Safety Data Sheet

< Master Mix UP >

Version 1 – Revision 0

For Research Use Only (RUO)

Not for use in diagnostic procedures. No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of disease.

Publication number: SDS_Master Mix UP_RUO_V1_R0

September 2023

Table of contents

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 as amended by Regulation (EU) No. 2020/878, and Regulation (EC) No. 1272/2008

SECTION 1: Identification of the substance / mixture and the company undertaking

1.1 Product identifier

- Product name: Master Mix UP

1.2 Relevant identified uses of the substance or mixture and uses advised against

- Recommended use: This product is for research and development only
- Uses advised against: No information available

1.3 Details of the supplier / manufacturer of the safety data sheet

Advanced Biological Laboratories (ABL) S.A.
52-54 Avenue du X Septembre, L-2550 Luxembourg
Technical Support Center at support-diag@ablsa.com
Call +339 7017 0300

1.4 Emergency telephone number

Please refer to your local or national poison control centers for emergency information service and to declare any data relevant to toxicovigilance and other vigilance schemes.

SECTION 2: Hazard identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Physical hazards
Not Hazardous

Health hazards
Not Hazardous

Environmental hazards
Not Hazardous

Additional information
Not applicable

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]
Hazard pictograms
None

Signal Word
None

Hazard Statements
Not Applicable

EU Specific Hazard Statements
Not Applicable

Precautionary Statements
Prevention
Not Applicable

Response
Not Applicable

Storage
Not Applicable

Disposal
Not Applicable

2.3 Other hazards

Not Applicable

SECTION 3: Composition/information on ingredients

3.1 Mixtures

The product contains no substances which at their given concentration, are considered to be hazardous to health. We recommend handling all chemicals with caution.

SECTION 4: First aid measures

4.1 Description of first aid measures

- Skin contact: Rinse skin with water. Immediate medical attention is not required.
- Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- Ingestion: Not expected to present a significant ingestion hazard under anticipated conditions of normal use. If you feel unwell, seek medical advice.
- Inhalation: Not expected to be an inhalation hazard under anticipated conditions of normal use of this material. Consult a physician if necessary.
- Notes to Physician: Treat symptomatically

4.2 Most important symptoms and effects, both acute and delayed

Not Applicable

4.3 Indication of any immediate medical attention and special treatment needed

None

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media: Water spray. Carbon dioxide (CO2). Foam. Dry chemical.
- Unsuitable extinguishing media: No information available

5.2 Special hazards arising from the substance or mixture

Not known

5.3 Advice for firefighters

Standard procedure for chemical fires.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation
Always wear recommended Personal Protective Equipment
Use personal protection equipment
See section 8 for more information

6.2 Environmental precautions

No special environmental precautions required.

6.3 Methods and material for containment and cleaning up

Soak up with inert absorbent material.

6.4 Reference to other sections

See section 8 for more information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Use personal protective equipment as required. No special handling advices are necessary.

7.2 Conditions for safe storage, including any incompatibilities

Keep in a dry, cool and well-ventilated place. Keep in properly labelled containers.

7.3 Storage conditions

Store at -25 °C to -15 °C

7.4 Specific end use(s)

For research use only. Not for use in diagnostic procedures.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Exposure Limits: Contains no substances with occupational exposure limit values.

Engineering Measures: Ensure adequate ventilation, especially in confined areas.

8.2 Exposure controls

Personal protection equipment

- **Respiratory protection:** In case of insufficient ventilation wear respirators and components tested and approved under appropriate government standards.
- **Hand protection:** Wear suitable gloves Glove material: Compatible chemical-resistant gloves.
- **Eye protection:** Tight sealing safety goggles.
- **Skin and Body Protection:** Wear suitable protective clothing.
- **Hygiene Measures:** Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls
No special environmental precautions required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid	
Colour	No data	
Odour	No information available	
Molecular Weight	No data	
Melting point / melting range	**°C** No data	**°F** No data
Boiling point / boiling range	**°C** No data	**°F** No data
Flammability (solid, gas)	No data	
Lower explosion limit	No data	
Upper explosion limit	No data	
Flash point	**°C** No data	**°F** No data
Autoignition Temperature	**°C** No data	**°F** No data
Decomposition temperature °	**°C** No data	**°F** No data
pH	No data	
Evaporation rate	No data	
Viscosity	No data	
Solubility	No data	
Partition coefficient:		
n-octanol/water	No data	
Vapour Pressure	No data	
Specific gravity	No data	

Relative density	No data
Vapour density	No data
Explosive properties	No data
Oxidising properties	No data
Particle characteristics	No data

9.2 Other information

Information with regards to physical hazard classes
No information available

Other safety characteristics
No information available

SECTION 10: Stability and reactivity

10.1 Reactivity

None known.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reaction has not been reported.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

No dangerous reaction known under conditions of normal use.

