Safety Data Sheet: AAV5 DetectCDx™

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: AAV5 Total Antibody Assay Coated Plate Set (ARUP Item # PD-0008-F036) - Coated Plate

SYNONYMS: Adeno-associated virus 5 (AAV5) coated plate; Replication-defective recombinant adeno-associated viral (rAAV) vector; unknown or variable composition, complex reaction products or biological materials (UVCB substance)

MANUFACTURER: ARUP Laboratories
ADDRESS: 500 Chipeta Way
Salt Lake City, UT 84108
USA

EMERGENCY PHONE: 1-800-522-2787
OTHER CALLS: 1-800-522-2787
Contact: safety161@aruplab.com

PREPARED BY: Brett Welch, PhD
REVISION DATE: 09 June 2023

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

OSHA Hazards

This product is not considered a hazardous material as defined by OSHA 1919.1200.

GHS Classification

This product is not classified in accordance with the Globally Harmonized System of Classification and Labelling (GHS) as it is a biological material and is outside the scope of this system. The toxicological properties of this material are not known.

Hazard Statement(s):

In accordance with NIH Guidelines for AAV vectors not encoding harmful genes, this product may be used under Biosafety Level 1 guidelines.

Precautionary Statement(s)

Hazards not otherwise classified (HNOC):

As with any chemical product of unknown toxicity, take precautions to prevent contact with eyes, skin and mucous membranes. Product should only be handled by technically qualified individuals trained in handling biological materials of unknown toxicity.

<1% of the mixture used to coat the plate consists of ingredient(s) of unknown acute toxicity.

HMIS Classification

Health Hazard:	0
Chronic Health Hazard:	0
Flammability:	0
Physical Hazards:	0

NFPA Rating

Health Hazard:	0
Fire:	0
Reactivity Hazard:	0

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	Classification	Concentration

Safety Data Sheet: AAV5 DetectCDx™

Adeno-associated virus 5 (AAV5) coated plate	Biohazard	N/A

SECTION 4: FIRST AID MEASURES

General Advice
No symptoms are anticipated after exposure.

In case of eye contact: Rinse with eyewash for at least 5 minutes. Seek medical attention if symptoms persist. Inform medical professional of exposure.

In case of skin contact: If the exposure draws blood, wash and scrub thoroughly for at least 5 minutes with soap and warm running water. If the exposure does not draw blood, wash and scrub for at least 1 minute. Seek medical attention if symptoms persist. Inform medical professional of exposure.

If swallowed: Do not induce vomiting unless directed to do so by medical personnel. Immediately seek medical attention or call Poison Control Center.

If inhaled: In case of exposure to aerosols, move affected individual to fresh air. Give oxygen if individual has difficulty breathing.

SECTION 5: FIRE-FIGHTING MEASURES

Conditions of flammability: AAV vectors do not pose a large flammability risk. Viral particles are suspended in a non-flammable liquid. High heat will deactivate AAV.

Suitable extinguishing media: Use fire fighting measures that suit the environment.

Special protective equipment for fire fighters: No special measures required.

Hazardous combustion products: None known

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment

Environmental precautions: Do not allow to enter sewers/ surface or ground water.

Methods and materials for containment and clean-up: Contain spill with absorbent material and decontaminate the area using 10% bleach (1% sodium hypochlorite) or detergent-based disinfectant and let stand for 10 minutes. Alcohols are not effective disinfectants for AAV.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Handle as a biohazardous material under Biosafety Level 1 guidelines. Wear appropriate protective equipment when handling. Do not eat or drink while handling this material. Avoid contact with eyes, skin and clothing.

Conditions for safe storage: The AAV coated plate is stable at room temperature and 4°C.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Component	CAS-No.	Value	Control parameter	Basis
N/A	N/A	N/A	N/A	N/A

Respiratory protection: Not required; except in case of aerosol formation. For practices that may produce aerosols, recommended engineering controls include mechanical ventilation (i.e. use of biological safety cabinets).

Eye protection: Eyewear complying with an approved standard.

Safety Data Sheet: AAV5 DetectCDx™

Hand protection: Protective gloves.

Skin and body protection: Wear an appropriate lab coat and closed-toe shoes.

Work hygiene measures: Wash hands after use and before eating, smoking and using the toilet. Do not eat, drink or smoke when using this product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Black 96-well plate

Odor: None

Safety data

pH:
N/A

Boiling point
No data available

Flash point
No data available

Ignition temperature
No data available

Auto-ignition temperature
No data available

Melting point
No data available

Freezing point
N/A

Vapor pressure (mmHg) @
No data available

Vapor density (AIR = 1) @
No data available

Specific gravity (H2O = 1) @
No data available

Evaporation rate
N/A

Solubility in water
N/A

Percent solids by weight
100%

Percent volatile by weight/by volume @
No data available

Molecular weight
N/A

Viscosity
N/A

Safety Data Sheet: AAV5 DetectCDx™

SECTION 10: STABILITY AND REACTIVITY

Stability
The AAV coated plate is stable at room temperature and 4°C.

Conditions to avoid
High temperatures will inactivate AAV.

Materials to avoid
None known

Hazardous decomposition products
None known

SECTION 11: TOXICOLOGICAL INFORMATION

Acute toxicity
Oral LD50
No data available
Inhalation LC50
No data available
Dermal LD50
No data available
Other information of acute toxicity
No data available

Skin corrosion/irritation
No data available
Serious eye damage/eye irritation
No data available
Respiratory or skin sensitization
No data available
Germ cell mutagenicity
Adeno-associated viruses have a very low probability of integrating into the host genome. This integration is not random.
Carcinogenicity

IARC: Substance is not listed.

NTP: Substance is not listed.

Reproductive toxicity
No data available
Teratogenicity
No data available
Specific target organ toxicity—single exposure (Globally Harmonized System)
No data available
Specific target organ toxicity—repeat exposure (Globally Harmonized System)
No data available
Aspiration hazard
No data available
Signs and Symptoms of exposure
None Known
Synergistic effect
No data available

SECTION 12: ECOLOGICAL INFORMATION

Toxicity
No relevant information available

Persistence and degradability
No relevant information available

Safety Data Sheet: AAV5 DetectCDx™

Bio-accumulative potential
No relevant information available

Mobility in soil
No relevant studies identified

PBT and vPvB assessment
No relevant information available

Other adverse effects
No relevant information available

SECTION 13: DISPOSAL CONSIDERATIONS

Product

Always dispose of in accordance with local, regional or national/federal regulations.

Possible options:
1) Dispose of in labeled “Biohazardous Waste” to be picked up by licensed disposal company
2) Autoclave at 125°C for a minimum of 30 minutes before regular trash disposal

Contaminated packaging

Same as product

SECTION 14: TRANSPORT INFORMATION

DOT: not regulated

IMDG: not regulated

IATA: not regulated

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

SARA 335 components
Substance is not listed.

