cobas®

Rx Only

cobas® DNA Sample Preparation Kit

For in vitro diagnostic use

IVD

cobas® DNA Sample Preparation Kit 24 Tests M/N: 05985536190

TABLE OF CONTENTS

Intended use

Principles of the procedure

Sample preparation 3

Materials and reagents

Materials and reagents provided 4

Reagent storage and handling 7

Additional materials required 7

Precautions and handling requirements

Warnings and precautions 8

Good laboratory practice 8

Contamination 9

Integrity 9

Disposal 9

Spillage and cleaning 9

Sample collection, transport, and storage 10

Sample collection and handling 10

Sample transport, storage, and stability 10

Processed sample storage and stability 10

Sample preparation procedure

Using the kit 10

Instructions for use 10

DNA quantitation 13

Additional information

Symbols 14

Technical support 16

Manufacturer and distributors 16

Trademarks and patents 16

Copyright 16

References 16

Document revision 17

Intended use

The **cobas**® DNA Sample Preparation Kit is used for manual sample preparation to isolate genomic DNA from formalin-fixed paraffin-embedded tumor tissue (FFPET) samples.

Principles of the procedure

Sample preparation

FFPET samples are processed and genomic DNA isolated using the **cobas**® DNA Sample Preparation Kit, a generic manual sample preparation based on nucleic acid binding to glass fibers. A deparaffinized 5-micron (µm) section of an FFPET sample is lysed by incubation at an elevated temperature with a protease and chaotropic lysis/binding buffer that releases nucleic acids and protects the released genomic DNA from DNases. Subsequently, isopropanol is added to the lysis mixture that is then centrifuged through a column with a glass fiber filter insert. During centrifugation, the genomic DNA is bound to the surface of the glass fiber filter. Unbound substances, such as salts, proteins and other impurities, are removed by centrifugation. The adsorbed nucleic acids are washed and then eluted with an aqueous solution. The amount of genomic DNA can be spectrophotometrically determined and adjusted to a fixed concentration.

Materials and reagents

Materials and reagents provided

Kit/Cassettes	Components and Reagent Ingredients	Quantity per Test	Safety Symbol and Warning[a]
cobas® DNA Sample Preparation Kit 24 Tests (M/N: 05985536190)	**DNA TLB** (DNA Tissue Lysis Buffer) (M/N: 05517613001) Tris-HCl buffer Potassium chloride 0.04% EDTA 0.1% Non-ionic detergent[b] 0.09% Sodium azide	1 x 10 mL	N/A
	PK (Proteinase K) (M/N: 05860695102) Proteinase K, lyophilized[b]	1 x 100 mg	 **DANGER** H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335: May cause respiratory irritation. P261: Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P264: Wash skin thoroughly after handling. P280: Wear protective gloves/ eye protection/ face protection. P284: Wear respiratory protection. P304 + P340 + P312: IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell. P342 + P311: If experiencing respiratory symptoms: Call a POISON CENTER/doctor. 39450-01-6 Proteinase, tritirachium album serine

Kit/Cassettes	Components and Reagent Ingredients	Quantity per Test	Safety Symbol and Warning[a]
cobas® DNA Sample Preparation Kit 24 Tests (M/N: 05985536190)	**DNA PBB** (DNA Paraffin Binding Buffer) (M/N: 05517621001) Tris-HCl buffer 49.6% Guanidine hydrochloride[b] 0.05% Urea 20% Non-ionic detergent[b]	1 x 10 mL	 **DANGER** H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. P264: Wash skin thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P280: Wear protective gloves/ eye protection/ face protection. P301 + P312 + P330: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth. P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P305 + P351 + P338 + P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. P501: Dispose of contents/ container to an approved waste disposal plant. 50-01-1 Guanidine, hydrochloride (1:1) 9002-92-0 Polidocanol
	WB I (DNA Wash Buffer I) (M/N: 05517656001) Tris-HCl buffer 64% Guanidine hydrochloride[b]	1 x 25 mL	 **WARNING** H302 + H332: Harmful if swallowed or if inhaled. H315: Causes skin irritation. H319: Causes serious eye irritation. P261: Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P264: Wash skin thoroughly after handling. P280: Wear protective gloves/ eye protection/ face protection. P304 + P340 + P312: IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell. P337 + P313: If eye irritation persists: Get medical advice/ attention. P501: Dispose of contents/ container to an approved waste disposal plant. 50-01-1 Guanidinium chloride