10.6 Hazardous decomposition products

No data available.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

There is no evidence available indicating acute toxicity.

Principal Routes of Exposure

Skin corrosion/irritation Data are conclusive but insufficient for classification

Serious eye damage/irritation Data are conclusive but insufficient for classification

Respiratory or skin sensitization Data are conclusive but insufficient for classification

Specific target organ toxicity (STOT) – single exposure Data are conclusive but insufficient for classification

Specific target organ toxicity (STOT) – repeated exposure Data are conclusive but insufficient for classification

Carcinogenicity Data are conclusive but insufficient for classification

Germ cell mutagenicity Data are conclusive but insufficient for classification

Reproductive Toxicity Data are conclusive but insufficient for classification

Aspiration Hazard Data are conclusive but insufficient for classification

11.2 Information on other hazards

Endocrine disrupting properties
No information available

Other information
No information available

SECTION 12: Ecological information

12.1 Toxicity

Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Endocrine disruption properties

This product does not contain any known or suspected endocrine disruptors

12.7 Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in according to approved disposal technique. Disposal of this product, its solutions or of any by-products, shall comply with the requirements of all applicable local, regional or national/federal regulations.

SECTION 14: Transport information

IATA / ADR / DOT-US / IMDG
Not regulated in the meaning of transport regulations

UN number or ID number Not Applicable
UN proper shipping name Not Applicable
Transport hazard class(es) Not Applicable
Packing group Not Applicable

Environmental hazards
Not Applicable

Special precautions for user
Not Applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Substances of Very High Concern
None

Substance subject to authorisation per REACH Annex XIV
None

Restricted substances under EC 1907/2006, Annex XVII
None

Regulation (EC) No 649/2012 (Rotterdam Convention - export/import of dangerous chemicals)
None

Regulation (EU) No 2019/1021 (Stockholm Convention – persistent organic pollutants)
None

EU - Substances Depleting the Ozone layer (1005/2009)
None

German Water hazard classes (Wassergefährdungsklassen)

Not classified.

Other International Inventories
No information available

15.2 Chemical Safety Assessment

No Chemical safety assessment has been carried out.

SECTION 16: Other information

References
- ECHA: http://echa.europa.eu/
- TOXNET: http://toxnet.nlm.nih.gov/
- eChemPortal: http://www.echemportal.org/
- LOLI database: https://www.chemadvisor.com/loli-database

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:
Not classified

Abbreviations and acronyms
TWA - Time-Weighted Average
OELs - Occupational Exposure Limits
STEL - Short Term Exposure Limit
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
KECL - Korean Existing and Evaluated Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
CEPA - Canadian Environmental Protection Act
EPA - Environmental Protection Agency
OSHA - Occupational Safety and Health Administration of the US Department of Labour
IATA - International Air Transport Association
DOT - Department of Transportation
IMDG - International Maritime Dangerous Goods
ACGIH - American Conference of Governmental Industrial Hygienists
NIOSH - National Institute for Occupational Safety and Health
AIHA - American Industrial Hygiene Association
HMIS - Department of Defense Hazardous Materials Information System
NTP - National Toxicology Program
IARC - International Agency for Research on Cancer

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No 1907/2006.

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Version

Title: SDS_Master Mix UP_RUO_V1_R0
Version: 1.0
Effective date: 25th September 2023

ADVANCED BIOLOGICAL LABORATORIES S.A.
52-54 Avenue du X Septembre
L-2550 Luxembourg
Tel : +352 26 66 93 68
www.ablsa.com

Improving Disease Management

Certification of Intended Use

Advanced Biological Laboratories (ABL) S.A declares that the product below is not declared as a medical device neither according to EU Directive 98/79/EC-In Vitro Diagnostics Medical Devices nor to EU Directive 94/42/EEC – Medical Devices.

The product is solely labeled as "RUO", "Research Use Only". It may freely be distributed in the European Economic Area including Luxembourg and other territories.