SARA 313 components
Substance is not listed.

California Prop. 65 Components
Substance is not listed.

SECTION 16: OTHER INFORMATION

AAV is a parvovirus that will enter mammalian cells and remain in episomal form in non-dividing cells. It exhibits no pathogenic symptoms in humans or animals and has been used in clinical trials for gene therapy and/or approved for market use by the FDA and other regulatory bodies. Wild-type AAV integrates stably at human chromosome 19. This product consists of recombinant, replication-defective AAV vectors, with rep and cap genes removed. This AAV is generated using insect-specific baculovirus as a helper virus instead of human pathogens such as adenovirus or herpes simplex virus (HSV). Therefore, residual adenovirus or HSV are not present in this product.

DISCLAIMER
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Safety Data Sheet: AAV5 DetectCDx™

and users of the materials described herein. All risks associated with use of such materials are assumed by the user. ARUP EXPRESSLY DISCLAIMS ALL WARRANTIES OF EVERY KIND AND NATURE IN CONNECTION WITH THE FOREGOING INFORMATION OR THE USE OF THE MATERIALS, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, ACCURACY AND COMPLETENESS.

Safety Data Sheet: AAV5 DetectCDx™

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: AAV5 Total Antibody Assay Coated Plate Set (ARUP Item # PD-0008-F036) - Confirmatory Reagent

SYNONYMS: Adeno-associated virus 5 (AAV5) capsid; AAV5 Antigen Set - Confirmatory Reagent; Replication-defective recombinant adeno-associated viral (rAAV) vector; unknown or variable composition, complex reaction products or biological materials (UVCB substance)

MANUFACTURER: ARUP Laboratories
ADDRESS: 500 Chipeta Way
Salt Lake City, UT 84108
USA

EMERGENCY PHONE: 1-800-522-2787
OTHER CALLS: 1-800-522-2787
Contact: safety161@aruplab.com

PREPARED BY: Brett Welch, PhD
REVISION DATE: 09 June 2023

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

OSHA Hazards

This product is not considered a hazardous material as defined by OSHA 1919.1200.

GHS Classification

This product is not classified in accordance with the Globally Harmonized System of Classification and Labelling (GHS) as it is a biological material and is outside the scope of this system. The toxicological properties of this material are not known.

Hazard Statement(s):

In accordance with NIH Guidelines for AAV vectors not encoding harmful genes, this product may be used under Biosafety Level 1 guidelines.

Precautionary Statement(s)

Hazards not otherwise classified (HNOC):

As with any chemical product of unknown toxicity, take precautions to prevent contact with eyes, skin and mucous membranes. Product should only be handled by technically qualified individuals trained in handling biological materials of unknown toxicity.

<1% of the mixture consists of ingredient(s) of unknown acute toxicity.

HMIS Classification

Health Hazard:	0
Chronic Health Hazard:	0
Flammability:	0
Physical Hazards:	0

NFPA Rating

Health Hazard:	0
Fire:	0
Reactivity Hazard:	0

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	Classification	Concentration

Safety Data Sheet: AAV5 DetectCDx™

Adeno-associated virus 5 (AAV5) capsid (Confirmatory Reagent)	Biohazard	<1%
Dulbecco's Phosphate buffered saline (DPBS)		>99%
Pluronic F-68		0.001%

SECTION 4: FIRST AID MEASURES

General Advice
No symptoms are anticipated after exposure.

In case of eye contact: Rinse with eyewash for at least 5 minutes. Seek medical attention if symptoms persist. Inform medical professional of exposure.

In case of skin contact: If the exposure draws blood, wash and scrub thoroughly for at least 5 minutes with soap and warm running water. If the exposure does not draw blood, wash and scrub for at least 1 minute. Seek medical attention if symptoms persist. Inform medical professional of exposure.

If swallowed: Do not induce vomiting unless directed to do so by medical personnel. Immediately seek medical attention or call Poison Control Center.

If inhaled: In case of exposure to aerosols, move affected individual to fresh air. Give oxygen if individual has difficulty breathing.

SECTION 5: FIRE-FIGHTING MEASURES

Conditions of flammability: AAV vectors do not pose a large flammability risk. Viral particles are suspended in a non-flammable liquid. High heat will deactivate AAV.

Suitable extinguishing media: Use fire fighting measures that suit the environment.

Special protective equipment for fire fighters: No special measures required.

Hazardous combustion products: None known

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment

Environmental precautions: Do not allow to enter sewers/ surface or ground water.

Methods and materials for containment and clean-up: Contain spill with absorbent material and decontaminate the area using 10% bleach (1% sodium hypochlorite) or detergent-based disinfectant and let stand for 10 minutes. Alcohols are not effective disinfectants for AAV.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Handle as a biohazardous material under Biosafety Level 1 guidelines. Wear appropriate protective equipment when handling. Do not eat or drink while handling this material. Avoid contact with eyes, skin and clothing.

Conditions for safe storage: AAV is stable at room temperature and 4°C. Store solutions at -80°C for long-term integrity.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Component	CAS-No.	Value	Control parameter	Basis
Pluronic F-68 0.001%	9003-11-6		STEL, TWA	No specific requirements

Safety Data Sheet: AAV5 DetectCDx™

Respiratory protection: Not required; except in case of aerosol formation. For practices that may produce aerosols, recommended engineering controls include mechanical ventilation (i.e. use of biological safety cabinets).

Eye protection: Eyewear complying with an approved standard.

Hand protection: Protective gloves.

Skin and body protection: Wear an appropriate lab coat and closed-toe shoes.

Work hygiene measures: Wash hands after use and before eating, smoking and using the toilet. Do not eat, drink or smoke when using this product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear colorless solution

Odor: None

Safety data

pH: 7.0 – 7.6

Boiling point
F: ~212
C: ~100
Flash point
Not flammable

Ignition temperature
No data available

Auto-ignition temperature
No data available

Melting point
F: ~32
C: ~0
Freezing point
F: ~32
C: ~0
Vapor pressure (mmHg) @
No data available

Vapor density (AIR = 1) @
No data available

Specific gravity (H2O = 1) @
No data available

Evaporation rate
No data available
Solubility in water
Complete

Percent solids by weight
No data available

Percent volatile by weight/by volume @
No data available

Molecular weight
~3746 kDa

Safety Data Sheet: AAV5 DetectCDx™

Viscosity
No data available

SECTION 10: STABILITY AND REACTIVITY

Stability
AAV is stable at room temperature and 4°C. Store solutions at -80°C for long-term integrity.

Conditions to avoid
High temperatures will inactivate AAV.