Kit/Cassettes	Components and Reagent Ingredients	Quantity per Test	Safety Symbol and Warning[a]
cobas® DNA Sample Preparation Kit 24 Tests (M/N: 05985536190)	**WB II** (DNA Wash Buffer II) (M/N: 05517664001) Tris-HCl buffer Sodium chloride	1 x 12.5 mL	N/A
	DNA EB (DNA Elution Buffer) (M/N: 05517630001) Tris-HCl buffer 0.09% Sodium azide	1 x 6 mL	N/A
	FT (Filter tubes with caps) (M/N: 05089506102)	1 x 25 pcs	N/A
	CT (Collection Tubes) (M/N: 05880513001)	3 x 25 pcs	N/A

[a] Product safety labeling primarily follows EU GHS guidance

[b] Hazardous substances

Reagent storage and handling

Reagent	Storage Temperature	Storage Time
cobas® DNA Sample Preparation Kit	15°C to 30°C	Once opened, stable up to 8 uses over 90 days or until the expiration date indicated, whichever comes first.

Note: *With the exception of the **PK** reagent, do not freeze reagents.*

Note: *After addition of sterile, nuclease free water to **PK**, store unused reconstituted **PK** in 450 µL aliquots at -20°C. Once reconstituted, **PK** must be used within 90 days or until the expiration date, whichever comes first. After addition of absolute ethanol, store **WB I** and **WB II** at 15°C to 30°C. These working solutions are stable for 90 days or until the expiration date, whichever comes first.*

Additional materials required

Materials	P/N
Xylene (ACS, ≥ 98.5% xylenes)	Any vendor
Absolute ethanol (200-proof, for Molecular Biology)	Sigma E7023 or Fisher Scientific BP2818-500 or equivalent
Isopropanol (ACS, ≥ 99.5%)	Sigma 190764 or Fisher Scientific A451-1 or equivalent
Sterile, nuclease-free water (for Molecular Biology grade)	Any vendor
Bleach	Any vendor
70% Ethanol	Any vendor
Sterile disposable, serological 5- and 25-mL pipettes	Any vendor
Adjustable pipettors* (Capable of pipetting 5 – 1000 µL)	Any vendor
Aerosol barrier or positive displacement DNase-free pipette tips	Any vendor
Pipet-Aid™*	Drummond 4-000-100 or equivalent
Benchtop microcentrifuge* (capable of 20,000 x g)	Eppendorf 5430 or 5430R or equivalent
Two dry heat blocks capable of heating microcentrifuge tubes to 56°C and 90°C*	Any vendor
Locking-lid microcentrifuge tubes (1.5 mL sterile, RNase/DNase free, PCR grade)	Any vendor
Microcentrifuge tube racks	Any vendor
Spectrophotometer for measuring DNA concentration*	Any vendor
Vortex mixer*	Any vendor
Freezer capable of -25°C to -15°C storage	Any vendor
Calibrated thermometers for dry heat block*	Any vendor
Waterbath* capable of maintaining 37°C	Any vendor
Single edged blade or similar	Any vendor
Disposable powder-free gloves	Any vendor

*All equipment should be properly maintained according to manufacturer's instructions.

For more information regarding the materials sold separately, contact your local Roche representative.

Precautions and handling requirements

Warnings and precautions

As with any test procedure, good laboratory practice is essential to the proper performance of this sample preparation kit.

- For *in vitro* diagnostic use only.
- Safety Data Sheets (SDS) are available upon request from your local Roche office.
- All samples should be handled as if infectious using safe laboratory procedures such as those outlined in Biosafety in Microbiological Laboratories[1] and in the CLSI Document M29-A4.[2]
- **DNA PBB** and **DNA TLB** contain a non-ionic detergent which is an irritant to mucous membranes. Avoid contact with eyes, skin, and mucous membranes.

Note: *Commercial liquid household bleach typically contains sodium hypochlorite at a concentration of 5.25%. A 1:10 dilution of household bleach will produce a 0.5% sodium hypochlorite solution.*

- Xylene is a hazardous chemical and should be used in a chemical hood. Discard into chemical waste in accordance with local, state, and federal regulations.
- The use of sterile disposable pipettes and DNase-free pipette tips is recommended.