Manufacturer:
Advanced Biological Laboratories (ABL) S.A,
52-54 Avenue du X Septembre,
2550 Luxembourg, Luxembourg

Catalogue Number	Product Name
106A24	DeepChek® Assay NS5A (GT2) Drug Resistance V1

Luxembourg, le 17/11/2021

In kind regards

Ronan Boulmé
ABL - GRC Manager / DPO
Quality Management Representative

As Reviewed by Luxembourg House of Entrepreneurship

The Chamber of Commerce of the Grand Duchy of Luxembourg hereby confirms that the affixed signature in this document corresponds to the specimen of the signature submitted by the company ABL to the Chamber of Commerce.

NOV. 18 2021

CHAMBER OF COMMERCE LUXEMBOURG
Tania MARTINS

ADVANCED BIOLOGICAL LABORATORIES S.A.
52-54 Avenue du X Septembre
L-2550 Luxembourg
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Manufacturer:
Advanced Biological Laboratories (ABL) S.A,
52-54 Avenue du X Septembre,
2550 Luxembourg, Luxembourg

Catalogue Number	Product Name
109A24	DeepChek® Assay CORE Genotyping V1

Luxembourg, le 17/11/2021

In kind regards

Ronan Boulmé
ABL - GRC Manager / DPO
Quality Management Representative

As Reviewed by Luxembourg House of Entrepreneurship

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Manufacturer:
Advanced Biological Laboratories (ABL) S.A,
52-54 Avenue du X Septembre,
2550 Luxembourg, Luxembourg

Catalogue Number	Product Name
110C24	DeepChek® Assay NS5B / 5'UTR Genotyping V3

Luxembourg, le 17/11/2021

In kind regards

Ronan Boulmé
ABL - GRC Manager / DPO
Quality Management Representative

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Manufacturer:
Advanced Biological Laboratories (ABL) S.A,
52-54 Avenue du X Septembre,
2550 Luxembourg, Luxembourg

Catalogue Number	Product Name
113A24	DeepChek® Assay RT Genotyping and Drug Resistance V1

Luxembourg, le 17/11/2021

In kind regards

Ronan Boulmé
ABL - GRC Manager / DPO
Quality Management Representative

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ADVANCED BIOLOGICAL LABORATORIES S.A.
52-54 Avenue du X Septembre
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Manufacturer:
Advanced Biological Laboratories (ABL) S.A,
52-54 Avenue du X Septembre,
2550 Luxembourg, Luxembourg

Catalogue Number	Product Name
114A24	UltraGene Assay VIRAL LOAD V1

Luxembourg, le 17/11/2021

In kind regards

Ronan Boulmé
ABL - GRC Manager / DPO
Quality Management Representative

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Tania MARTINS

ADVANCED BIOLOGICAL LABORATORIES S.A.
52-54 Avenue du X Septembre
L-2550 Luxembourg
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www.ablsa.com

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Manufacturer:
Advanced Biological Laboratories (ABL) S.A,
52-54 Avenue du X Septembre,
2550 Luxembourg, Luxembourg

Catalogue Number	Product Name
168A	DeepChek® HCV Genotyping External Controls V1

Luxembourg, le 17/11/2021

In kind regards

Ronan Boulmé
ABL - GRC Manager / DPO
Quality Management Representative

As Reviewed by Luxembourg House of Entrepreneurship

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52-54 Avenue du X Septembre
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www.ablsa.com

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Manufacturer:
Advanced Biological Laboratories (ABL) S.A,
52-54 Avenue du X Septembre,
2550 Luxembourg, Luxembourg

Catalogue Number	Product Name
105A24	DeepChek® Assay NS5A Genotyping and Drug Resistance V1.X

Luxembourg, le 03/01/2022

In kind regards

Ronan Boulmé
ABL - GRC Manager / DPO
Quality Management Representative

As Reviewed by Luxembourg House of Entrepreneurship

JAN. 04 2022

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CHAMBER OF COMMERCE LUXEMBOURG
Tania MARTINS

ADVANCED BIOLOGICAL LABORATORIES S.A.
52-54 Avenue du X Septembre
L-2550 Luxembourg
Tel : +352 26 66 93 68
www.ablsa.com

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Manufacturer:
Advanced Biological Laboratories (ABL) S.A,
52-54 Avenue du X Septembre,
2550 Luxembourg, Luxembourg

Catalogue Number	Product Name
110B24	DeepChek® Assay NS5B / 5'UTR Genotyping V2.X

