# MATERIAL SAFETY DATA SHEET
## Mono Test Device Kit

According to REACH Regulation (EC) No. 1907/2006, Annex II

This documentation contains MSDS for the following kit components
Test Device
Positive Control & Negative Control
Whole Blood Buffer

## 1. Identification of the substance/preparation and of the company/undertaking

**Identification of the substance or preparation**

| Trade name: | Reference No. | Part No. |
|---|---|---|
| Pro Advantage® Infectious Mononucleosis Test Device | IMO-402 | P080016 |

**Use of the substance/preparation:** In vitro diagnostic medical device. For professional use only.

**Company/undertaking identification:**
Inverness Medical Innovations North America, Inc.
30 South Keller Road, Suite 100
Orlando, FL 32810 USA
Tel: + 1-877-441-7440
Fax: + 1-877-441-7441
Email: imi.customercare@invmed.com

**Further information obtainable from:** For further information, contact your local distributor/supplier.

**Emergency telephone:** ChemTel Inc. International access: + (0)1-813-248-0585
ChemTel Inc. Free phone (North America only): 1-(800)-255-3924

## 2. Hazards identification

**Hazard description:**
Preparation not classified as dangerous according to Directive 1999/45/EC.

**Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

**Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:**
As an article, the device is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200.

## 3. Composition/information on ingredients

**Chemical characterisation**
**Description:**
In vitro diagnostic medical device. Test strip impregnated with dried chemical / biochemical reagents.

**Dangerous components:**

| Component | CAS No. | EINECS No. | Classification | Concentration |
|---|---|---|---|---|
| Tris (hydroxymethyl) aminomethane | 77-86-1 | 201-064-4 | Xi, R 36/37/38 | 2 – 5 % |

**Additional information:**
Each device is packaged in a foil pouch.
For the wording of the listed risk phrases refer to section 16.

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## 4. First-aid measures

**General Information:**
The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.
**After skin contact:**
Wash with soap and water and rinse thoroughly.
**After eye contact:**
Rinse opened eye for several minutes under running water.
**After ingestion:**
If desiccant or other components are swallowed seek medical attention.

## 5. Fire-fighting measures

**Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire-extinguishing methods suitable to surrounding conditions.
**Special hazards caused by the substance, its products of combustion or resulting gases:**
In case of fire, the following can be released: Hazardous fumes and vapours, Carbon oxides ($CO_x$), Nitrogen oxides ($NO_x$),
**Protective equipment:**
Wear full protective suit and self-contained respiratory protective device when extinguishing fires.
**Additional information:**
The device contains combustible materials.

## 6. Accidental release measures

**Person-related safety precautions:**
Refer to Section 8 for protective measures when handling the spillage.
**Measures for environmental protection:**
Avoid release to the environment.
**Measures for cleaning/collecting:**
Collect material and dispose of as waste according to Section 13.

## 7. Handling and storage

**Information for safe handling:**
Keep out of reach of children.
**Storage:**
Store in the original container at 2 - 30°C
**Requirements to be met by storerooms and receptacles:**
No special requirements.

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## 8. Exposure controls/personal protection

**Ingredients with limit values that require monitoring in the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

**Additional information:**
The lists valid during the creation of this MSDS were used as a basis for this assessment.

**Personal protective equipment:**
**General protective and hygienic measures:**
Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54EC or US regulation 29 CFR 1910.1030 for information on handling bio hazardous materials.
Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.
**Respiratory protection:**
Not required
**Protection of hands:**
Disposable gloves (for sample handling)
**Material of gloves:**
Latex/natural rubber
**Penetration time of glove material:**
Glove resistance is not critical as the gloves are intended to provide protection against the sample material.
**Eye protection:**
Not required
**Body protection:**
Lab coat

## 9. Physical and chemical properties

**General Information**
**Form:** The device is an article containing solid components
**Appearance:** Laminated test strip, which may be housed in a plastic holder.
**Odour:** Odourless
**Flash point:** Not applicable.
**Self-igniting:** Product is not self-igniting.
**Danger of explosion:** Product does not present an explosion hazard.

## 10. Stability and reactivity

**Stability:** The product is stable in accordance with the recommended storage conditions.
**Materials to be avoided:** None
**Hazardous reactions:** No dangerous reactions known.
**Hazardous decomposition products:** No dangerous decomposition products known.

## 11. Toxicological information

**Acute toxicity:**
Quantitative data on the toxic effects of this product is not available.
**Primary effects:**
**After skin contact:** No irritating effects anticipated.
**After eye contact:** No irritating effects anticipated.
**Sensitisation:** No sensitising effects known.

**MATERIAL SAFETY DATA SHEET**
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## 12. Ecological information

**Environmental Toxicity:**
Quantitative data on the toxic effects of this product is not available.
**Persistence and Degradability:**
The device contains plastic and other components that are not readily degradable.

## 13. Disposal considerations

**Product:**
Used devices and other contaminated materials should be disposed of as potentially bio hazardous waste.
To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

**European waste catalogue:**
18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.

**Packaging:**
Disposal must be made in accordance with local waste management regulations.
Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

## 14. Transport information

**Land transport ADR/RID (cross-border)**
Not regulated for transport.

**US DOT Transport Regulations:**
Not regulated for transport.

**Maritime transport IMDG:**
Not regulated for transport.
**Marine pollutant:** No

**Air transport ICAO-TI and IATA-DGR:**
Not regulated for transport.

**MATERIAL SAFETY DATA SHEET**
**Mono Test Device Kit**
According to REACH Regulation (EC) No. 1907/2006, Annex II

This documentation contains MSDS for the following kit components
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## 15. Regulatory information

**Labelling according to EU guidelines:**
Safety data sheet available for professional user on request.

**Note:**
The preparation is exempt from the above labelling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

**US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:**
Not required.

**Chemical inventory listings relevant to US regulations:**

**Carcinogen listings**

| | |
|---|---|
| IARC: | None of the ingredients is listed. |
| NTP: | None of the ingredients is listed. |
| ACGIH: | None of the ingredients is listed. |
| OSHA: | None of the ingredients is listed. |
| EPA | None of the ingredients is listed. |

**Californian Proposition 65**

| | |
|---|---|
| Chemicals known to cause cancer: | None of the ingredients is listed. |
| Chemicals known to cause reproductive toxicity: | None of the ingredients is listed. |

**SARA**

| | |
|---|---|
| Section 355 (extremely hazardous substances): | None of the ingredients is listed. |
| Section 313 (specific toxic chemical listings): | None of the ingredients is listed. |

## 16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

**Relevant R-phrases**
36/37/38 Irritating to eyes, respiratory system and skin.

# MATERIAL SAFETY DATA SHEET
## Mono Test Device Kit

According to REACH Regulation (EC) No. 1907/2006, Annex II

This documentation contains MSDS for the following kit components
Test Device
Positive Control & Negative Control
Whole Blood Buffer

## 1. Identification of the substance/preparation and of the company/undertaking

**Identification of the substance or preparation**

**Trade name: Mono, Negative Control**

| Trade name: | Reference No. | Part No. |
|---|---|---|
| Pro Advantage® Infectious Mononucleosis Test Device | IMO-402 | P080016 |

**Use of the substance/preparation:** In vitro diagnostic medical device. For professional use only.

**Company/undertaking identification:**
Inverness Medical Innovations North America, Inc.
30 South Keller Road, Suite 100
Orlando, FL 32810 USA
Tel: + 1-877-441-7440
Fax: + 1-877-441-7441
Email: imi.customercare@invmed.com

**Further information obtainable from:** For further information, contact your local distributor/supplier.

**Emergency telephone:** ChemTel Inc. International access: + (0)1-813-248-0585
ChemTel Inc. Free phone (North America only): 1-(800)-255-3924

## 2. Hazards identification

**Hazard description:**
Xn, Harmful

**Information concerning particular hazards for human and environment:**
R 22 Harmful if swallowed.

**Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

**Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:**
Not classified as hazardous.

**MATERIAL SAFETY DATA SHEET**
**Mono Test Device Kit**
According to REACH Regulation (EC) No. 1907/2006, Annex II

This documentation contains MSDS for the following kit components
Test Device
Positive Control & Negative Control
Whole Blood Buffer

## 3. Composition/information on ingredients

**Chemical characterisation**
**Description:**
Aqueous preparation containing the hazardous components listed below. Also contains materials of human origin.