Good laboratory practice

- Do not pipette by mouth.
- Do not eat, drink or smoke in laboratory work areas.
- Wash hands thoroughly after handling specimens and kit reagents.
- Wear eye protection, laboratory coats and disposable gloves when handling any reagents. Avoid contact of these materials with the skin, eyes or mucous membranes. If contact does occur, immediately wash with large amounts of water. Burns can occur if left untreated. If spills occur, dilute with water before wiping dry.
- Thoroughly clean and disinfect all laboratory work surfaces with a freshly prepared solution of 0.5% sodium hypochlorite in distilled or deionized water (dilute household bleach 1:10). Follow by wiping the surface with 70% ethanol.

Note: *Commercial liquid household bleach typically contains sodium hypochlorite at a concentration of 5.25%. A 1:10 dilution of household bleach will produce a 0.5% sodium hypochlorite solution.*

Contamination

- Gloves must be worn and must be changed between handling samples and **cobas**® DNA Sample Preparation Kit reagents to prevent contamination. Avoid contaminating gloves when handling samples.
- Gloves must be changed frequently to reduce the potential for contamination.
- Gloves must be changed before leaving DNA isolation areas or if contact with solutions or a sample is suspected.
- Avoid microbial and ribonuclease contamination of reagents.
- Supplies and equipment should be dedicated to each activity and not used for other activities or moved between areas. For example, pipettors and supplies used for DNA isolation must not be used to prepare reagents for amplification and detection.
- It is highly recommended that workflow in the laboratory proceed in a uni-directional manner, completing one activity before proceeding to the next activity. For example, DNA isolation should be completed before starting amplification and detection. DNA isolation should be performed in an area separate from amplification and detection.

Integrity

- Do not use kits after their expiration dates.
- Do not pool reagents from different kits or lots.
- Do not use disposable items beyond their expiration date.
- All disposable items are for one-time use. Do not reuse.
- All equipment should be properly maintained according to the manufacturer's instructions.

Disposal

- **DNA EB** and **DNA TLB** contain sodium azide. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. While disposing of sodium azide containing solutions down laboratory sinks, flush the drains with a large volume of cold water to prevent azide buildup.
- Dispose of unused reagents and waste in accordance with country, federal, state and local regulations.

Spillage and cleaning

- **DNA PBB** and **WB I** contain guanidine hydrochloride. If liquid containing this buffer is spilled, clean with suitable laboratory detergent and water. If a spill occurs with potentially infectious agents, clean the affected area first with laboratory detergent and water, and then with 0.5% sodium hypochlorite.

Sample collection, transport, and storage

Note: *Handle all samples as if they are capable of transmitting infectious agents.*

Sample collection and handling

The **cobas**® DNA Sample Preparation Kit has been developed for use with FFPET samples.

Sample transport, storage, and stability

FFPET specimens can be transported at 15°C to 30°C. Transportation of FFPET samples must comply with country, federal, state, and local regulations for the transport of etiologic agents.[3]

Refer to the **Sample collection, transport, and storage** section of the assay specific Instructions for Use for storage recommendations.

Processed sample storage and stability

Refer to the **Sample collection, transport, and storage** section of the assay specific Instructions for Use for storage recommendations.

Extracted DNA should be used within the recommended storage periods or before the expiration date of the **cobas**® DNA Sample Preparation Kit used to extract the DNA, whichever comes first.

Prior to using extracted, stored DNA stocks, pulse vortex and centrifuge the elution tube containing the stock.

Sample preparation procedure

Using the kit

Figure 1 **cobas**® DNA Sample Preparation Kit workflow

1	Remove samples and reagents from storage
2	Deparaffinize samples
3	Perform DNA isolation
4	Elute DNA

Instructions for use

Note: *The **cobas**® DNA Sample Preparation Kit was developed for use with FFPET sections of 5-micron thickness.*

Note: *Mutation detection tests may have specific requirements for tumor content and the need for macro-dissection after deparaffinization.*

Note: *Dry heat blocks capable of heating locking-lid microcentrifuge tubes should be turned on and set at 56°C and 90°C.*

Reagent preparation and storage

Prepare working reagents as shown in the table below prior to using the kit for the first time. Use a 5-mL serological pipette to dispense the water. Use 25-mL serological pipettes to dispense the ethanol. If the Proteinase K has already been reconstituted and frozen, thaw a sufficient number of aliquots to process the number of specimens to be run.