Luxembourg, le 03/01/2022

In kind regards

Ronan Boulmé
ABL - GRC Manager / DPO
Quality Management Representative

As Reviewed by Luxembourg House of Entrepreneurship

JAN. 04 2022

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Tania MARTINS

ADVANCED BIOLOGICAL LABORATORIES S.A.
52-54 Avenue du X Septembre
L-2550 Luxembourg
Tel : +352 26 66 93 68
www.ablsa.com

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Manufacturer:
Advanced Biological Laboratories (ABL) S.A,
52-54 Avenue du X Septembre,
2550 Luxembourg, Luxembourg

Catalogue Number	Product Name
184A24	DeepChek® Assay Whole Genome HBV Genotyping V1

Luxembourg, le 09/06/2022

In kind regards

Ronan Boulmé
ABL - GRC Manager / DPO
Quality Management Representative

As Reviewed by Luxembourg House of Entrepreneurship

15 JUIN 2022
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CHAMBER OF COMMERCE LUXEMBOURG
Melissa RAMDEDOVIC

ADVANCED BIOLOGICAL LABORATORIES S.A.
52-54 Avenue du X Septembre
L-2550 Luxembourg
Tel : +352 26 66 93 68
www.ablsa.com

Improving Disease Management

Certification of Intended Use

Advanced Biological Laboratories (ABL) S.A declares that the product below is not declared as a medical device neither according to EU Regulation 2017/746 - In Vitro Diagnostics Medical Devices nor to EU Regulation 2017/745 – Medical Devices.

The product is solely labeled as "RUO", "Research Use Only". It may freely be distributed in the European Economic Area including Luxembourg and other territories.

Manufacturer:
Advanced Biological Laboratories (ABL) S.A,
52-54 Avenue du X Septembre,
2550 Luxembourg, Luxembourg

Catalogue Number	Product Name
199A24	DeepChek® Assay Whole Genome HDV Genotyping V1.x

Luxembourg, le 14/09/2023

In kind regards,

Dr Chalom B. Sayada
Administrateur Délégué
ABL S.A.

As Reviewed by Luxembourg House of Entrepreneurship

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Nr. V 83 2023 00624

Grand Duché du Luxembourg
14/09/2023

Camille Schneider

ADVANCED BIOLOGICAL LABORATORIES S.A.
52-54 Avenue du X Septembre
L-2550 Luxembourg
Tel : +352 26 66 93 68
www.ablsa.com

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Manufacturer:
Advanced Biological Laboratories (ABL) S.A,
52-54 Avenue du X Septembre,
2550 Luxembourg, Luxembourg

Catalogue Number	Product Name
113B24	DeepChek® Assay RT Genotyping and Drug Resistance V2.x

Luxembourg, on 18th of September 2025

In kind regards,

Dr Chalom B. Sayada
Administrateur Délégué
ABL S.A.

As Reviewed by Luxembourg House of Entrepreneurship

Grand Duché du Luxembourg
18/09/2025

Camille Schneider

illumina®

Certificate of Conformance #1002428959

This Document Certifies that products identified below conform to Illumina requirements and specifications.

Catalog ID /Part #	Item	Lot #/Batch #
MS-102-2002	MiSeq® Reagent Kit v2 (300 cycle)	
15033624	MiSeq® v2 RGT Kit 300 cyc PE-Bx 1 of 2	20975910
15033626	MiSeq® v2 Reagent Kit Box 2 of2	20972698
20060059	ILMN DNA LP (M)Tag (96 Spl, IPB)	
20049006	ILMN DNA Prep, IPB + Buffers 96	20972288
20015829	ILMN DNA Prep, PCR + Buffers 96	20974064
20015880	ILMN DNA Prep, Tag Beads (M) 96	20972805
20091660	ILMN DNA/RNA UDI D Tag 96 Idx 96 Spl	
20091649	ILMN DNA/RNA UD Index Set D	20965933

Sep-17-2025

Signature

Corin Nisly

Name

Sr. Manager, Quality Ops, Quality Assurance

Title

illumina®

Certificate of Conformance #1002462633

This Document Certifies that products identified below conform to Illumina requirements and specifications.

Catalog ID /Part #	Item	Lot #/Batch #
MS-103-1003	MiSeq® Reagent Nano Kit v2 (500 Cycles)	
15033625	MiSeq® v2 RGT Kit 500 cyc PE-Bx 1 of 2	20984851
15036714	MiSeq® Reagent Nano Kit v2 - Box 2 of 2	20989006

Nov-13-2025

Signature

Corin Nisly

Name

Sr. Manager, Quality Ops, Quality Assurance

Title

illumina®

Certificate of Conformance #1002482187

This Document Certifies that products identified below conform to Illumina requirements and specifications.