**Dangerous components:**

| Component | CAS No. | EINECS No. | Classification | Concentration |
|---|---|---|---|---|
| Sodium Azide | 26628-22-8 | 247-852-1 | T+, N, R 28-32-50/53 | 0.09 % |

**Additional information:**
Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1/2 on a single donor basis and found to be non-reactive.
For the wording of the listed risk phrases refer to section 16.

## 4. First-aid measures

**After inhalation:** Supply fresh air; consult doctor in case of complaints.
**After skin contact:**
Wash with soap and water and rinse thoroughly. Remove soiled clothing.
**After eye contact:**
Rinse opened eye for several minutes under running water. Consult a doctor in case of complaints.
**After ingestion:**
Wash out mouth with water. Consult a doctor.

## 5. Fire-fighting measures

**Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire-extinguishing methods suitable to surrounding conditions.
**Special hazards caused by the substance, its products of combustion or resulting gases:**
In case of fire, the following can be released: Carbon oxides ($CO_x$), Nitrogen oxides ($NO_x$), Phosphorous oxides ($P_xO_y$)
**Protective equipment:**
Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

## 6. Accidental release measures

**Person-related safety precautions:**
Isolate spillage and clean up immediately.
Refer to Section 8 for protective measures when handling the spillage.
**Measures for environmental protection:**
Do not allow the undiluted product to enter sewers/surface or ground water.
**Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, and universal binders)
Dispose of contaminated material as waste according to Section 13.
Swab down area with hypochlorite solution or other disinfecting agent.

**MATERIAL SAFETY DATA SHEET**
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## 7. Handling and storage

**Information for safe handling:**
This product should be handled as a potentially infectious material, as no known test method can offer complete assurance that products derived from human blood will not transmit infectious agents.
Avoid contact with the eyes, skin and mucous membranes.
Keep out of reach of children.

**Storage:**
Store in the original container at 2 - 30°C

**Requirements to be met by storerooms and receptacles:**
No special requirements.

## 8. Exposure controls/personal protection

**Ingredients with limit values that require monitoring in the workplace:**
Sodium azide CAS No.: 26628-22-8
UK WEL / IRL OELV 8-hour TWA: 0.1 mg/m³ Short-term value: 0.3 mg/m³ as $NaN_3$

**Additional information:**
The lists valid during the creation of this MSDS were used as a basis for this assessment.

**Personal protective equipment:**

**General protective and hygienic measures:**
Adhere to EU Directive 2000/54/EC / OSHA Regulation 29 CFR 1910.1030 for handling bio hazardous materials.
Clean work areas with hypochlorite solution or other disinfecting agent.
Wash hands before breaks and at the end of work.

**Respiratory protection:**
Face mask

**Protection of hands:**
Disposable gloves

**Material of gloves:**
Latex/natural rubber

**Penetration time of glove material:**
Gloves resistance is not critical when the product is handled according to the instructions for use.

**Eye protection:**
Safety glasses

**Body protection:**
Lab coat

**MATERIAL SAFETY DATA SHEET**
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Whole Blood Buffer

## 9. Physical and chemical properties

**General Information**
**Form:** Liquid
**Colour:** Colourless
**Odour:** Odourless
**Change in condition**
**Melting point/Melting range**: Similar to water, approximately 0°C.
**Boiling point/Boiling range:** Similar to water, approximately 100°C.
**Flash point:** Not applicable.
**Self-igniting:** Product is not self-igniting.
**Danger of explosion:** Product does not present an explosion hazard.
**Vapour pressure:** Similar to water, approximately 23 hPa.
**Density at 20°C:** 1.01 g/cm³
**Solubility in/Miscibility with:**
**Water:** Fully miscible.
**pH-value at 20°C:** 7.4

## 10. Stability and reactivity

**Stability:** The product is stable in accordance with the recommended storage conditions.
**Materials to be avoided:** concentrated acids, heavy metals, metallic salts
**Hazardous reactions:** Preparation contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic (azide) gas. Hazardous polymerisation will not occur.
**Hazardous decomposition products:** No dangerous decomposition products known.

## 11. Toxicological information

**Acute toxicity:**
Quantitative data on the toxic effects of this product is not available.

**$LD_{50}/LC_{50}$ values relevant for classification:**
Sodium azide CAS No.: 26628-22-8
$LD_{50}$ (Oral, rat): 27 mg/kg
$TDL_0$ (Human): 0.71 mg/kg
$LD_{50}$ (Dermal, rabbit): 20 mg/kg
**Primary effects:**
**After skin contact:** No irritating effects anticipated.
**After eye contact:** No irritating effects anticipated.
**After ingestion:** Possible systemic effects following ingestion of substantial quantities: headache, dizziness, nausea, vomiting, CNS disorders, drop in blood pressure, cardiovascular failure, collapse.
**Sensitization:** No sensitizing effects known.

**MATERIAL SAFETY DATA SHEET**
**Mono Test Device Kit**
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This documentation contains MSDS for the following kit components
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Positive Control & Negative Control
Whole Blood Buffer

## 12. Ecological information

**Ecotoxic Effects:**
Quantitative data on the toxic effects of this product are not available.
No ecological problems are to be expected when the product is handled and used with due care and attention.

**Aquatic toxicity:**
Sodium azide CAS No.: 26628-22-8
$LC_{50}$ (96 h, Fish): 0.7 mg/l
$EC_{50}$ (96 h, Daphnia): 4.2 mg/l

**Persistence and Degradability:**
The product is biodegradable.

**Mobility and bioaccumulation potential:**
Does not accumulate in organisms

## 13. Disposal considerations

**Product:**
Dispose of as potentially bio hazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
To avoid the possible build-up of azide compounds, flush plumbing with water after the disposal of undiluted reagent.

**European waste catalogue:**
18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.

**Packaging:**
Disposal must be made in accordance with local waste management regulations.
Contaminated packaging must be disposed of in the same manner as the product.
Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

## 14. Transport information

**Land transport ADR/RID (cross-border)**
Not regulated for transport.
**US DOT Transport Regulations:**
Not regulated for transport.
**Maritime transport IMDG:**
Not regulated for transport.
**Marine pollutant:** No
**Air transport ICAO-TI and IATA-DGR:**
Not regulated for transport.