Materials to avoid
None known

Hazardous decomposition products
None known

SECTION 11: TOXICOLOGICAL INFORMATION

Acute toxicity
Oral LD50
No data available
Inhalation LC50
No data available
Dermal LD50
No data available
Other information of acute toxicity
No data available

Skin corrosion/irritation
No data available
Serious eye damage/eye irritation
No data available
Respiratory or skin sensitization
No data available
Germ cell mutagenicity
Adeno-associated viruses have a very low probability of integrating into the host genome. This integration is not random.
Carcinogenicity

IARC: Substance is not listed.

NTP: Substance is not listed.

Reproductive toxicity
No data available
Teratogenicity
No data available
Specific target organ toxicity—single exposure (Globally Harmonized System)
No data available
Specific target organ toxicity—repeat exposure (Globally Harmonized System)
No data available
Aspiration hazard
No data available
Signs and Symptoms of exposure
None Known
Synergistic effect
No data available

SECTION 12: ECOLOGICAL INFORMATION

Toxicity
No relevant information available

Safety Data Sheet: AAV5 DetectCDx™

Persistence and degradability
No relevant information available

Bio-accumulative potential
No relevant information available

Mobility in soil
No relevant studies identified

PBT and vPvB assessment
No relevant information available

Other adverse effects
No relevant information available

SECTION 13: DISPOSAL CONSIDERATIONS

Product

Always dispose of in accordance with local, regional or national/federal regulations.

Possible options:
1) Dispose of in labeled “Biohazardous Waste” to be picked up by licensed disposal company
2) Autoclave at 125°C for a minimum of 30 minutes before regular trash disposal
3) Disinfect with 10% chlorine bleach (1% sodium hypochlorite) for 10 minutes before drain disposal

Contaminated packaging

Same as product

SECTION 14: TRANSPORT INFORMATION

DOT: not regulated

IMDG: not regulated

IATA: not regulated

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

SARA 335 components
Substance is not listed.

SARA 313 components
Substance is not listed.

California Prop. 65 Components
Substance is not listed.

SECTION 16: OTHER INFORMATION

AAV is a parvovirus that will enter mammalian cells and remain in episomal form in non-dividing cells. It exhibits no pathogenic symptoms in humans or animals and has been used in clinical trials for gene therapy and/or approved for market use by the FDA and other regulatory bodies. Wild-type AAV integrates stably at human chromosome 19. This product consists of recombinant, replication-defective AAV vectors, with rep and cap genes removed. This AAV is generated using insect-specific baculovirus as a helper virus instead of human pathogens such as adenovirus or herpes simplex virus (HSV). Therefore, residual adenovirus or HSV are not present in this product.

DISCLAIMER
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above may present unknown hazards and should be used with caution. Although certain hazards are described above, we cannot guarantee that these are the only hazards that exist. Conditions of use and suitability of these materials for particular uses are beyond ARUP's control. Final determination of suitability of any material is therefore the sole responsibility of the user. Appropriate warnings and safe handling procedures are also the responsibility of the handlers and users of the materials described herein. All risks associated with use of such materials are assumed by the user. ARUP EXPRESSLY DISCLAIMS ALL WARRANTIES OF EVERY KIND AND NATURE IN CONNECTION WITH THE FOREGOING INFORMATION OR THE USE OF THE MATERIALS, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, ACCURACY AND COMPLETENESS.

Safety Data Sheet: AAV5 DetectCDx™

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: AAV5 Total Antibody Assay Coated Plate Set (ARUP Item # PD-0008-F036) - Detection Reagent

SYNONYMS: Adeno-associated virus 5 (AAV5) capsid; AAV5 Antigen Set - Detection Reagent; Replication-defective recombinant adeno-associated viral (rAAV) vector; unknown or variable composition, complex reaction products or biological materials (UVCB substance)

MANUFACTURER: ARUP Laboratories
ADDRESS: 500 Chipeta Way
Salt Lake City, UT 84108
USA

EMERGENCY PHONE: 1-800-522-2787
OTHER CALLS: 1-800-522-2787
Contact: safety161@aruplab.com

PREPARED BY: Brett Welch, PhD
REVISION DATE: 09 June 2023

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

OSHA Hazards

This product is not considered a hazardous material as defined by OSHA 1919.1200.

GHS Classification

This product is not classified in accordance with the Globally Harmonized System of Classification and Labelling (GHS) as it is a biological material and is outside the scope of this system. The toxicological properties of this material are not known.

Hazard Statement(s):

In accordance with NIH Guidelines for AAV vectors not encoding harmful genes, this product may be used under Biosafety Level 1 guidelines.

Precautionary Statement(s)

Hazards not otherwise classified (HNOC):

As with any chemical product of unknown toxicity, take precautions to prevent contact with eyes, skin and mucous membranes. Product should only be handled by technically qualified individuals trained in handling biological materials of unknown toxicity.

<1% of the mixture consists of ingredient(s) of unknown acute toxicity.

HMIS Classification

Health Hazard:	0
Chronic Health Hazard:	0
Flammability:	0
Physical Hazards:	0

NFPA Rating

Health Hazard:	0
Fire:	0
Reactivity Hazard:	0

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	Classification	Concentration

Safety Data Sheet: AAV5 DetectCDx™

Adeno-associated virus 5 (AAV5) capsid labeled with Ruthenium (II) tris-bipyridine, N-hydroxysuccinimide (Detection Reagent)	Biohazard	<1%
Dulbecco's Phosphate buffered saline (DPBS)		>99%
Pluronic F-68		0.001%

SECTION 4: FIRST AID MEASURES

General Advice
No symptoms are anticipated after exposure.

In case of eye contact: Rinse with eyewash for at least 5 minutes. Seek medical attention if symptoms persist. Inform medical professional of exposure.

In case of skin contact: If the exposure draws blood, wash and scrub thoroughly for at least 5 minutes with soap and warm running water. If the exposure does not draw blood, wash and scrub for at least 1 minute. Seek medical attention if symptoms persist. Inform medical professional of exposure.

If swallowed: Do not induce vomiting unless directed to do so by medical personnel. Immediately seek medical attention or call Poison Control Center.

If inhaled: In case of exposure to aerosols, move affected individual to fresh air. Give oxygen if individual has difficulty breathing.

SECTION 5: FIRE-FIGHTING MEASURES

Conditions of flammability: AAV vectors do not pose a large flammability risk. Viral particles are suspended in a non-flammable liquid. High heat will deactivate AAV.

Suitable extinguishing media: Use fire fighting measures that suit the environment.

Special protective equipment for fire fighters: No special measures required.

Hazardous combustion products: None known

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment

Environmental precautions: Do not allow to enter sewers/ surface or ground water.

Methods and materials for containment and clean-up: Contain spill with absorbent material and decontaminate the area using 10% bleach (1% sodium hypochlorite) or detergent-based disinfectant and let stand for 10 minutes. Alcohols are not effective disinfectants for AAV.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Handle as a biohazardous material under Biosafety Level 1 guidelines. Wear appropriate protective equipment when handling. Do not eat or drink while handling this material. Avoid contact with eyes, skin and clothing.