Catalog ID /Part #	Item	Lot #/Batch #
OP-101-1001	TruSight® Tumor 15 Kit	
15069871	TRUSIGHT TUMOR 15, LIBRARY PREP BX 1OF3	20978683
15069871	TRUSIGHT TUMOR 15, LIBRARY PREP BX 1OF3	20988405
15069872	TRUSIGHT TUMOR 15, LIBRARY PREP BX 2OF3	20978684
15069872	TRUSIGHT TUMOR 15, LIBRARY PREP BX 2OF3	20986784
15069873	TRUSIGHT TUMOR 15, LIBRARY PREP BX 3OF3	20978687
15069873	TRUSIGHT TUMOR 15, LIBRARY PREP BX 3OF3	20986785
15043895	MiSeq® RGT Kit v3 600 cyc PE-Bx 1 of 2	20984861
15043894	MiSeq® Reagent Kit v3 - Box 2of 2	21007947
MS-103-1002	MiSeq® Reagent Micro Kit v2 (300 Cycles)	
15033624	MiSeq® v2 RGT Kit 300 cyc PE-Bx 1 of 2	20992969
15036715	MiSeq® Reagent Micro Kit v2 -Box 2 of 2	21004057
MS-103-1001	MiSeq® Reagent Nano Kit v2 (300 Cycles)	
15033624	MiSeq® v2 RGT Kit 300 cyc PE-Bx 1 of 2	20992969
15036714	MiSeq® Reagent Nano Kit v2 - Box 2 of 2	21012393
HNA-HS-1001-48	oncoReveal™ Multi-Cancer with CNV	25PB1182

Dec-11-2025

Signature

Corin Nisly

Name

Sr. Manager, Quality Ops, Quality Assurance

Title

DeepChek® Assay

Whole Genome HDV Genotyping

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User Guide

Version 1 – Revision 1

For Research Use Only (RUO). Not for use in diagnostic procedures. No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of disease.

REF **199A24** **GTIN: 05407007961085**

Publication number: IFU_199A24_RUO_EN_V1_R1

July 2024

Document control

Date	Device version	IFU version	Description of change
2024/07/03	A	1.1	Correction of volumes reported on table 1
2023/10/12	A	1.0	Document creation

Contents

Application

For Research Use Only (RUO). Not for use in diagnostic procedures. No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of disease.

The ***DeepChek® Assay Whole Genome HDV Genotyping (RUO)*** aims to amplify the complete genome of the Human Hepatitis delta virus in two PCR reactions. This nucleic acid amplification method screens the mutations in the small Human Hepatitis delta genome that has approximately 1700 nucleotides.

The ***DeepChek® Assay Whole Genome HDV Genotyping (RUO)*** is intended for use by trained laboratory personnel specifically instructed and trained in the techniques of PCR and sequencing workflows.

Principles of the assay

The ***DeepChek® Assay Whole Genome HDV Genotyping (RUO)*** is a reverse transcriptase-polymerase chain reaction test which includes primers, reverse and forward, designed to amplify HDV extracted RNA specimens.

During each round of thermal cycling, amplification products dissociate to single strands at high temperature allowing primer annealing and extension as the temperature is lowered. Exponential amplification of the product is achieved through repeated cycling between high and low temperatures, resulting in a billion-fold or greater amplification of target sequences.

The ***DeepChek® Assay Whole Genome HDV Genotyping (RUO)*** is performed on a PCR instrument.

Assay components

The ***DeepChek® Assay Whole Genome HDV Genotyping*** is provided in one model of 24 reactions (reference: 199A24).