**MATERIAL SAFETY DATA SHEET**
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According to REACH Regulation (EC) No. 1907/2006, Annex II

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Test Device
Positive Control & Negative Control
Whole Blood Buffer

## 15. Regulatory information

**Labelling according to EU guidelines:**
**Code letter and hazard designation of product:**


Xn Harmful

**Hazard-determining components of labelling:**
Sodium Azide
**Risk phrases:**
22 Harmful if swallowed.
**Safety phrases:**
S2 Keep out of reach of children
35 This material and its container must be disposed of in a safe way.
46 If swallowed, seek medical advice immediately and show this container or label.
**Water Hazard Class (Germany):** WGK -, not hazardous for water.
**US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:**
Not required.
**Chemical inventory listings relevant to US regulations:**
**Carcinogen listings**

| | |
|---|---|
| IARC: | None of the ingredients is listed. |
| NTP: | None of the ingredients is listed. |
| ACGIH: | None of the ingredients is listed. |
| OSHA: | None of the ingredients is listed. |
| EPA | None of the ingredients is listed. |

**Californian Proposition 65**

| | |
|---|---|
| Chemicals known to cause cancer: | None of the ingredients is listed. |
| Chemicals known to cause reproductive toxicity: | None of the ingredients is listed. |

**SARA**

| | |
|---|---|
| Section 355 (extremely hazardous substances): | Yes, Sodium azide CAS No. 26628-22-8. |
| Section 313 (specific toxic chemical listings): | Yes, Sodium azide CAS No. 26628-22-8 |

## 16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

**Relevant R-phrases**

| | |
|---|---|
| 28 | Very toxic if swallowed. |
| 32 | Contact with acids liberates very toxic gas. |
| 50/53 | Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment. |

# MATERIAL SAFETY DATA SHEET
## Mono Test Device Kit

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This documentation contains MSDS for the following kit components
Test Device
Positive Control & Negative Control
Whole Blood Buffer

## 1. Identification of the substance/preparation and of the company/undertaking

**Identification of the substance or preparation**

**Trade name: Mono Positive Control**

| Trade name: | Reference No. | Part No. |
|---|---|---|
| Pro Advantage® Infectious Mononucleosis Test Device | IMO-402 | P080016 |

**Use of the substance/preparation:** In vitro diagnostic medical device. For professional use only.

**Company/undertaking identification:**
Inverness Medical Innovations North America, Inc.
30 South Keller Road, Suite 100
Orlando, FL 32810 USA
Tel: + 1-877-441-7440
Fax: + 1-877-441-7441
Email: imi.customercare@invmed.com

**Further information obtainable from:** For further information, contact your local distributor/supplier.

**Emergency telephone:** ChemTel Inc. International access: + (0)1-813-248-0585
ChemTel Inc. Free phone (North America only): 1-(800)-255-3924

## 2. Hazards identification

**Hazard description:**
Xn, Harmful

**Information concerning particular hazards for human and environment:**
R 22 Harmful if swallowed.

**Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

**Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:**
Not classified as hazardous.

## 3. Composition/information on ingredients

**Chemical characterisation**
**Description:**
Aqueous preparation containing the hazardous components listed below.
**Dangerous components:**

| Component | CAS No. | EINECS No. | Classification | Concentration |
|---|---|---|---|---|
| Sodium Azide | 26628-22-8 | 247-852-1 | T+, N, R 28-32-50/53 | 0.1 – 0.2 % |

**Additional information:**
Also contains goat anti-mono antibody.
For the wording of the listed risk phrases refer to section 16.

**MATERIAL SAFETY DATA SHEET**
**Mono Test Device Kit**
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This documentation contains MSDS for the following kit components
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Whole Blood Buffer

## 4. First-aid measures

**After inhalation:** Supply fresh air; consult doctor in case of complaints.
**After skin contact:**
Wash with soap and water and rinse thoroughly. Remove soiled clothing.
**After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
**After ingestion:**
Wash out mouth with water. Consult a doctor.

## 5. Fire-fighting measures

**Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire-extinguishing methods suitable to surrounding conditions.
**Special hazards caused by the substance, its products of combustion or resulting gases:**
In case of fire, the following can be released: Carbon oxides ($CO_x$), Nitrogen oxides ($NO_x$), Phosphorous oxides ($P_xO_y$)
**Protective equipment:**
Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

## 6. Accidental release measures

**Person-related safety precautions:**
Isolate spillage and clean up immediately.
Refer to Section 8 for protective measures when handling the spillage.
**Measures for environmental protection:**
Do not allow to enter sewers/surface or ground water.
**Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust)
Dispose of contaminated material as waste according to Section 13.
Rinse off area with water.

## 7. Handling and storage

**Information for safe handling:**
Observe the general safety regulations when handling chemicals.
Avoid contact with the eyes, skin and mucous membranes.
Keep out of reach of children.
**Storage:**
Store in the original container at 2 - 30°C
**Requirements to be met by storerooms and receptacles:**
No special requirements.

**MATERIAL SAFETY DATA SHEET**
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## 8. Exposure controls/personal protection

**Ingredients with limit values that require monitoring in the workplace:**
Sodium azide CAS No.: 26628-22-8
UK WEL / IRL OELV 8-hour TWA: 0.1 mg/m³ Short-term value: 0.3 mg/m³ as $NaN_3$
TLV (ACGIH) Short-term value: 0.29 mg/m$^3$ as $NaN_3$, 0.11ppm as $HN_3$

**Additional information:**
The lists valid during the creation of this MSDS were used as a basis for this assessment.
**Personal protective equipment:**
**General protective and hygienic measures:**
Adhere to good laboratory practices (GLP).
Wash hands before breaks and at the end of work.
**Respiratory protection:**
Not required
**Protection of hands:**
Disposable gloves
**Material of gloves:**
Latex/natural rubber
**Penetration time of glove material:**
Gloves resistance is not critical when the product is handled according to the instructions for use.
**Eye protection:**
Not required
**Body protection:**
Lab coat

## 9. Physical and chemical properties

**General Information**
**Form:** Liquid
**Colour:** Colourless
**Odour:** Odourless
**Change in condition**
**Melting point/Melting range**: Similar to water, approximately 0°C.
**Boiling point/Boiling range:** Similar to water, approximately 100°C.
**Flash point:** Not applicable.
**Self-igniting:** Product is not self-igniting.
**Danger of explosion:** Product does not present an explosion hazard.
**Vapour pressure:** Similar to water, approximately 23 hPa.
**Density at 20°C:** 1.01 g/cm³
**Solubility in/Miscibility with:**
**Water:** Fully miscible.
**pH-value at 20°C:** 7.4

## 10. Stability and reactivity

**Stability:** The product is stable in accordance with the recommended storage conditions.
**Materials to be avoided:** concentrated acids, heavy metals, metallic salts
**Hazardous reactions:** Preparation contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic (azide) gas. Hazardous polymerisation will not occur.
**Hazardous decomposition products:** No dangerous decomposition products known.

**MATERIAL SAFETY DATA SHEET**
**Mono Test Device Kit**
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This documentation contains MSDS for the following kit components
Test Device
Positive Control & Negative Control
Whole Blood Buffer

## 11. Toxicological information

**Acute toxicity:**
Quantitative data on the toxic effects of this product is not available.

**$LD_{50}$/$LC_{50}$ values relevant for classification:**
Sodium azide CAS No.: 26628-22-8
$LD_{50}$ (Oral, rat): 27 mg/kg
$TDL_0$ (Human): 0.71 mg/kg
$LD_{50}$ (Dermal, rabbit): 20 mg/kg

**Primary effects:**
**After skin contact:** No irritating effects anticipated.
**After eye contact:** No irritating effects anticipated.
**After ingestion:** Possible systemic effects following ingestion of substantial quantities: headache, dizziness, nausea, vomiting, CNS disorders, drop in blood pressure, cardiovascular failure, collapse.
**Sensitization:** No sensitizing effects known.