Conditions for safe storage: AAV is stable at room temperature and 4°C. Store solutions at -80°C for long-term integrity.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Component	CAS-No.	Value	Control parameter	Basis
Pluronic F-68 0.001%	9003-11-6		STEL, TWA	No specific requirements

Safety Data Sheet: AAV5 DetectCDx™

Respiratory protection: Not required; except in case of aerosol formation. For practices that may produce aerosols, recommended engineering controls include mechanical ventilation (i.e. use of biological safety cabinets).

Eye protection: Eyewear complying with an approved standard.

Hand protection: Protective gloves.

Skin and body protection: Wear an appropriate lab coat and closed-toe shoes.

Work hygiene measures: Wash hands after use and before eating, smoking and using the toilet. Do not eat, drink or smoke when using this product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear colorless solution

Odor: None

Safety data

pH: 7.0 – 7.6

Boiling point
F: ~212
C: ~100
Flash point
Not flammable

Ignition temperature
No data available

Auto-ignition temperature
No data available

Melting point
F: ~32
C: ~0
Freezing point
F: ~32
C: ~0
Vapor pressure (mmHg) @
No data available

Vapor density (AIR = 1) @
No data available

Specific gravity (H2O = 1) @
No data available

Evaporation rate
No data available
Solubility in water
Complete

Percent solids by weight
No data available

Percent volatile by weight/by volume @
No data available

Molecular weight
~3746 kDa

Safety Data Sheet: AAV5 DetectCDx™

Viscosity
No data available

SECTION 10: STABILITY AND REACTIVITY

Stability
AAV is stable at room temperature and 4°C. Store solutions at -80°C for long-term integrity.

Conditions to avoid
High temperatures will inactivate AAV.

Materials to avoid
None known

Hazardous decomposition products
None known

SECTION 11: TOXICOLOGICAL INFORMATION

Acute toxicity
Oral LD50
No data available
Inhalation LC50
No data available
Dermal LD50
No data available
Other information of acute toxicity
No data available

Skin corrosion/irritation
No data available
Serious eye damage/eye irritation
No data available
Respiratory or skin sensitization
No data available
Germ cell mutagenicity
Adeno-associated viruses have a very low probability of integrating into the host genome. This integration is not random.
Carcinogenicity

IARC: Substance is not listed.

NTP: Substance is not listed.

Reproductive toxicity
No data available
Teratogenicity
No data available
Specific target organ toxicity—single exposure (Globally Harmonized System)
No data available
Specific target organ toxicity—repeat exposure (Globally Harmonized System)
No data available
Aspiration hazard
No data available
Signs and Symptoms of exposure
None Known
Synergistic effect
No data available

SECTION 12: ECOLOGICAL INFORMATION

Toxicity
No relevant information available

Safety Data Sheet: AAV5 DetectCDx™

Persistence and degradability
No relevant information available

Bio-accumulative potential
No relevant information available

Mobility in soil
No relevant studies identified

PBT and vPvB assessment
No relevant information available

Other adverse effects
No relevant information available

SECTION 13: DISPOSAL CONSIDERATIONS

Product

Always dispose of in accordance with local, regional or national/federal regulations.

Possible options:
1) Dispose of in labeled “Biohazardous Waste” to be picked up by licensed disposal company
2) Autoclave at 125°C for a minimum of 30 minutes before regular trash disposal
3) Disinfect with 10% chlorine bleach (1% sodium hypochlorite) for 10 minutes before drain disposal

Contaminated packaging

Same as product

SECTION 14: TRANSPORT INFORMATION

DOT: not regulated

IMDG: not regulated

IATA: not regulated

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

SARA 335 components
Substance is not listed.

SARA 313 components
Substance is not listed.

California Prop. 65 Components
Substance is not listed.

SECTION 16: OTHER INFORMATION

AAV is a parvovirus that will enter mammalian cells and remain in episomal form in non-dividing cells. It exhibits no pathogenic symptoms in humans or animals and has been used in clinical trials for gene therapy and/or approved for market use by the FDA and other regulatory bodies. Wild-type AAV integrates stably at human chromosome 19. This product consists of recombinant, replication-defective AAV vectors, with rep and cap genes removed. This AAV is generated using insect-specific baculovirus as a helper virus instead of human pathogens such as adenovirus or herpes simplex virus (HSV). Therefore, residual adenovirus or HSV are not present in this product.

Safety Data Sheet: AAV5 DetectCDx™

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Safety Data Sheet: AAV5 DetectCDx™

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: AAV5 Total Antibody Assay Run Controls (ARUP Item # PD-0008-F045) - Cutpoint Run Control (CC5)
SYNONYMS: Human plasma; unknown or variable composition, complex reaction products or biological materials (UVCB substance)

MANUFACTURER: ARUP Laboratories
ADDRESS: 500 Chipeta Way
Salt Lake City, UT 84108
USA

EMERGENCY PHONE: 1-800-522-2787
OTHER CALLS: 1-800-522-2787
Contact: safety161@aruplab.com

PREPARED BY: Brett Welch, PhD
REVISION DATE: 09 June 2023

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

GHS Classification

This product is not classified in accordance with the Globally Harmonized System of Classification and Labelling (GHS).

Precautionary Statement(s)

Hazards not otherwise classified (HNOC):

Take precautions to prevent contact with eyes, skin and mucous membranes. Product should only be handled by technically qualified individuals trained in handling biological materials including bloodborne pathogens.

This product should be handled as biohazardous material. Biosafety Level 1 guidelines apply.

The mixture consists of ingredient(s) of unknown acute toxicity.

HMIS Classification
Health Hazard: 0
Chronic Health Hazard: 0
Flammability: 0
Physical Hazards: 0

NFPA Rating
Health Hazard: 0
Fire: 0
Reactivity Hazard: 0

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	Classification	Concentration
Cutpoint Run Control (CC5)	Biohazard	Human plasma screened for negative interaction with AAV5 capsid

SECTION 4: FIRST AID MEASURES

General Advice

Safety Data Sheet: AAV5 DetectCDx™

No symptoms are anticipated after exposure.

In case of eye contact: Rinse with eyewash for at least 5 minutes. Seek medical attention if symptoms persist. Inform medical professional of exposure.

In case of skin contact: Generally, the product does not irritate the skin.

If swallowed: Do not induce vomiting unless directed to do so by medical personnel. Immediately seek medical attention or call Poison Control Center.

If inhaled: In case of exposure to aerosols, move affected individual to fresh air. Give oxygen if individual has difficulty breathing.

SECTION 5: FIRE-FIGHTING MEASURES

Conditions of flammability: This material is not flammable

Suitable extinguishing media: Use fire fighting measures that suit the environment.