Reagents	Reconstitution / Preparation
Proteinase K **(PK)**	Reconstitute **PK** by adding 4.5 mL of sterile, nuclease-free (PCR grade) water to the vial using a sterile, disposable 5-mL serological pipette. Mix by inverting the vial 5 to 10 times. Aliquot 450 µL of reconstituted **PK** into 1.5-mL locking-lid microcentrifuge tubes and store at -20°C for up to 90 days or until the expiration date, whichever comes first. If the **PK** has already been reconstituted and frozen, thaw sufficient number of aliquots to process the number of samples to be run (70 µL of reconstituted **PK** is required for each sample).
Wash Buffer I **(WB I)**	Prepare working **WB I** by adding 15 mL of absolute ethanol to the bottle of **WB I**. Mix by inverting the bottle 5 to 10 times. Note on the bottle that ethanol has been added and the date. Store working **WB I** at 15°C to 30°C for up to 90 days or until the expiration date, whichever comes first.
Wash Buffer II **(WB II)**	Prepare working **WB II** by adding 50 mL of absolute ethanol to the bottle of **WB II**. Mix by inverting the bottle 5 to 10 times. Note on the bottle that ethanol has been added and the date. Store working **WB II** at 15°C to 30°C for up to 90 days or until the expiration date, whichever comes first.

All solutions stored at 15°C to 30°C should be clear. If precipitate is present in any reagent, warm the solution in a 37°C water bath until the precipitate dissolves. Do not use until all precipitate has been dissolved.

Deparaffinization of FFPET sections mounted on slides

Note: *Xylene is a hazardous chemical. All steps for deparaffinization should be performed under a chemical hood. See* ***Warnings and precautions****.*

1. Add a slide with a mounted 5-micron FFPET section to a container with sufficient xylene to cover the tissue; soak for 5 minutes.
2. Transfer the slide to a container with sufficient absolute ethanol to cover the tissue; soak for 5 minutes.
3. Remove the slide from the ethanol and allow the section to air dry completely (5 to 10 minutes).
4. Perform macro-dissection, if required.
5. Label one 1.5-mL locking-lid microcentrifuge tube for each sample with the sample identification information.
6. Add 180 µL **DNA TLB** to the 1.5-mL locking-lid microcentrifuge tube.
7. Add 70 µL of reconstituted **PK** to the locking-lid microcentrifuge tube containing **DNA TLB**.
8. Scrape the tissue off the slide and into the locking-lid microcentrifuge tube. Immerse the tissue in the **DNA TLB/PK** mixture.
9. Continue with Step 1 of the **DNA isolation procedure**.

Deparaffinization of FFPET sections not mounted on slides

Note: *Xylene is a hazardous chemical. All steps for deparaffinization should be performed under a chemical hood. See* ***Warnings and precautions*** *section.*

Note: *If the sample requires macro-dissection, the section must be mounted on a slide and the procedure detailed in* ***Deparaffinization of FFPET sections mounted on slides*** *section must be followed.*

1. Place one 5-micron FFPET section into a 1.5-mL locking-lid microcentrifuge tube labeled with the sample identification information for each sample.
2. Add 500 µL Xylene to the locking-lid microcentrifuge tube containing the FFPET section.

3. Mix well by vortexing for 10 seconds.
4. Let the tube stand for 5 minutes at 15°C to 30°C.
5. Add 500 µL absolute ethanol and mix by vortexing for 10 seconds.
6. Let the tube stand for 5 minutes at 15°C to 30°C.
7. Centrifuge at 16,000 x g to 20,000 x g for 2 minutes. Remove the supernatant without disturbing the pellet. Discard the supernatant into chemical waste.
8. Add 1 mL absolute ethanol and vortex for 10 seconds.
9. Centrifuge at 16,000 x g to 20,000 x g for 2 minutes. Remove the supernatant without disturbing the pellet. Discard the supernatant into chemical waste.
10. If the pellet is floating in the remaining supernatant, spin again for 1 minute at 16,000 x g to 20,000 x g. Remove any remaining supernatant.
11. Dry the tissue pellet for 10 minutes at 56°C in a heating block with the tube open.
12. Make sure the ethanol is completely evaporated and the pellet is dry before proceeding to the next step.
13. If needed, dry pellets can be stored up to 24 hours at 2°C to 8°C.
14. Resuspend the tissue pellet in 180 µL **DNA TLB**.
15. Add 70 µL of reconstituted **PK**.
16. Continue with Step 1 of the next section: **DNA isolation procedure**.