## 12. Ecological information

**Ecotoxic Effects:**
Quantitative data on the toxic effects of this product are not available.
No ecological problems are to be expected when the product is handled and used with due care and attention.

**Aquatic toxicity:**
Sodium azide CAS No. 26628-22-8
$LC_{50}$ (96 h, Fish): 0.7 mg/l
$EC_{50}$ (96 h, Daphnia): 4.2 mg/l

**Persistence and Degradability:**
The product is biodegradable.

**Mobility and bioaccumulation potential:**
Does not accumulate in organisms

## 13. Disposal considerations

**Product:**
Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
To avoid the possible build-up of azide compounds, flush plumbing with water after the disposal of undiluted reagent.

**European waste catalogue:**
18 01 06 chemicals consisting of or containing dangerous substances

**Packaging:**
Disposal must be made in accordance with local waste management regulations.
Contaminated packaging must be disposed of in the same manner as the product.
Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

**MATERIAL SAFETY DATA SHEET**
**Mono Test Device Kit**
According to REACH Regulation (EC) No. 1907/2006, Annex II

This documentation contains MSDS for the following kit components
Test Device
Positive Control & Negative Control
Whole Blood Buffer

## 14. Transport information

**Land transport ADR/RID (cross-border)**
Not regulated for transport.
**US DOT Transport Regulations:**
Not regulated for transport.
**Maritime transport IMDG:**
Not regulated for transport.
**Marine pollutant:** No
**Air transport ICAO-TI and IATA-DGR:**
Not regulated for transport.

## 15. Regulatory information

**Labelling according to EU guidelines:**
**Code letter and hazard designation of product:**


Xn Harmful

**Hazard-determining components of labelling:**
Sodium Azide
**Risk phrases:**
22 Harmful if swallowed.
**Safety phrases:**
S2 Keep out of reach of children
35 This material and its container must be disposed of in a safe way.
46 If swallowed, seek medical advice immediately and show this container or label.
**Water Hazard Class (Germany):** WGK -, not hazardous for water.
**US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:**
Not required.
**Chemical inventory listings relevant to US regulations:**
**Carcinogen listings**

| | |
|---|---|
| IARC: | None of the ingredients is listed. |
| NTP: | None of the ingredients is listed. |
| ACGIH: | None of the ingredients is listed. |
| OSHA: | None of the ingredients is listed. |
| EPA | None of the ingredients is listed. |

**Californian Proposition 65**

| | |
|---|---|
| Chemicals known to cause cancer: | None of the ingredients is listed. |
| Chemicals known to cause reproductive toxicity: | None of the ingredients is listed. |

**SARA**

| | |
|---|---|
| Section 355 (extremely hazardous substances): | Yes, Sodium azide CAS No. 26628-22-8. |
| Section 313 (specific toxic chemical listings): | Yes, Sodium azide CAS No. 26628-22-8. |

**MATERIAL SAFETY DATA SHEET**
**Mono Test Device Kit**
According to REACH Regulation (EC) No. 1907/2006, Annex II

This documentation contains MSDS for the following kit components
Test Device
Positive Control & Negative Control
Whole Blood Buffer

## 16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

**Relevant R-phrases**

28 Very toxic if swallowed.
32 Contact with acids liberates very toxic gas.
50/53 Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

# MATERIAL SAFETY DATA SHEET
## Mono Test Device Kit

According to REACH Regulation (EC) No. 1907/2006, Annex II

This documentation contains MSDS for the following kit components
Test Device
Positive Control & Negative Control
Whole Blood Buffer

## 1. Identification of the substance/preparation and of the company/undertaking

**Identification of the substance or preparation**

**Trade name: Whole blood buffer**

| Trade name: | Reference No. | Part No. |
|---|---|---|
| Pro Advantage® Infectious Mononucleosis Test Device | IMO-402 | P080016 |

**Use of the substance/preparation:** In vitro diagnostic medical device. For professional use only.

**Company/undertaking identification:**
Inverness Medical Innovations North America, Inc.
30 South Keller Road, Suite 100
Orlando, FL 32810 USA
Tel: + 1-877-441-7440
Fax: + 1-877-441-7441
Email: imi.customercare@invmed.com

**Further information obtainable from:** For further information, contact your local distributor/supplier.

**Emergency telephone:** ChemTel Inc. International access: + (0)1-813-248-0585
ChemTel Inc. Free phone (North America only): 1-(800)-255-3924

## 2. Hazards identification

**Hazard description:**
Preparation not classified as dangerous according to Directive 1999/45/EC.
**Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
**Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:**
Not classified as hazardous.

## 3. Composition/information on ingredients

**Chemical characterisation**
**Description:**
Aqueous preparation
**Dangerous components:**
The preparation does not contain reportable quantities of hazardous components.

## 4. First-aid measures

**After inhalation:** Supply fresh air; consult doctor in case of complaints.
**After skin contact:**
Wash with soap and water and rinse thoroughly. Remove soiled clothing.
**After eye contact:**
Rinse opened eye for several minutes under running water. Consult a doctor in case of complaints.
**After ingestion:**
Wash out mouth with water. Consult a doctor in case of complaint.

**MATERIAL SAFETY DATA SHEET**
**Mono Test Device Kit**
According to REACH Regulation (EC) No. 1907/2006, Annex II

This documentation contains MSDS for the following kit components
Test Device
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Whole Blood Buffer

## 5. Fire-fighting measures

**Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire-extinguishing methods suitable to surrounding conditions.
**Special hazards caused by the substance, its products of combustion or resulting gases:**
In case of fire, the following can be released: Carbon oxides ($CO_x$), Nitrogen oxides ($NO_x$), Phosphorous oxides ($P_xO_y$)
**Protective equipment:**
Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

## 6. Accidental release measures

**Person-related safety precautions:**
Isolate spillage and clean up immediately.
Refer to Section 8 for protective measures when handling the spillage.
**Measures for environmental protection:**
Do not allow the undiluted product to enter sewers/surface or ground water.
**Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust)
Dispose of contaminated material as waste according to Section 13.
Rinse off area with water.

## 7. Handling and storage

**Information for safe handling:**
Observe the general safety regulations when handling chemicals.
Avoid contact with the eyes, skin and mucous membranes.
Keep out of reach of children.
**Storage:**
Store in the original container at 2 - 30°C
**Requirements to be met by storerooms and receptacles:**
No special requirements.