Special protective equipment for fire fighters: No special measures required.

Hazardous combustion products: None known

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment

Environmental precautions: Do not allow to enter sewers/ surface or ground water.

Methods and materials for containment and clean-up: Contain spill with absorbent material and decontaminate the area using 10% bleach (1% sodium hypochlorite) or detergent-based disinfectant and let stand for 10 minutes.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Handle as a biohazardous material under Biosafety Level 1 guidelines. Wear appropriate protective equipment when handling. Do not eat or drink while handling this material. Avoid contact with eyes, skin and clothing.

Conditions for safe storage: Product is stable at room temperature and 4°C. Store at -80°C for long-term integrity.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Component	CAS-No.	Value	Control parameter	Basis
None				

Respiratory protection: Not required; except in case of aerosol formation. For practices that may produce aerosols, recommended engineering controls include mechanical ventilation (i.e. use of biological safety cabinets).

Eye protection: Eyewear complying with an approved standard.

Hand protection: Protective gloves.

Skin and body protection: Wear an appropriate lab coat and closed-toe shoes.

Work hygiene measures: Wash hands after use and before eating, smoking and using the toilet. Do not eat, drink or smoke when using this product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Safety Data Sheet: AAV5 DetectCDx™

Appearance: Clear to slightly cloudy amber color liquid

Odor: None

Safety data

pH: 7.2 – 7.6

Boiling point
F: ~212
C: ~100
Flash point
Not flammable

Ignition temperature
No data available

Auto-ignition temperature
No data available

Melting point
F: ~32
C: ~0
Freezing point
F: ~32
C: ~0
Vapor pressure (mmHg) @
No data available

Vapor density (AIR = 1) @
No data available

Specific gravity (H2O = 1) @
No data available

Evaporation rate
BASIS: No data available
Solubility in water
Complete

Percent solids by weight
No data available

Percent volatile by weight/by volume @
No data available

Molecular weight
Not applicable

Viscosity
No data available

SECTION 10: STABILITY AND REACTIVITY

Stability
Human plasma is stable at room temperature and 4°C. Store at -80°C for long-term integrity.

Conditions to avoid
High temperatures

Materials to avoid
None known

Safety Data Sheet: AAV5 DetectCDx™

Hazardous decomposition products
None known

SECTION 11: TOXICOLOGICAL INFORMATION

Acute toxicity
Oral LD50
No data available
Inhalation LC50
No data available
Dermal LD50
No data available
Other information of acute toxicity
No data available

Skin corrosion/irritation
No data available
Serious eye damage/eye irritation
No data available
Respiratory or skin sensitization
No data available
Germ cell mutagenicity
.No data available
Carcinogenicity

IARC: Substance is not listed.

NTP: Substance is not listed.

Reproductive toxicity
No data available
Teratogenicity
No data available
Specific target organ toxicity—single exposure (Globally Harmonized System)
No data available
Specific target organ toxicity—repeat exposure (Globally Harmonized System)
No data available
Aspiration hazard
No data available
Signs and Symptoms of exposure
None known
Synergistic effect
No data available

SECTION 12: ECOLOGICAL INFORMATION

Toxicity
No relevant information available.

Persistence and degradability
No relevant information available.

Bio-accumulative potential
No relevant information available.

Mobility in soil
No relevant studies identified

PBT and vPvB assessment
No relevant information available.

Other adverse effects
No relevant information available.

Safety Data Sheet: AAV5 DetectCDx™

SECTION 13: DISPOSAL CONSIDERATIONS

Product

Always dispose of in accordance with local, regional or national/federal regulations.

Possible options:
1) Dispose of in labeled “Biohazardous Waste” to be picked up by licensed disposal company
2) Autoclave at 125°C for a minimum of 30 minutes before regular trash disposal
3) Disinfect with 10% chlorine bleach (1% sodium hypochlorite) for 10 minutes before drain disposal

Contaminated packaging

Same as product

SECTION 14: TRANSPORT INFORMATION

DOT: not regulated

IMDG: not regulated

IATA: not regulated

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

SARA 335 components
Substance is not listed.

SARA 313 components
Substance is not listed.

California Prop. 65 Components
Substance is not listed.

SECTION 16: OTHER INFORMATION

Human plasma is used in the manufacturing of certain AAV5 DetectCDx™ reagents. Bloodborne pathogen training and universal precautions apply in order to safely handle these reagents.

The human plasma used in AAV5 DetectCDx™ reagent manufacturing is sourced from reputable biobanks, which screen samples for common bloodborne pathogens using FDA CBER licensed screening tests (title 21 - CFR part 610.40) to show the following: HBV surface antigen and NAT negative, HIV 1 & 2 antibody and NAT negative, HCV antibody and NAT negative, syphilis negative, West Nile virus NAT negative, Zika virus RNA negative, and the donor(s) has tested negative by a licensed test for antibodies to T.cruzi either on the current donation or at least one previous donation.

DISCLAIMER

The foregoing information is offered in good faith as accurate, but without guarantee of any kind. ARUP assumes no liability whatsoever for the accuracy or completeness of the information contained herein. The material(s) described above may present unknown hazards and should be used with caution. Although certain hazards are described above, we cannot guarantee that these are the only hazards that exist. Conditions of use and suitability of these materials for particular uses are beyond ARUP’s control. Final determination of suitability of any material is therefore the sole responsibility of the user. Appropriate warnings and safe handling procedures are also the responsibility of the handlers and users of the materials described herein. All risks associated with use of such materials are assumed by the user. ARUP EXPRESSLY DISCLAIMS ALL WARRANTIES OF EVERY KIND AND NATURE IN CONNECTION WITH THE FOREGOING INFORMATION OR THE USE OF THE MATERIALS, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, ACCURACY AND COMPLETENESS.

Safety Data Sheet: AAV5 DetectCDx™

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: AAV5 Total Antibody Assay Run Controls (ARUP Item # PD-0008-F045) - High Positive Run Control (HPC5)
SYNONYMS: Human plasma; unknown or variable composition, complex reaction products or biological materials (UVCB substance)

MANUFACTURER: ARUP Laboratories
ADDRESS: 500 Chipeta Way
Salt Lake City, UT 84108
USA

EMERGENCY PHONE: 1-800-522-2787
OTHER CALLS: 1-800-522-2787
Contact: safety161@aruplab.com

PREPARED BY: Brett Welch, PhD
REVISION DATE: 09 June 2023

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

GHS Classification

This product is not classified in accordance with the Globally Harmonized System of Classification and Labelling (GHS).

Precautionary Statement(s)

Hazards not otherwise classified (HNOC):

Take precautions to prevent contact with eyes, skin and mucous membranes. Product should only be handled by technically qualified individuals trained in handling biological materials including bloodborne pathogens.

This product should be handled as biohazardous material. Biosafety Level 1 guidelines apply.