DNA isolation procedure

Note: *If required for the test, process a negative control concurrently with the sample(s). Prepare the negative control by combining 180 µL **DNA TLB** and 70 µL **PK** solution in a 1.5-mL locking-lid microcentrifuge tube labeled as **NEG**. The negative control should be processed following the same procedure as the samples.*

1. Vortex the tubes containing the sample/**DNA TLB**/**PK** mixture and the negative control mixture (**NEG**) for 30 seconds.

Note: *The tissue must be fully immersed in the **DNA TLB**/**PK** mixture.*

2. Place tubes in the 56°C dry heat block and incubate for 60 minutes.
3. Vortex the tubes for 10 seconds.

Note: *The tissue must be fully immersed in the **DNA TLB**/**PK** mixture.*

4. Place tubes in the 90°C dry heat block and incubate for 60 minutes.

Note: *During the incubation, prepare the required number of filter tubes (**FT**s) with hinged caps by placing the **FT** onto a collection tube (**CT**) and labeling each **FT** cap with the proper sample or control identification.*

Note: *Each sample will need 1 **FT**, 3 **CT**s and 1 elution tube (1.5-mL locking-lid microcentrifuge tube).*

Note: *During the incubation, label the required number of elution tubes (1.5-mL microcentrifuge tube) with the proper sample or control identification information.*

5. Allow the tubes to cool to 15°C to 30°C. After cooling, pulse-centrifuge the tubes to collect liquid from the caps.
6. Add 200 µL **DNA PBB** to each tube; mix by pipetting up and down 3 times.
7. Incubate the tubes at 15°C to 30°C for 10 minutes.
8. Add 100 µL isopropanol to each tube; mix lysate by pipetting up and down 3 times.
9. Transfer each lysate into the appropriately labeled **FT**/**CT** unit.
10. Centrifuge the **FT**/**CT** units at 8,000 x g for 1 minute.

11. Place each **FT** onto a new **CT**. Discard the flow-through from the old **CT** into chemical waste, and properly dispose of the used **CT**.
12. Add 500 µL working **WB I** to each **FT**.

Note: *Preparation of working **WB I** is described in the **Reagent preparation** section.*

13. Centrifuge the **FT/CT** units at 8,000 x g for 1 minute.
14. Discard the flow-through in each **CT** into chemical waste. Place the **FT** back into the same **CT**.
15. Add 500 µL working **WB II** to each **FT**.

Note: *Preparation of working **WB II** is described in the **Reagent preparation** section.*

16. Centrifuge the **FT/CT** units at 8,000 x g for 1 minute.
17. Place each **FT** onto a new **CT**. Discard the flow-through from the old **CT** into chemical waste, and properly dispose of the used **CT**.
18. Centrifuge the **FT/CT** units at 16,000 to 20,000 x g for 1 minute to dry the filter membranes.
19. Place each **FT** into an elution tube (1.5-mL microcentrifuge tube) pre-labeled with sample or control identification. Discard the flow-through from the used **CT** into chemical waste, and properly dispose of the used **CT**.
20. Add 100 µL **DNA EB** to the center of each **FT** membrane without touching the **FT** membrane.
21. Incubate the **FT** with elution tube at 15°C to 30°C for 5 minutes.
22. Centrifuge the **FT** with elution tube at 8,000 x g for 1 minute to collect eluate into the elution tube. Properly dispose of the used **FT**.
23. Close the cap on the elution tube. The elution tube contains the DNA Stock.
24. For DNA quantitation, proceed to the **DNA quantitation** section.