Table 1: Volumes and storage conditions of the assay with reference ***199A24 V1 (RUO)***

Label	Volume for 24 Rxn. (nb. tube x volume)	Color cap	Storage
RT SuperMix	1 x 65 µL	Green	-25°C to - 15 °C
Master Mix HF	1 x 600 µL	Yellow	-25°C to - 15 °C
H_2O	1 x 500 µL	Blue	-25°C to - 15 °C
HDV-A1 FOR (10 µM)	1 x 35 µL	Brown	-25°C to - 15 °C
HDV-A2 REV (10 µM)	1 x 35 µL	Red	-25°C to - 15 °C
HDV-B1 FOR (10 µM)	1 x 35 µL	Pink	-25°C to - 15 °C
HDV-B2 REV (10 µM)	1 x 35 µL	Black	-25°C to - 15 °C

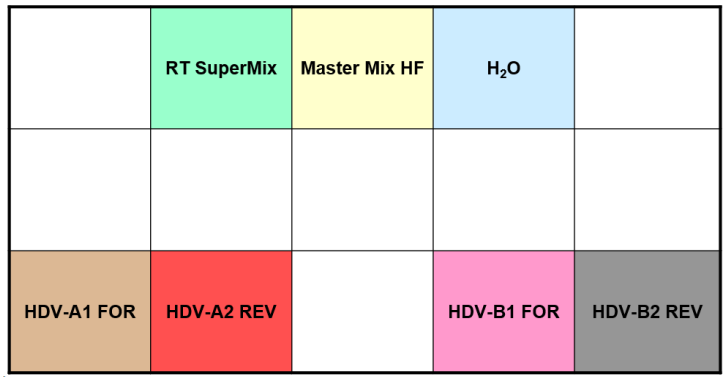


Figure 1: Disposal of the assay components for the assay with reference ***199A24 V1 (RUO)***

Reagent storage and handling

The ***DeepChek® Assay Whole Genome HDV Genotyping*** is shipped on dry ice and should be maintained and stored immediately upon receipt at –20°C to avoid compromising cold chain integrity.

Expiration date: please refer to the label on the kit box.

Materials required but not provided

- Thermocycler
- 96-well plate cooler (Eppendorf / 22510509)
- 96-well PCR plates (Eppendorf / 951020303)
- Plate thermo seals (Thermo Scientific / AB-0558)
- Plate centrifuge
- 0.2 mL thin-wall 8 strips & domed caps (Thermo Scientific / AB-0266)
- 1.5 mL centrifuge tubes (Dot Scientific Inc. / RN1700-GST)
- Centrifuge tubes (see your specific centrifuge manual)
- Mini centrifuge (see your specific centrifuge manual)
- Microliter pipettes dedicated to PCR (0.1-2.5 µL; 1-10 or 1-20 µL; 20-200 µL)
- Ice

Note: Ensure that instruments have been checked and calibrated according to the manufacturer's recommendations and to the relevant manufacturer's Instructions for Use (IFU) to proceed with the instrument.

Warnings and precautions

- **For Research Use Only (RUO). Not for use in diagnostic procedures.** No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of disease.
- Store assay reagents as indicated on their individual labels.
- Do not mix reagents from different kit lots.
- Reagents must be stored and handled as specified in these instructions for use. Do not use reagents past the expiration date.
- Work surfaces and pipettes should be cleaned and decontaminated with cleaning products such as 10% bleach, "DNAZap™" or "RNase AWAY®" to minimize risk of nucleic acid contamination. Residual bleach should be removed from the surface by wiping with 70% ethanol.
- Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious specimens.
- Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- Always use pipette tips with aerosol barriers. Tips that are used must be sterile and free from DNases and RNases.
- Dispose of waste in compliance with applicable regulations.
- Frequent cleaning of the wells of the PCR instrument thermos-blocks is recommended to prevent contamination.
- To avoid contamination, use separated and segregated working areas for extraction and PCR/sequencing preparation, respectively.
- Check whether the PCR reaction tubes are tightly closed before loading on the PCR instrument to prevent contamination of the instrument from leaking tubes.

Workflow

Starting

- Identify the product.
- Verify the expiration date.
- Verify the latest instruction for use available for the product lot number.
- Verify if the product was used already. If yes, check the remaining tests available.

RNA Extraction

To achieve optimal and sensitive HDV RNA analysis, for the best representation of the viral quasispecies, it is recommended to extract **1 mL** of specimen for subsequent cDNA and amplicon generation and elute in the minimum volume required for your preferred extraction kit. Samples which are hemolyzed, icteric or lipemic can invalidate extraction.

The ***DeepChek® Assay Whole Genome HDV Genotyping*** will work with at least an extraction of 400 µL of specimen (i.e., plasma, serum, whole blood) specimens, to be eluted in 60 µL.

For specimens with low viral load, we recommend:

- To perform an ultracentrifugation procedure. Pellet the virus for 1.5 hours at 40'000 g (or alternatively for 2 hours at 24'000g), and at 4°C. Remove enough supernatant to leave the required amount of specimen for your preferred extraction kit.