The mixture consists of ingredient(s) of unknown acute toxicity.

HMIS Classification
Health Hazard: 0
Chronic Health Hazard: 0
Flammability: 0
Physical Hazards: 0

NFPA Rating
Health Hazard: 0
Fire: 0
Reactivity Hazard: 0

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	Classification	Concentration
High Positive Run Control (HPC5)	Biohazard	Human plasma containing anti-AAV5 rabbit polyclonal antibody

SECTION 4: FIRST AID MEASURES

General Advice
No symptoms are anticipated after exposure.

Safety Data Sheet: AAV5 DetectCDx™

In case of eye contact: Rinse with eyewash for at least 5 minutes. Seek medical attention if symptoms persist. Inform medical professional of exposure.

In case of skin contact: Generally, the product does not irritate the skin.

If swallowed: Do not induce vomiting unless directed to do so by medical personnel. Immediately seek medical attention or call Poison Control Center.

If inhaled: In case of exposure to aerosols, move affected individual to fresh air. Give oxygen if individual has difficulty breathing.

SECTION 5: FIRE-FIGHTING MEASURES

Conditions of flammability: This material is not flammable

Suitable extinguishing media: Use fire fighting measures that suit the environment.

Special protective equipment for fire fighters: No special measures required.

Hazardous combustion products: None known

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment

Environmental precautions: Do not allow to enter sewers/ surface or ground water.

Methods and materials for containment and clean-up: Contain spill with absorbent material and decontaminate the area using 10% bleach (1% sodium hypochlorite) or detergent-based disinfectant and let stand for 10 minutes.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Handle as a biohazardous material under Biosafety Level 1 guidelines. Wear appropriate protective equipment when handling. Do not eat or drink while handling this material. Avoid contact with eyes, skin and clothing.

Conditions for safe storage: Product is stable at room temperature and 4°C. Store at -80°C for long-term integrity.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Component	CAS-No.	Value	Control parameter	Basis
None				

Respiratory protection: Not required; except in case of aerosol formation. For practices that may produce aerosols, recommended engineering controls include mechanical ventilation (i.e. use of biological safety cabinets).

Eye protection: Eyewear complying with an approved standard.

Hand protection: Protective gloves.

Skin and body protection: Wear an appropriate lab coat and closed-toe shoes.

Work hygiene measures: Wash hands after use and before eating, smoking and using the toilet. Do not eat, drink or smoke when using this product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear to slightly cloudy amber color liquid

Safety Data Sheet: AAV5 DetectCDx™

Odor: None

Safety data

pH: 7.2 – 7.6

Boiling point
F: ~212
C: ~100
Flash point
Not flammable

Ignition temperature
No data available

Auto-ignition temperature
No data available

Melting point
F: ~32
C: ~0
Freezing point
F: ~32
C: ~0
Vapor pressure (mmHg) @
No data available

Vapor density (AIR = 1) @
No data available

Specific gravity (H2O = 1) @
No data available

Evaporation rate
BASIS: No data available
Solubility in water
Complete

Percent solids by weight
No data available

Percent volatile by weight/by volume @
No data available

Molecular weight
Not applicable

Viscosity
No data available

SECTION 10: STABILITY AND REACTIVITY

Stability
Human plasma is stable at room temperature and 4°C. Store at -80°C for long-term integrity.

Conditions to avoid
High temperatures

Materials to avoid
None known

Safety Data Sheet: AAV5 DetectCDx™

Hazardous decomposition products
None known

SECTION 11: TOXICOLOGICAL INFORMATION

Acute toxicity
Oral LD50
No data available
Inhalation LC50
No data available
Dermal LD50
No data available
Other information of acute toxicity
No data available

Skin corrosion/irritation
No data available
Serious eye damage/eye irritation
No data available
Respiratory or skin sensitization
No data available
Germ cell mutagenicity
.No data available
Carcinogenicity

IARC: Substance is not listed.

NTP: Substance is not listed.

Reproductive toxicity
No data available
Teratogenicity
No data available
Specific target organ toxicity—single exposure (Globally Harmonized System)
No data available
Specific target organ toxicity—repeat exposure (Globally Harmonized System)
No data available
Aspiration hazard
No data available
Signs and Symptoms of exposure
None known
Synergistic effect
No data available

SECTION 12: ECOLOGICAL INFORMATION

Toxicity
No relevant information available.

Persistence and degradability
No relevant information available.

Bio-accumulative potential
No relevant information available.

Mobility in soil
No relevant studies identified

PBT and vPvB assessment
No relevant information available.

Other adverse effects
No relevant information available.

SECTION 13: DISPOSAL CONSIDERATIONS

Safety Data Sheet: AAV5 DetectCDx™

Product

Always dispose of in accordance with local, regional or national/federal regulations.

Possible options:
1) Dispose of in labeled “Biohazardous Waste” to be picked up by licensed disposal company
2) Autoclave at 125°C for a minimum of 30 minutes before regular trash disposal
3) Disinfect with 10% chlorine bleach (1% sodium hypochlorite) for 10 minutes before drain disposal

Contaminated packaging

Same as product

SECTION 14: TRANSPORT INFORMATION

DOT: not regulated

IMDG: not regulated

IATA: not regulated

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

SARA 335 components
Substance is not listed.

SARA 313 components
Substance is not listed.

California Prop. 65 Components
Substance is not listed.

SECTION 16: OTHER INFORMATION

Human plasma is used in the manufacturing of certain AAV5 DetectCDx™ reagents. Bloodborne pathogen training and universal precautions apply in order to safely handle these reagents.

The human plasma used in AAV5 DetectCDx™ reagent manufacturing is sourced from reputable biobanks, which screen samples for common bloodborne pathogens using FDA CBER licensed screening tests (title 21 - CFR part 610.40) to show the following: HBV surface antigen and NAT negative, HIV 1 & 2 antibody and NAT negative, HCV antibody and NAT negative, syphilis negative, West Nile virus NAT negative, Zika virus RNA negative, and the donor(s) has tested negative by a licensed test for antibodies to T.cruzi either on the current donation or at least one previous donation.

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Safety Data Sheet: AAV5 DetectCDx™

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: AAV5 Total Antibody Assay Run Controls (ARUP Item # PD-0008-F045) - Low Positive Run Control (LPC5)
SYNONYMS: Human plasma; unknown or variable composition, complex reaction products or biological materials (UVCB substance)

MANUFACTURER: ARUP Laboratories
ADDRESS: 500 Chipeta Way
Salt Lake City, UT 84108
USA

EMERGENCY PHONE: 1-800-522-2787
OTHER CALLS: 1-800-522-2787
Contact: safety161@aruplab.com

PREPARED BY: Brett Welch, PhD
REVISION DATE: 09 June 2023

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

GHS Classification

This product is not classified in accordance with the Globally Harmonized System of Classification and Labelling (GHS).

