate and placed in the Autosampling block section for robotic sampling of wells 25 - 48.
Robot sampling from 96 well plate samples 49-72	Nucleic acid extracts are stored in a 96-well plate and placed in the Autosampling block section for robotic sampling of wells 49 - 72.
Robot sampling from 96 well plate samples 73-96	Nucleic acid extracts are stored in a 96-well plate and placed in the Autosampling block section for robotic sampling of wells 73 - 96.

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 kits 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 Faecal Panels (REF 91031) contains all targets for Enteric Viruses (8-well).

The Synthetic Positive Controls IFU must be read before using this product.

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

This product does not include a sample adequacy control as an indicator of the suitability of the nucleic acid extract.

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 that a known positive control be included per extraction run. The Synthetic Positive Controls for Faecal Panels (REF 91031) can be used for a DNA control, and known positive RNA sample must be used to control for RNA extraction.

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 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. EXPECTED CLINICAL PERFORMANCE

10.1 REPRODUCIBILITY AND REPEATABILITY

The reproducibility of the assays on the High-Plex 24 System was assessed by testing 10 nucleic acid extracts of clinical specimens and 11 synthetic positive controls using 3 batches, 3 systems, and 3 operators over 3 days. The coefficient of variation (CV) for the resulting mean cycle take-off values (Ct values) for each of the samples were compared. The CV values within each sample were all below 7%.

The repeatability of the assays on the High-Plex 24 System was assessed by testing 10 clinical nucleic acid extracts and 11 synthetic positive controls on a single High-Plex 24 System. The CV for the resulting mean Ct values for each of the samples were compared. The CV values within each sample were all below 7%.

The low CV 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 were tested for potential PCR interference. Minimal or no interference was seen due to the presence of any one of the substances tested.

Some interference was observed with the RNA Mastermix when using substances containing high concentrations of ethanol. Ethanol-based wash buffers used in nucleic acid extraction should not be carried over to PCR. The presence of the internal control, SPIKE, in all AusDiagnostics products 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

Pathogens that are likely to be present in the specimen types used during the clinical validation were tested for cross-reactivity with the assays in this product. No cross-reactivity was seen.

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)
Rotavirus	8	200
noro-1	14 - 35	350 - 875
noro-2	13 - 16	208
EV	3	75
hAdV F,G (Adenovirus)	8 - 16	200 - 400
SaV (Sapovirus)	18 - 72	450 - 1800
HastV (Astrovirus)	17	425

10.5 CLINICAL PERFORMANCE

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)
Rotavirus	100.0 (89.1 - 100.0)	98.9 (96.6 - 99.7)
noro-1*	100.0 (74.7 - 100.0)	99.0 (93.7 - 99.9)
noro-2*	92.9 (64.2 - 99.6)	94.0 (89.9 - 96.5)
EV	100.0 (81.5 - 100.0)	99.4 (96.2 - 100.0)
hAdV F,G (Adenovirus)	100.0 (80.7 - 100.0)	97.4 (94.7 - 98.7)
SaV (Sapovirus)*	100.0 (73.2 - 100.0)	100.0 (65.5- 100.0)
HastV (Astrovirus)	100.0 (85.9 - 100.0)	100.0 (51.7 - 100.0)

*These assays have been validated with <20 confirmed positive samples. During primer design for each assay, bioinformatics analysis is conducted whereby the target sequence of the primers is analysed in all publicly available sequences. This analysis is based on published research and in-house studies on the importance of any mismatches in primer sequence on the efficiency of qPCR. This provides evidence that AusDiagnostics assays should detect all specified targets, and therefore assays validated with a low number of confirmed samples can be relied upon.

11. LIMITATIONS OF THE PROCEDURE

- This product is only for use by suitably trained personnel in qualified laboratories.

- The Enteric Viruses (8-well) panel performance has only been established on 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: faecal samples and culture
- The performance of this test has not been established for patients without symptoms of gastrointestinal illness.
- The performance of this test has not been established for immunocompromised individuals.
- The Enteric Viruses (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.

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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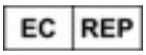
14. GLOSSARY

The following symbols can be found on AusDiagnostics Enteric Viruses (8-well) Kit 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.
	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)
DEVICE FOR PERFORMANCE STUDY ONLY (PSO)	The device is intended for performance study only. The device is not IVD marked or intended for IVD purposes.
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

Kit: A set of kit components that are intended to be used together to detect a specific group ("panel") of targets. Kit components include Step 1 tubes, Step 2 plates, Mastermix, and template.

Kit-specific IFU: Instructions for Use (IFU) which contain information specific to a kit.

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"

PSO: PERFORMANCE STUDY ONLY (PSO).

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

15. REFERENCES

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16. DOCUMENT HISTORY

This document replaces the previous Enteric Viruses (8-well) IFU (Document ID: 25037r04). See changes below.

Document ID of IFU	Date of Change	Changes
25037r05	4 April 2018	IFU updated for new Step 1 tubes which now come in quantities of 12 x 8-well strips assembled in a 96-well frame, and are foiled sealed. Step 2 now comes in quantities of 288 samples. No desiccant is present in Step 1 foil sealed tube packaging, so statement is removed. Addition of Section 11. LIMITATIONS OF THE PROCEDURE.
25037r04	4 Dec. 2017	Manufacturer address updated
25037r03	12 Sept. 2017	Instrument name updated to *High*-Plex 24 System consisting of MT Processor and MT Analyser. Software now referred to as MT Assay Setup Software and MT Analysis. *High*-Plex 24 System and Synthetic Positive Control IFU document IDs updated (section 2).
25037r02	28 July 2017	New version of product released (version 6) with updated noro-2 assay. Performance data (sensitivity and specificity) updated. In section 6.1: addition of validated sample preparation method of Qiagen's Buffer ASL – stool lysis buffer, and S.T.A.R buffer recommendation section updated. Statement added to section 1 "For further safety information, please consult the relevant Safety Data Sheets (SDS). These can be accessed online at http://www.ausdiagnostics.com/regulatory.html" Addition of statement "No AusDiagnostics reagents contain hazardous substances, ….according to the Globally Harmonised System (GHS) Classification" in section 5. New statement in section 9.2: "DO NOT USE BLEACH TO CLEAN THE INSTRUMENT."
25037r01	1 Aug. 2016	New product specific IFUs released from 1st August 2016. Updated format to comply with relevant standards.