Note: *Measurement of DNA concentration should be performed immediately after the DNA isolation procedure and prior to storage.*

DNA quantitation

1. Mix each DNA Stock by vortexing for 5 seconds.
2. Quantify DNA using a spectrophotometer according to the manufacturer's protocol. Use DNA EB as the blank for the instrument. An average of two consistent readings is necessary.

Note: *The two measurements should be within ±10% of each other when the DNA concentration readings are ≥ 20.0 ng/µL. For DNA concentration readings < 20.0 ng/µL, the two measurements should be within ± 2 ng/µL. If the two measurements are not within ± 10% of each other when the DNA concentration readings are ≥ 20.0 ng/µL or within ± 2 ng/µL when the DNA concentration readings are < 20.0 ng/µL, an additional 2 readings must be taken until the requirements are met. The average of these two new measurements should then be calculated.*

Note: *If a full processed negative control (**NEG**) is required, the DNA Stock for the **NEG** does not need to be measured.*

Note: *Stored, extracted DNA should be amplified within the recommended storage periods in the assay-specific Instructions for Use or before the expiration date of the **cobas**® DNA Sample Preparation Kit used to extract the DNA, whichever comes first.*

Note: *Refer to the assay specific Instructions for Use for the concentration of DNA required for testing.*

Additional information

Symbols

The following symbols are used in labeling for Roche PCR diagnostic products.

Table 1 Symbols used in labeling for Roche PCR diagnostic products

Age/DOB	Age or Date of Birth
SW	Ancillary Software
Assigned Range [copies/mL]	Assigned Range (copies/mL)
Assigned Range [IU/mL]	Assigned Range (IU/mL)
EC REP	Authorized representative in the European Community
BARCODE	Barcode Data Sheet
LOT	Batch code
	Biological risks
REF	Catalogue number
Collect Date	Collect date
	Consult instructions for use
Σ	Contains sufficient for <*n*> tests
CONTENT	Contents of kit
CONTROL	Control
	Date of manufacture
D	Distributed by
	Do not re-use
	Female
	For IVD performance evaluation only
GTIN	Global Trade Item Number
IVD	*In vitro* diagnostic medical device
LLR	Lower Limit of Assigned Range
	Male
	Manufacturer
CONTROL −	Negative control
NON STERILE	Non sterile
#	Patient number
?	Patient Name


Peel here

CONTROL + Positive control

QS copies / PCR QS copies per PCR reaction, use the QS copies per PCR reaction in calculation of the results.

QS IU/PCR QS IU per PCR reaction, use the QS International Units (IU) per PCR reaction in calculation of the results.

SN Serial number

Site Site

Procedure Standard Standard Procedure

STERILE EO Sterilized using ethylene oxide


Store in the dark


Temperature limit

Test Definition File

CE CE marking of conformity; this device is in conformity with the applicable requirements for CE marking of an *in vitro* diagnostic medical device


This way up

UDI Unique Device Identification

Procedure UltraSensitive Ultrasensitive Procedure

ULR Upper Limit of Assigned Range

Urine Fill Line Urine Fill Line

Rx Only US Only: Federal law restricts this device to sale by or on the order of a physician.


Use-by date


Device for near-patient testing


Device Not for Near Patient Testing


Device for self-testing


Device not for self-testing

Technical support

For technical support (assistance) please reach out to your local affiliate:
https://www.roche.com/about/business/roche_worldwide.htm

Manufacturer and distributors

Table 2 Manufacturer and distributors

Manufactured in the United States

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany
www.roche.com

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250-0457 USA
(For Technical Assistance call the
Roche Response Center
toll-free: 1-800-526-1247)

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany

Trademarks and patents

See http://www.roche-diagnostics.us/patents

Copyright

CE

References

1. Chosewood LC, Wilson DE. Biosafety and microbiological and biomedical laboratories-Fifth Edition. US Department of Health and Human Services Publication, CDC. 2009;21-1112.
2. Clinical and Laboratory Standards Institute (CLSI). Protection of laboratory workers from occupationally acquired infections. Approved Guideline-Fourth Edition. CLSI Document M29-A4: Wayne, PA; CLSI, 2014.
3. International Air Transport Association. Dangerous Goods Regulations, 60th Edition. 2019.

Document revision

Document Revision Information	
Doc Rev. 1.0 06/2020	First Publishing.