Precautionary Statement(s)

Hazards not otherwise classified (HNOC):

Take precautions to prevent contact with eyes, skin and mucous membranes. Product should only be handled by technically qualified individuals trained in handling biological materials including bloodborne pathogens.

This product should be handled as biohazardous material. Biosafety Level 1 guidelines apply.

The mixture consists of ingredient(s) of unknown acute toxicity.

HMIS Classification
Health Hazard: 0
Chronic Health Hazard: 0
Flammability: 0
Physical Hazards: 0

NFPA Rating
Health Hazard: 0
Fire: 0
Reactivity Hazard: 0

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	Classification	Concentration
Low Positive Run Control (HPC5)	Biohazard	Human plasma containing anti-AAV5 rabbit polyclonal antibody

SECTION 4: FIRST AID MEASURES

General Advice
No symptoms are anticipated after exposure.

Safety Data Sheet: AAV5 DetectCDx™

In case of eye contact: Rinse with eyewash for at least 5 minutes. Seek medical attention if symptoms persist. Inform medical professional of exposure.

In case of skin contact: Generally, the product does not irritate the skin.

If swallowed: Do not induce vomiting unless directed to do so by medical personnel. Immediately seek medical attention or call Poison Control Center.

If inhaled: In case of exposure to aerosols, move affected individual to fresh air. Give oxygen if individual has difficulty breathing.

SECTION 5: FIRE-FIGHTING MEASURES

Conditions of flammability: This material is not flammable

Suitable extinguishing media: Use fire fighting measures that suit the environment.

Special protective equipment for fire fighters: No special measures required.

Hazardous combustion products: None known

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment

Environmental precautions: Do not allow to enter sewers/ surface or ground water.

Methods and materials for containment and clean-up: Contain spill with absorbent material and decontaminate the area using 10% bleach (1% sodium hypochlorite) or detergent-based disinfectant and let stand for 10 minutes.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Handle as a biohazardous material under Biosafety Level 1 guidelines. Wear appropriate protective equipment when handling. Do not eat or drink while handling this material. Avoid contact with eyes, skin and clothing.

Conditions for safe storage: Product is stable at room temperature and 4°C. Store at -80°C for long-term integrity.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Component	CAS-No.	Value	Control parameter	Basis
None				

Respiratory protection: Not required; except in case of aerosol formation. For practices that may produce aerosols, recommended engineering controls include mechanical ventilation (i.e. use of biological safety cabinets).

Eye protection: Eyewear complying with an approved standard.

Hand protection: Protective gloves.

Skin and body protection: Wear an appropriate lab coat and closed-toe shoes.

Work hygiene measures: Wash hands after use and before eating, smoking and using the toilet. Do not eat, drink or smoke when using this product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear to slightly cloudy amber color liquid

Safety Data Sheet: AAV5 DetectCDx™

Odor: None

Safety data

pH: 7.2 – 7.6

Boiling point
F: ~212
C: ~100
Flash point
Not flammable

Ignition temperature
No data available

Auto-ignition temperature
No data available

Melting point
F: ~32
C: ~0
Freezing point
F: ~32
C: ~0
Vapor pressure (mmHg) @
No data available

Vapor density (AIR = 1) @
No data available

Specific gravity (H2O = 1) @
No data available

Evaporation rate
BASIS: No data available
Solubility in water
Complete

Percent solids by weight
No data available

Percent volatile by weight/by volume @
No data available

Molecular weight
Not applicable

Viscosity
No data available

SECTION 10: STABILITY AND REACTIVITY

Stability
Human plasma is stable at room temperature and 4°C. Store at -80°C for long-term integrity.

Conditions to avoid
High temperatures

Materials to avoid
None known

Safety Data Sheet: AAV5 DetectCDx™

Hazardous decomposition products
None known

SECTION 11: TOXICOLOGICAL INFORMATION

Acute toxicity
Oral LD50
No data available
Inhalation LC50
No data available
Dermal LD50
No data available
Other information of acute toxicity
No data available

Skin corrosion/irritation
No data available
Serious eye damage/eye irritation
No data available
Respiratory or skin sensitization
No data available
Germ cell mutagenicity
.No data available
Carcinogenicity

IARC: Substance is not listed.

NTP: Substance is not listed.

Reproductive toxicity
No data available
Teratogenicity
No data available
Specific target organ toxicity—single exposure (Globally Harmonized System)
No data available
Specific target organ toxicity—repeat exposure (Globally Harmonized System)
No data available
Aspiration hazard
No data available
Signs and Symptoms of exposure
None known
Synergistic effect
No data available

SECTION 12: ECOLOGICAL INFORMATION

Toxicity
No relevant information available.

Persistence and degradability
No relevant information available.

Bio-accumulative potential
No relevant information available.

Mobility in soil
No relevant studies identified

PBT and vPvB assessment
No relevant information available.

Other adverse effects
No relevant information available.

SECTION 13: DISPOSAL CONSIDERATIONS

Safety Data Sheet: AAV5 DetectCDx™

Product

Always dispose of in accordance with local, regional or national/federal regulations.

Possible options:
1) Dispose of in labeled “Biohazardous Waste” to be picked up by licensed disposal company
2) Autoclave at 125°C for a minimum of 30 minutes before regular trash disposal
3) Disinfect with 10% chlorine bleach (1% sodium hypochlorite) for 10 minutes before drain disposal

Contaminated packaging

Same as product

SECTION 14: TRANSPORT INFORMATION

DOT: not regulated

IMDG: not regulated

IATA: not regulated

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

SARA 335 components
Substance is not listed.

SARA 313 components
Substance is not listed.

California Prop. 65 Components
Substance is not listed.

SECTION 16: OTHER INFORMATION

Human plasma is used in the manufacturing of certain AAV5 DetectCDx™ reagents. Bloodborne pathogen training and universal precautions apply in order to safely handle these reagents.

The human plasma used in AAV5 DetectCDx™ reagent manufacturing is sourced from reputable biobanks, which screen samples for common bloodborne pathogens using FDA CBER licensed screening tests (title 21 - CFR part 610.40) to show the following: HBV surface antigen and NAT negative, HIV 1 & 2 antibody and NAT negative, HCV antibody and NAT negative, syphilis negative, West Nile virus NAT negative, Zika virus RNA negative, and the donor(s) has tested negative by a licensed test for antibodies to T.cruzi either on the current donation or at least one previous donation.