## 8. Exposure controls/personal protection

**Ingredients with limit values that require monitoring in the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.
**Additional information:**
The lists valid during the creation of this MSDS were used as a basis for this assessment.
**Personal protective equipment:**
**General protective and hygienic measures:**
Adhere to good laboratory practices (GLP).
Wash hands before breaks and at the end of work.
**Respiratory protection:**
Not required
**Protection of hands:**
Disposable gloves
**Material of gloves:**
Latex/natural rubber
**Penetration time of glove material:**
Gloves resistance is not critical when the product is handled according to the instructions for use.
**Eye protection:**
Not required
**Body protection:**
Lab coat

**MATERIAL SAFETY DATA SHEET**
**Mono Test Device Kit**
According to REACH Regulation (EC) No. 1907/2006, Annex II

This documentation contains MSDS for the following kit components
Test Device
Positive Control & Negative Control
Whole Blood Buffer

## 9. Physical and chemical properties

**General Information**
**Form:** Liquid
**Colour:** Colourless
**Odour:** Odourless
**Change in condition**
**Melting point/Melting range**: Similar to water, approximately 0°C.
**Boiling point/Boiling range:** Similar to water, approximately 100°C.
**Flash point:** Not applicable.
**Self-igniting:** Product is not self-igniting.
**Danger of explosion:** Product does not present an explosion hazard.
**Vapour pressure:** Similar to water, approximately 23 hPa.
**Density at 20°C:** 1.01 g/cm³
**Solubility in/Miscibility with:**
**Water:** Fully miscible.
**pH-value at 20°C:** 7.4

## 10. Stability and reactivity

**Stability:** The product is stable in accordance with the recommended storage conditions.
**Materials to be avoided:** concentrated acids, heavy metals, metallic salts
**Hazardous reactions:** Preparation contains sodium azide, which may react with lead to form explosive compounds. Contact with acids may liberate trace amounts of toxic (azide) gas. Hazardous polymerisation will not occur.
**Hazardous decomposition products:** No dangerous decomposition products known.

## 11. Toxicological information

**Acute toxicity:**
Quantitative data on the toxic effects of this product is not available.

**Primary effects:**
**After skin contact:** No irritating effects anticipated.
**After eye contact:** No irritating effects anticipated.
**After ingestion:** No significant harmful effects anticipated
**Sensitization:** No sensitizing effects known.

**Additional information:**
The preparation contains trace amounts of Kanamycin sulphate, a chemical that may cause harm to the unborn child.

## 12. Ecological information

**Ecotoxic Effects:**
Quantitative data on the toxic effects of this product are not available.
No ecological problems are to be expected when the product is handled and used with due care and attention.

**Persistence and Degradability:**
The product is biodegradable.

**Mobility and bioaccumulation potential:**
Does not accumulate in organisms

**MATERIAL SAFETY DATA SHEET**
**Mono Test Device Kit**
According to REACH Regulation (EC) No. 1907/2006, Annex II

This documentation contains MSDS for the following kit components
Test Device
Positive Control & Negative Control
Whole Blood Buffer

## 13. Disposal considerations

**Product:**
Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
To avoid the possible build-up of azide compounds, flush plumbing with water after the disposal of undiluted reagent.
**European waste catalogue:**
18 01 07 chemicals other than those mentioned in 18 01 06.
**Packaging:**
Disposal must be made in accordance with local waste management regulations.
Contaminated packaging must be disposed of in the same manner as the product.
Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

## 14. Transport information

**Land transport ADR/RID (cross-border)**
Not regulated for transport.

**US DOT Transport Regulations:**
Not regulated for transport.

**Maritime transport IMDG:**
Not regulated for transport.
**Marine pollutant:** No

**Air transport ICAO-TI and IATA-DGR:**
Not regulated for transport.

## 15. Regulatory information

**Labelling according to EU guidelines:**
No marking required.
**Water Hazard Class (Germany):** WGK -, not hazardous for water.
**US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:**
Not required.

**Chemical inventory listings relevant to US regulations:**
**Carcinogen listings**

| | |
|---|---|
| IARC: | None of the ingredients is listed. |
| NTP: | None of the ingredients is listed. |
| ACGIH: | None of the ingredients is listed. |
| OSHA: | None of the ingredients is listed. |
| EPA | None of the ingredients is listed. |

**Californian Proposition 65**

| | |
|---|---|
| Chemicals known to cause cancer: | None of the ingredients is listed. |
| Chemicals known to cause reproductive toxicity: | None of the ingredients is listed. |

**SARA**

| | |
|---|---|
| Section 355 (extremely hazardous substances): | None of the ingredients is listed. |
| Section 313 (specific toxic chemical listings): | None of the ingredients is listed. |

**MATERIAL SAFETY DATA SHEET**
**Mono Test Device Kit**
According to REACH Regulation (EC) No. 1907/2006, Annex II

This documentation contains MSDS for the following kit components
Test Device
Positive Control & Negative Control
Whole Blood Buffer

## 16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Laboratory: _____ Date Implemented: _____

Address: _____

_____

_____

## ProAdvantage® by NDC Infectious Mononucleosis Test Device (Whole Blood/Serum/Plasma) Laboratory Procedure

### I. Test Principle

The Infectious Mononucleosis Test Device (Whole Blood/Serum/Plasma) is a qualitative membrane strip based immunoassay for the detection of IM heterophile antibodies in whole blood, serum or plasma. In this test procedure, bovine erythrocyte extracted antigen is coated on the test line region of the device. The sample reacts with bovine erythrocyte extracted antigen coated particles that have been applied to the label pad. This mixture migrates chromatographically along the length of the test strip and interacts with the coated bovine erythrocyte extracted antigen. If the sample contains IM antibodies, a colored line will appear in the test line region indicating a positive result. If the sample does not contain IM heterophile antibodies, a colored line will not appear in this region, indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

### II. Specimen Collection/Treatment

A. Specimen: Whole Blood specimen from venipuncture or fingerstick, serum or plasma.

B. Specimen Collection:

**Venipuncture Whole Blood samples:** Collect anti-coagulated blood sample (sodium or potassium heparin, sodium or potassium EDTA, sodium or potassium citrate and sodium oxalate) following standard laboratory procedures.

**Fingerstick Whole Blood samples:**

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Touch the end of the capillary tube to the blood until filled to the line; avoid air bubbles.
- Place the bulb onto the top end of the capillary tube.
- Squeeze the bulb to dispense the whole blood.

**Separate serum or plasma from blood** as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed samples.

C. Specimen Storage: Do not leave the samples at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2°-8°C (36°-46°F) if the test is to be run within 2 days of collection. Whole blood collected by fingerstick should be tested immediately. Do not freeze whole blood samples. Serum or plasma samples may be stored at 2°-8°C (36°-46°F) for up to 3 days. For long-term storage, samples should be kept below -20°C (-4°F).

Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.

If samples are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

D. Handling Precautions: Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.

## III. Reagents and Equipment

### A. Reagents and Materials Provided

- 20 individually packaged test devices
- 20 disposable sample droppers
- 1 containers of disposable heparinized capillary tubes
- 1 dispensing bulbs
- 1 Mono sample buffer (5mL): containing 0.09% sodium azide
- 1 Mono negative control (1mL): Diluted human plasma, 0.09% sodium azide
- 1 Mono positive control (1mL): Diluted human plasma containing IM heterophile antibodies, 0.09% sodium azide
- 1 procedure card
- 1 directional inserts: 1 (CLIA waived on front and moderately complex on back)

### B. Materials Required but not Provided

- Sample collection container (for venipuncture whole blood)
- Lancet (for fingerstick whole blood only)
- Centrifuge (for serum or plasma only)
- Timer

### C. Storage and Stability

The kit can be stored at room temperature or refrigerated 2°-30°C (36°-86°F). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

### D. Quality Control

**Internal Quality Control**

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient sample volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

**External Quality Control**

It is recommended that external positive and negative controls be tested with each new kit, lot or shipment of product, with each change in operator with in the test kit, weekly as a check on continued storage conditions, and as otherwise required by your laboratory's internal quality system procedures.

External positive and negative controls are supplied in the kit. If controls do not perform as expected, assay results are invalid.

**Procedure for External Quality Control Testing**

Using the positive or negative external controls in place of a patient sample, add 1 drop of positive or negative control solution to a sample well (S) of a new test device, then add 1 drop of Sample Buffer. Start the timer. Continue with Step 3 in the Test Procedure section.