Or

- To extract one or 2 mL of specimen and elute in the minimum volume required for your preferred extraction kit.

RT reaction setup

1. Thaw extracted template RNA, RT SuperMix, and RNase-free water and place them on ice. Load all the tubes into the centrifuge. Spin the tube at 11,000 g for 10 seconds. And then pipette up and down the mix several times before dispensing.
2. The master mix typically contains all the components required for RT except the template RNA. Prepare a volume of mix greater (n+1) than that required for the total number of reactions to be performed.
3. Vortex the master mix thoroughly and dispense 10 µL into PCR tubes.
4. Add 10 µL of RNA in the PCR tubes. Mix by pipetting the solution up and down a few times.

Table 2: Reaction components for RT.

Reagent	Volume / Reaction
RT SuperMix	2 µL
Extracted viral RNA template	10 µL
H_2O	8 µL

5. Program the thermal cycler according to the program in the next table.

Table 3: RT cycling program.

Cycle	Temperature (°C)	Time
1	25 °C	2 min
1	55 °C	10 min
1	95 °C	1 min
	4 °C	Hold

Note: Ramp rate shall be at 6°C/s.

PCR reaction setup

1. The master mix typically contains all the components required for PCR except the template cDNA. Prepare a volume of master mix greater (n+1) than that required for the total number of reactions to be performed. Prepare PCR WG Fragment 1 & 2 master mix according to next table and following instructions.
2. Vortex the master mix thoroughly and dispense **14** µL into PCR tubes.
3. Add **6** µL of cDNA from the RT step in the PCR tubes. Mix by pipetting the solution up and down a few times.

Table 4: Reaction components for PCR.

Reagent	Volume / Reaction
PCR WG Fragment 1	
Master Mix HF	10 µL
HDV-A1 FOR	1 µL
HDV-A2 REV	1 µL
H_2O	2 µL
PCR WG Fragment 2	
Master Mix HF	10 µL
HDV-B1 FOR	1 µL
HDV-B2 REV	1 µL
H_2O	2 µL

4. Program the thermal cycler according to the program in **Table 5**.

Table 5: PCR cycling program

Cycle	Temperature (°C)	Time
Enzyme activation	98 °C	30 sec
35 cycles	98 °C	10 sec
	65 °C	30 sec
	72 °C	30 sec
Final extension	72 °C	2 min
	4 °C	Hold

Note: Ramp rate shall be at 6°C/s.

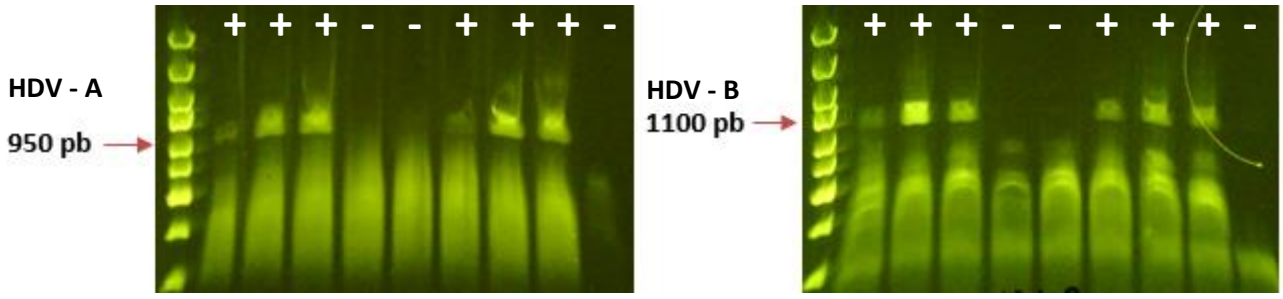
5. Start the program while PCR tubes are still on ice.
6. Once ready, place the PCR-tubes in the designated positions of the thermo block to run the amplification process.

Δ Safe Stopping Point: After amplification, specimens can be stored overnight at 2–10°C, or at -20°C for long-term storage.

7. PCR products shall be controlled through electrophoresis on a 1% agarose gel. Check the intensity of the signal. Even though low-intensity bands usually lead to a successful sequencing, it is recommended to avoid the process if no band can be observed. In that case, please read the troubleshooting section hereinafter.

Note: Primer pairs used in this assay produce two partially overlapping segments covering the entire HDV genome.