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Safety Data Sheet: AAV5 DetectCDx™

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: AAV5 Total Antibody Assay Run Controls (ARUP Item # PD-0008-F045) - Negative Run Control (NEG5)
SYNONYMS: Human plasma; unknown or variable composition, complex reaction products or biological materials (UVCB substance)

MANUFACTURER: ARUP Laboratories
ADDRESS: 500 Chipeta Way
Salt Lake City, UT 84108
USA

EMERGENCY PHONE: 1-800-522-2787
OTHER CALLS: 1-800-522-2787
Contact: safety161@aruplab.com

PREPARED BY: Brett Welch, PhD
REVISION DATE: 09 June 2023

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

GHS Classification

This product is not classified in accordance with the Globally Harmonized System of Classification and Labelling (GHS).

Precautionary Statement(s)

Hazards not otherwise classified (HNOC):

Take precautions to prevent contact with eyes, skin and mucous membranes. Product should only be handled by technically qualified individuals trained in handling biological materials including bloodborne pathogens.

This product should be handled as biohazardous material. Biosafety Level 1 guidelines apply.

The mixture consists of ingredient(s) of unknown acute toxicity.

HMIS Classification
Health Hazard: 0
Chronic Health Hazard: 0
Flammability: 0
Physical Hazards: 0

NFPA Rating
Health Hazard: 0
Fire: 0
Reactivity Hazard: 0

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	Classification	Concentration
Negative Run Control (NEG5)	Biohazard	Human plasma screened for negative interaction with AAV5 capsid

SECTION 4: FIRST AID MEASURES

General Advice

Safety Data Sheet: AAV5 DetectCDx™

No symptoms are anticipated after exposure.

In case of eye contact: Rinse with eyewash for at least 5 minutes. Seek medical attention if symptoms persist. Inform medical professional of exposure.

In case of skin contact: Generally, the product does not irritate the skin.

If swallowed: Do not induce vomiting unless directed to do so by medical personnel. Immediately seek medical attention or call Poison Control Center.

If inhaled: In case of exposure to aerosols, move affected individual to fresh air. Give oxygen if individual has difficulty breathing.

SECTION 5: FIRE-FIGHTING MEASURES

Conditions of flammability: This material is not flammable

Suitable extinguishing media: Use fire fighting measures that suit the environment.

Special protective equipment for fire fighters: No special measures required.

Hazardous combustion products: None known

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment

Environmental precautions: Do not allow to enter sewers/ surface or ground water.

Methods and materials for containment and clean-up: Contain spill with absorbent material and decontaminate the area using 10% bleach (1% sodium hypochlorite) or detergent-based disinfectant and let stand for 10 minutes.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Handle as a biohazardous material under Biosafety Level 1 guidelines. Wear appropriate protective equipment when handling. Do not eat or drink while handling this material. Avoid contact with eyes, skin and clothing.

Conditions for safe storage: Product is stable at room temperature and 4°C. Store at -80°C for long-term integrity.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Component	CAS-No.	Value	Control parameter	Basis
None				

Respiratory protection: Not required; except in case of aerosol formation. For practices that may produce aerosols, recommended engineering controls include mechanical ventilation (i.e. use of biological safety cabinets).

Eye protection: Eyewear complying with an approved standard.

Hand protection: Protective gloves.

Skin and body protection: Wear an appropriate lab coat and closed-toe shoes.

Work hygiene measures: Wash hands after use and before eating, smoking and using the toilet. Do not eat, drink or smoke when using this product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Safety Data Sheet: AAV5 DetectCDx™

Appearance: Clear to slightly cloudy amber color liquid

Odor: None

Safety data

pH: 7.2 – 7.6

Boiling point
F: ~212
C: ~100
Flash point
Not flammable

Ignition temperature
No data available

Auto-ignition temperature
No data available

Melting point
F: ~32
C: ~0
Freezing point
F: ~32
C: ~0
Vapor pressure (mmHg) @
No data available

Vapor density (AIR = 1) @
No data available

Specific gravity (H2O = 1) @
No data available

Evaporation rate
BASIS: No data available
Solubility in water
Complete

Percent solids by weight
No data available

Percent volatile by weight/by volume @
No data available

Molecular weight
Not applicable

Viscosity
No data available

SECTION 10: STABILITY AND REACTIVITY

Stability
Human plasma is stable at room temperature and 4°C. Store at -80°C for long-term integrity.

Conditions to avoid
High temperatures

Materials to avoid
None known

Safety Data Sheet: AAV5 DetectCDx™

Hazardous decomposition products
None known

SECTION 11: TOXICOLOGICAL INFORMATION

Acute toxicity
Oral LD50
No data available
Inhalation LC50
No data available
Dermal LD50
No data available
Other information of acute toxicity
No data available

Skin corrosion/irritation
No data available
Serious eye damage/eye irritation
No data available
Respiratory or skin sensitization
No data available
Germ cell mutagenicity
.No data available
Carcinogenicity

IARC: Substance is not listed.

NTP: Substance is not listed.

Reproductive toxicity
No data available
Teratogenicity
No data available
Specific target organ toxicity—single exposure (Globally Harmonized System)
No data available
Specific target organ toxicity—repeat exposure (Globally Harmonized System)
No data available
Aspiration hazard
No data available
Signs and Symptoms of exposure
None known
Synergistic effect
No data available

SECTION 12: ECOLOGICAL INFORMATION

Toxicity
No relevant information available.

Persistence and degradability
No relevant information available.

Bio-accumulative potential
No relevant information available.

Mobility in soil
No relevant studies identified

PBT and vPvB assessment
No relevant information available.

Other adverse effects
No relevant information available.

Safety Data Sheet: AAV5 DetectCDx™

SECTION 13: DISPOSAL CONSIDERATIONS

Product

Always dispose of in accordance with local, regional or national/federal regulations.

Possible options:
1) Dispose of in labeled “Biohazardous Waste” to be picked up by licensed disposal company
2) Autoclave at 125°C for a minimum of 30 minutes before regular trash disposal
3) Disinfect with 10% chlorine bleach (1% sodium hypochlorite) for 10 minutes before drain disposal

Contaminated packaging

Same as product

SECTION 14: TRANSPORT INFORMATION

DOT: not regulated

IMDG: not regulated

IATA: not regulated

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

SARA 335 components
Substance is not listed.

SARA 313 components
Substance is not listed.

California Prop. 65 Components
Substance is not listed.

SECTION 16: OTHER INFORMATION

Human plasma is used in the manufacturing of certain AAV5 DetectCDx™ reagents. Bloodborne pathogen training and universal precautions apply in order to safely handle these reagents.

The human plasma used in AAV5 DetectCDx™ reagent manufacturing is sourced from reputable biobanks, which screen samples for common bloodborne pathogens using FDA CBER licensed screening tests (title 21 - CFR part 610.40) to show the following: HBV surface antigen and NAT negative, HIV 1 & 2 antibody and NAT negative, HCV antibody and NAT negative, syphilis negative, West Nile virus NAT negative, Zika virus RNA negative, and the donor(s) has tested negative by a licensed test for antibodies to T.cruzi either on the current donation or at least one previous donation.

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