**Remedial Actions**

If unexpected results are seen when running the controls, review the Direction for Use, Interpretation of Results and Limitations sections and repeat the test with another device. If the result is still invalid, stop using the test kit and contact your distributor.

### E. Precautions

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimen samples and kits are handled.
- Handle all specimens and controls as if they contain infectious agents. Positive and negative controls contain human plasma. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimen samples.
- The positive and negative controls contain sodium azide as a preservative, which may form potentially explosive metal azide if it reacts with lead or copper plumbing. Large quantities of water should be used to flush discarded controls down a sink.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimen samples are assayed.
- Humidity and temperature can adversely affect results.
- Do not reuse the test.
- Discard the test device if package is torn, ripped or if device itself is damaged.
- Do not mix buffer and controls from different lots.

## IV. Test Procedure

**Allow the test device, sample, buffer and controls to reach room temperature 15° - 30°(59°- 86°F) before testing.**

1. Remove the test device from the foil pouch and use it as soon as possible. For best results, perform the test immediately after opening the foil pouch.
2. Place the test device on a clean and level surface.
   **For Whole Blood (Venipuncture) samples:**
   - Hold the dropper upright and add 2 drops of whole blood (about 50 μL) to the sample well (S) of the test device.
   - Add 1 drop of Sample Buffer to the sample well.
   - Start the timer.

   **For Whole Blood (Fingerstick) samples:**
   - Add one capillary tube of blood (about 50 μL) to the sample well (S) of the test device.
   - Add 1 drop of Sample Buffer to the sample well.
   - Start the timer.

   **For Serum or Plasma samples:**
   - Hold the dropper upright and add 1 drop of serum or plasma (about 25 μL) to the sample well (S) of the test device.
   - Add 1 drop of Sample Buffer to the sample well.
   - Start the timer.
   - Avoid trapping air bubbles in the sample well
3. Wait for the red line(s) to appear. The result should be read at 5 minutes. The background should be clear before the result is read.

NOTE: Low titers of IM heterophile antibodies might result in a weak line appearing in the test line region (T) after a long period of time. Do not read the result after 10 minutes.

## V. Interpretation of Test Results

**POSITIVE*:** Two distinct red lines appear. One line should be in the control line region (C) and another line should be in the test line region (T). A positive result indicates that IM heterophile antibodies were detected in the sample.
*** NOTE:** The shade of the red color in the test line region (T) will vary based on the amount of IM heterophile antibodies in the sample. Any shade of red in the test line region (T) should be considered positive.

**NEGATIVE:** One red line appears in the control line region (C). No apparent red or pink line appears in the test line region (T). A negative result means that IM heterophile antibodies were not found in the sample or are below the detection limit of the test.

**INVALID:** No line appears in the control line region (C). If this occurs, read the directions again and repeat the test with a new test device. If the result is still invalid, stop using the test kit and contact your distributor.

## VI. Limitations

1. The Infectious Mononucleosis Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of IM heterophile antibodies in whole blood, serum and plasma samples only. Neither the quantitative value nor the rate of increase in Mononucleosis antibody concentration can be determined by this qualitative test.
2. The Infectious Mononucleosis Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of IM heterophile antibodies in the sample and should not be used as the sole criteria for the diagnosis of Mononucleosis infection.
3. Grossly hemolyzed samples will yield invalid results. Strictly follow the Directional Insert instructions to obtain accurate results.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. This assay has not been established for patients under 18 years of age.

## VII. Expected Values

Epstein-Barr virus infection during adolescence or young adulthood causes infectious mononucleosis 35% to 50% of the time.[1,5]

The incidence of EBV-associated infectious mononucleosis in the USA has been estimated at 45 per 100,000 and is highest in adolescent and young adults- about 2 out of 1,000. No seasonal pattern of EBV infection exists. The incubation period is 10 to 60 days, though 7 to 14 days is common for children and adolescents.

## VIII. Performance Characteristics

A total of 611 clinical samples were tested by three independent sites in a clinical study. Slide agglutination served as the reference method for the study. Serum, plasma and whole blood were also collected for the detection of IM heterophile antibodies by the Infectious Mononucleosis Test Device.

Of the 611 clinical samples collected, 185 were considered positive and 426 clinical specimens were considered negative by slide agglutination method. The results for each sample matrix are summarized below.

| SERUM | Slide agglutination | | |
|---|---|---|---|
| | | + | – |
| Infectious Mononucleosis Test Device | + | 72 | 0 |
| | – | 0 | 168 |

Positive Agreement = 72/72 > 99% (95%-100%)**
Negative Agreement = 168/168 > 99% (98%-100%)**
Overall Agreement = 240/240 > 99% (98%-100%)**

| PLASMA | Slide agglutination | | |
|---|---|---|---|
| | | + | – |
| Infectious Mononucleosis Test Device | + | 58 | 1 |
| | – | 0 | 181 |

Positive Agreement = 58/58 > 99% (94%-100%)**
Negative Agreement = 181/182 > 99% (97%-99%)*
Overall Agreement = 239/240 > 99% (98%-99%)*

| WHOLE BLOOD | Slide agglutination | | |
|---|---|---|---|
| | | + | – |
| Infectious Mononucleosis Test Device | + | 50 | 0 |
| | – | 5 | 76 |

Positive Agreement = 50/55 = 91% (80%-97%)*
Negative Agreement = 76/76 > 99% (95%-100%)**
Overall Agreement = 126/131 = 96% (91%-99%)*

| ALL SPECIMENS | Slide agglutination | | |
|---|---|---|---|
| | | + | – |
| Infectious Mononucleosis Test Device | + | 180 | 1 |
| | – | 5 | 425 |

Positive Agreement = 180/185 = 97% (94%-99%)*
Negative Agreement = 425/426 > 99% (98%-99.99%)*
Overall Agreement = 605/611 = 99% (98%-99%)*

* Denotes 95% Confidence Interval
** Denotes 97.5% Confidence Interval

In addition, the clinical samples were tested with a commercially available rapid diagnostic test kit. 611 serum, plasma and whole blood specimens were used to compare the Infectious Mononucleosis Test Device (Whole Blood/Serum/Plasma) to a comparator test. The results showed a >99% agreement between the two test kits. The results for each sample matrix are summarized below.

| SERUM | Comparator test | | |
|---|---|---|---|
| | | + | – |
| Infectious Mononucleosis Test Device | + | 72 | 0 |
| | – | 1 | 167 |

Positive Agreement= 72/73 > 99% (93%-99%)*
Negative Agreement= 167/167 > 99% (98%-100%)**
Overall Agreement= 239/240 > 99% (98%-99%)**

| PLASMA | Comparator test | | |
|---|---|---|---|
| | | + | – |
| Infectious Mononucleosis Test Device | + | 59 | 0 |
| | – | 1 | 180 |

Positive Agreement= 59/60 = 98% (91%-99%)*
Negative Agreement= 180/180 > 99% (98%-100%)**
Overall Agreement= 239/240 > 99% (98%-99%)*

| WHOLE BLOOD | Comparator test | | |
|---|---|---|---|
| | | + | – |
| Infectious Mononucleosis Test Device | + | 50 | 0 |
| | – | 1 | 80 |

Positive Agreement= 50/51 = 98% (90%-99%)*
Negative Agreement= 80/80 > 99% (96%-100%)**
Overall Agreement= 130/131 > 99% (96%-99%)*

| ALL SPECIMENS | | Comparator test | | |
|---|---|---|---|---|
| | | + | – | |
| Infectious Mononucleosis Test Device | + | 181 | 0 | Positive Agreement= 181/184 = 98% (95%-99%)*<br>Negative Agreement= 427/427 > 99% (99%-100%)**<br>Overall Agreement= 608/611 > 99% (99%-99.9%)* |
| | – | 3 | 427 | |

* Denotes 95% Confidence Interval
** Denotes 97.5% Confidence Interval

**Interfering Substances**

No interference with theInfectious Mononucleosis Test Device (Whole Blood/Serum/Plasma) results was observed in samples containing high levels of hemoglobin (up to 1,000 µg/dL), bilirubin (up to 1,000 mg/dL) and human serum albumin (up to 2,000 mg/dL). The test results were also unaffected when the hematocrit was altered ranging from 20% to 60% and when icteric and lipemic samples were tested.