The expected amplicon sizes are **PCR 1 ≈ 950 bp (HDV-A)** and **PCR 2 ≈ 1100 bp (HDV-B).**



Troubleshooting guide

Use the following troubleshooting table to diagnose and solve problems. The troubleshooting recommendations assume that all the DeepChek® Assay reagents are stored according to the specifications and that the directions in this guide have been followed correctly.

	Comments and suggestions
Negative controls are positive	
Cross-contamination	Replace all critical reagents. Repeat the experiment with new reagents. Always handle samples, assay components, and consumables in accordance with commonly accepted practices to prevent carry-over contamination.
Absent or low signal in samples	
a. Poor DNA quality or inadequate concentration	Check your (capillary) gel electrophoresis preparation. You may dilute your DNA product according to your (capillary) gel electrophoresis procedure. Follow the instructions for use if using a capillary electrophoresis instrument. Rerun your (capillary) gel electrophoresis.
b. Sample prepared too long before analysis leading to evaporation	Check the volume of the RT-PCR product in the PCR tube/plate. Repeat the PCR of the affected sample target.
c. Poor agarose gel conditions or capillary electrophoresis instrument reagents used are incorrect or unproper	Use new (capillary) gel electrophoresis reagents. Rerun your (capillary) gel electrophoresis.

Comments and suggestions	
No band signal for one or few samples	
a. The PCR didn't work	Take the corresponding PCR product. Run the (capillary) gel electrophoresis. If still no band signal, start again the whole protocol.
b. Degraded RNA isolation from initial blood sample	Check again the viral load of the HDV test. A too low RNA concentration (<10 fg) may result in a negative result. If the RNA concentration is > 10 fg then you may repeat the whole protocol or improve the conditions of the specimen (e.g., ultra-centrifugation, RNA concentration) and do a new RNA isolation on fresh or frozen specimen and start again the whole protocol. Contact our technical support.
c. Limitation variant	If you obtain repeatedly negative results, and other potential error sources have been ruled out, the sample could contain a variant that contains mutations in the primer binding site. Contact our technical support.

Post PCR

Next Generation Sequencing

The main volume of the product outputs is then used for next generation sequencing (NGS). The NGS workflow can be different as the NGS techniques and NGS analyzers vary. NGS sequencing instruments are general laboratory use devices. Sequencing and library preparation reagents are general laboratory use products.

While performing the verification studies, we used the Illumina iSeq 100 Sequencing System (catalog #20021535), the Illumina MiSeq Sequencing System (catalog #SY-410-1003) and the following combination of reagents: ABL ***DeepChek® NGS Library preparation*** (catalog #116BX, 24 or 48 or 96 tests), ABL ***DeepChek® Assay Adapters*** (catalog #124BX, 1-24, 1-48 or 1-96) , Illumina iSeq 100 Reagent (catalog # 20021533, 300 cycles) and Illumina MiSeq Reagent (catalog #MS-102-2003, 500 cycles)

Details available on demand for other NGS analyzers and NGS reagents and technology, please contact our technical support.

Downstream NGS data analysis

The sequencing raw data can then be uploaded in a specific downstream software or a generic bioinformatics tool for HDV genome analysis and results. This software can be classified a standalone medical device according to its intended use. Users shall then follow the software user guide.

Product quality control

In accordance with ABL's Quality Management System, each lot of the assay is tested against predetermined specifications to ensure consistent product quality. Certificates of Analysis are available upon request.

Symbols

 <N>	Contains reagents enough for <N> reactions		Consult instructions for use
	Caution		Temperature limitation

REF	Catalog number	SN	Serial Number
	Use by	**R*n***	R is for revision of the Instructions for Use (IFU) and n is the revision number
	Manufacturer		Country of manufacturing
	Distributor		

Contact Information

For technical assistance and more information, please see our Technical Support Center at Online: support-diag.ablsa.com; Email: support-diag@ablsa.com; Call +339 7017 0300 Or contact your ABL Field-Application Specialist or your local distributor. For up-to-date licensing information or product-specific disclaimers, see the respective ABL Assay User Guide. ABL User Guides are available at **www.ablsa.com/ifu** or can be requested from ABL Technical Services or your local distributor.

Manufacturer and distributors

Advanced Biological Laboratories (ABL) S.A.
52-54 avenue du X Septembre
2550 Luxembourg, Luxembourg

AdvancedDx Biological Laboratories USA Inc.
5-7 Perry Way, Unit 15 Newburyport, MA 01950, USA

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Version 1.1

Effective date: 3rd of July 2024