**POL Studies**

Three physicians' offices were used to conduct an evaluation of the Infectious Mononucleosis Test Device (Whole Blood/Serum/Plasma). Personnel with various educational backgrounds performed the testing. Each physician's office tested a randomly coded panel of samples consisting of negative (15), low positive (15), moderate positive (15) and invalid (15) for three days. The results obtained had a >99% correlation with the expected results.

**Non-Laboratory User Study**

A total of 77 untrained, inexperienced, non-laboratory participants were enrolled at three separate locations to demonstrate that they could follow the product instructions and perform the Infectious Mononucleosis Test Device (Whole Blood/Serum/Plasma) and obtain results similar to those obtained by trained laboratory technicians. Each participant received four blinded spiked whole blood samples: one negative, one invalid, one low positive and one medium positive.

Study participants were instructed to follow the Instructional Insert and Procedure Card instructions to test the provided samples and record their test results. No other instruction or training was given. Upon completion of the test, participants filled out a brief questionnaire regarding the test procedure and ease of use of the labeling. The following results were obtained:

| Site | Low Positive | Medium Positive | Negative | Invalid | Total Correct |
|---|---|---|---|---|---|
| A | 23/27=85% (66-96%)* | 25/27=93% (76-99%)* | 27/27>99% (87-100%)* | 27/27>99% (87-100%)* | 102/108=94% (88-98%)* |
| B | 25/27=93% (76-99%)* | 25/27=93% (76-99%)* | 27/27>99% (87-100%)* | 27/27>99% (87-100%)* | 104/108=96% (91-99%)* |
| C | 23/23>99% (85-100%)* | 23/23>99% (85-100%)* | 23/23>99% (85-100%)* | 23/23>99% (85-100%)* | 92/ 92>99% (96-100%)* |

*Denotes 95% Confidence Interval

## IX. References


1. *Pediatr Clin North Am.* 1997 Dec; 44(6):1541-56
2. Omori, M. *2002 Mononucleosis.* http://www.emedicine.com/EMERG/topic319.htm
3. Linde, A. 1996, *Scand J Infect Dis Suppl*. 100:83-8
4. Papesch, M. & Watkins, R. *2001 Clin. Otolaryngol*. 26, 3-8
5. *CDC National Center for infectious Diseases: EBV & IM:* www.cdc.gov/ncidod/diseases/ebv.htm
6. ProAdvantage® by NDC Infectious Mononucleosis Test Device Package Insert

## Test Procedure Review

| Supervisor | Date Reviewed | Supervisor | Date Reviewed |
|---|---|---|---|
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Laboratory: _____ Date Implemented: _____

Address: _____

_____

_____

## ProAdvantage® by NDC Infectious Mononucleosis Test Device (Whole Blood) Laboratory Procedure

### I. Test Principle

The Infectious Mononucleosis Test Device (Whole Blood) is a qualitative membrane strip based immunoassay for the detection of IM heterophile antibodies in whole blood, serum or plasma. In this test procedure, bovine erythrocyte extracted antigen is coated on the test line region of the device. The sample reacts with bovine erythrocyte extracted antigen coated particles that have been applied to the label pad. This mixture migrates chromatographically along the length of the test strip and interacts with the coated bovine erythrocyte extracted antigen. If the sample contains IM antibodies, a colored line will appear in the test line region indicating a positive result. If the sample does not contain IM heterophile antibodies, a colored line will not appear in this region, indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

### II. Specimen Collection/Treatment

A. Specimen: Whole Blood specimen from venipuncture or fingerstick.

B. Specimen Collection: **Venipuncture Whole Blood samples:** Collect anti-coagulated blood sample (sodium or potassium heparin, sodium or potassium EDTA, sodium or potassium citrate and sodium oxalate) following standard laboratory procedures.

**Fingerstick Whole Blood samples:**

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Touch the end of the capillary tube to the blood until filled to the line; avoid air bubbles.
- Place the bulb onto the top end of the capillary tube.
- Squeeze the bulb to dispense the whole blood.

C. Specimen Storage: Do not leave the samples at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2°-8°C (36°-46°F) if the test is to be run within 2 days of collection. Whole blood collected by fingerstick should be tested immediately. Do not freeze whole blood samples. Bring samples to room temperature prior to testing.

If samples are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

D. Handling Precautions: Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.

## III. Reagents and Equipment

### A. Reagents and Materials Provided

- 20 individually packaged test devices
- 20 disposable sample droppers
- 1 containers of disposable heparinized capillary tubes
- 1 dispensing bulbs
- 1 Mono sample buffer (5mL): containing 0.09% sodium azide
- 1 Mono negative control (1mL): Diluted human plasma, 0.09% sodium azide
- 1 Mono positive control (1mL): Diluted human plasma containing IM heterophile antibodies, 0.09% sodium azide
- 1 procedure card
- 1 directional inserts: 1 (CLIA waived on front and moderately complex on back)

### B. Materials Required but not Provided

- Sample collection container (for venipuncture whole blood)
- Lancet (for fingerstick whole blood only)
- Timer

### C. Storage and Stability

The kit can be stored at room temperature or refrigerated 2°-30°C (36°-86°F). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

### D. Quality Control

**Internal Quality Control**

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient sample volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

**External Quality Control**

It is recommended that external positive and negative controls be tested with each new kit, lot or shipment of product, with each change in operator with in the test kit, weekly as a check on continued storage conditions, and as otherwise required by your laboratory's internal quality system procedures. External positive and negative controls are supplied in the kit. If controls do not perform as expected, assay results are invalid.

**Procedure for External Quality Control Testing**

Using the positive or negative external controls in place of a patient sample, add 1 drop of positive or negative control solution to a sample well (S) of a new test device, then add 1 drop of Sample Buffer. Start the timer. Continue with Step 3 in the Test Procedure section.

**Remedial Actions**

If unexpected results are seen when running the controls, review the Direction for Use, Interpretation of Results and Limitations sections and repeat the test with another device. If the result is still invalid, stop using the test kit and contact your distributor.

### E. Precautions

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimen samples and kits are handled.
- Handle all specimens and controls as if they contain infectious agents. Positive and negative controls contain human plasma. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimen samples.

- The positive and negative controls contain sodium azide as a preservative, which may form potentially explosive metal azide if it reacts with lead or copper plumbing. Large quantities of water should be used to flush discarded controls down a sink.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimen samples are assayed.
- Humidity and temperature can adversely affect results.
- Do not reuse the test.
- Discard the test device if package is torn, ripped or if device itself is damaged.
- Do not mix buffer and controls from different lots.

## IV. Test Procedure

**Allow the test device, sample, buffer and controls to reach room temperature 15° - 30°(59°- 86°F) before testing.**

1. Remove the test device from the foil pouch and use it as soon as possible. For best results, perform the test immediately after opening the foil pouch.
2. Place the test device on a clean and level surface.
   **For Whole Blood (Venipuncture) samples:**
   - Hold the dropper upright and add 2 drops of whole blood (about 50 μL) to the sample well (S) of the test device.
   - Add 1 drop of Sample Buffer to the sample well.
   - Start the timer.

   **For Whole Blood (Fingerstick) samples**:
   - Add one capillary tube of blood (about 50 μL) to the sample well (S) of the test device.
   - Add 1 drop of Sample Buffer to the sample well.
   - Start the timer.
3. Wait for the red line(s) to appear. The result should be read at 5 minutes. The background should be clear before the result is read.

NOTE: Low titers of IM heterophile antibodies might result in a weak line appearing in the test line region (T) after a long period of time. Do not read the result after 10 minutes.

## V. Interpretation of Test Results

**POSITIVE*:** Two distinct red lines appear. One line should be in the control line region (C) and another line should be in the test line region (T). A positive result indicates that IM heterophile antibodies were detected in the sample.
*** NOTE:** The shade of the red color in the test line region (T) will vary based on the amount of IM heterophile antibodies in the sample. Any shade of red in the test line region (T) should be considered positive.

**NEGATIVE:** One red line appears in the control line region (C). No apparent red or pink line appears in the test line region (T). A negative result means that IM heterophile antibodies were not found in the sample or are below the detection limit of the test.

**INVALID:** No line appears in the control line region (C). If this occurs, read the directions again and repeat the test with a new test device. If the result is still invalid, stop using the test kit and contact your distributor.

## VI. Limitations

1. The Infectious Mononucleosis Test Device (Whole Blood) is for *in vitro* diagnostic use only. The test should be used for the detection of IM heterophile antibodies in whole blood, serum and plasma samples only. Neither the quantitative value nor the rate of increase in Mononucleosis antibody concentration can be determined by this qualitative test.
2. The Infectious Mononucleosis Test Device (Whole Blood) will only indicate the presence of IM heterophile antibodies in the sample and should not be used as the sole criteria for the diagnosis of Mononucleosis infection.

3. Grossly hemolyzed samples will yield invalid results. Strictly follow the Directional Insert instructions to obtain accurate results.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. This assay has not been established for patients under 18 years of age.

## VII. Expected Values

Epstein-Barr virus infection during adolescence or young adulthood causes infectious mononucleosis 35% to 50% of the time.[1,5]

The incidence of EBV-associated infectious mononucleosis in the USA has been estimated at 45 per 100,000 and is highest in adolescent and young adults- about 2 out of 1,000. No seasonal pattern of EBV infection exists. The incubation period is 10 to 60 days, though 7 to 14 days is common for children and adolescents.

## VIII. Performance Characteristics

A total of 611 clinical samples were tested by three independent sites in a clinical study. Slide agglutination served as the reference method for the study. Serum, plasma and whole blood were also collected for the detection of IM heterophile antibodies by the Infectious Mononucleosis Test Device.

Of the 611 clinical samples collected, 185 were considered positive and 426 clinical specimens were considered negative by slide agglutination method. The results for each sample matrix are summarized below.

| **SERUM** | **Slide agglutination** | | | |
|---|---|---|---|---|
| | | + | – | Positive Agreement = 72/72 > 99% (95%-100%)**<br>Negative Agreement = 168/168 > 99% (98%-100%)**<br>Overall Agreement = 240/240 > 99% (98%-100%)** |
| **Infectious Mononucleosis Test Device** | + | 72 | 0 | |
| | – | 0 | 168 | |

| **PLASMA** | **Slide agglutination** | | | |
|---|---|---|---|---|
| | | + | – | Positive Agreement = 58/58 > 99% (94%-100%)**<br>Negative Agreement = 181/182 > 99% (97%-99%)*<br>Overall Agreement = 239/240 > 99% (98%-99%)* |
| **Infectious Mononucleosis Test Device** | + | 58 | 1 | |
| | – | 0 | 181 | |

| **WHOLE BLOOD** | **Slide agglutination** | | | |
|---|---|---|---|---|
| | | + | – | Positive Agreement = 50/55 = 91% (80%-97%)*<br>Negative Agreement = 76/76 > 99% (95%-100%)**<br>Overall Agreement = 126/131 = 96% (91%-99%)* |
| **Infectious Mononucleosis Test Device** | + | 50 | 0 | |
| | – | 5 | 76 | |

| **ALL SPECIMENS** | **Slide agglutination** | | | |
|---|---|---|---|---|
| | | + | – | Positive Agreement = 180/185 = 97% (94%-99%)*<br>Negative Agreement = 425/426 > 99% (98%-99.99%)*<br>Overall Agreement = 605/611 = 99% (98%-99%)* |
| **Infectious Mononucleosis Test Device** | + | 180 | 1 | |
| | – | 5 | 425 | |

* Denotes 95% Confidence Interval
** Denotes 97.5% Confidence Interval

In addition, the clinical samples were tested with a commercially available rapid diagnostic test kit. 611 serum, plasma and whole blood specimens were used to compare the Infectious Mononucleosis Test Device (Whole Blood) to a comparator test. The results showed a >99% agreement between the two test kits. The results for each sample matrix are summarized below.

| **SERUM** | **Comparator test** | | | |
|---|---|---|---|---|
| | | + | – | Positive Agreement= 72/73 > 99% (93%-99%)*<br>Negative Agreement= 167/167 > 99% (98%-100%)**<br>Overall Agreement= 239/240 > 99% (98%-99%)** |
| **Infectious Mononucleosis Test Device** | + | 72 | 0 | |
| | – | 1 | 167 | |

| **PLASMA** | **Comparator test** | | | |
|---|---|---|---|---|
| | | + | – | Positive Agreement= 59/60 = 98% (91%-99%)*<br>Negative Agreement= 180/180 > 99% (98%-100%)**<br>Overall Agreement= 239/240 > 99% (98%-99%)* |
| **Infectious Mononucleosis Test Device** | + | 59 | 0 | |
| | – | 1 | 180 | |

| **WHOLE BLOOD** | **Comparator test** | | | |
|---|---|---|---|---|
| | | + | – | Positive Agreement= 50/51 = 98% (90%-99%)*<br>Negative Agreement= 80/80 > 99% (96%-100%)**<br>Overall Agreement= 130/131 > 99% (96%-99%)* |
| **Infectious Mononucleosis Test Device** | + | 50 | 0 | |
| | – | 1 | 80 | |

| **ALL SPECIMENS** | **Comparator test** | | | |
|---|---|---|---|---|
| | | + | – | Positive Agreement= 181/184 = 98% (95%-99%)*<br>Negative Agreement= 427/427 > 99% (99%-100%)**<br>Overall Agreement= 608/611 > 99% (99%-99.9%)* |
| **Infectious Mononucleosis Test Device** | + | 181 | 0 | |
| | – | 3 | 427 | |

* Denotes 95% Confidence Interval
** Denotes 97.5% Confidence Interval

**Interfering Substances**

No interference with the Infectious Mononucleosis Test Device (Whole Blood) results was observed in samples containing high levels of hemoglobin (up to 1,000 µg/dL), bilirubin (up to 1,000 mg/dL) and human serum albumin (up to 2,000 mg/dL). The test results were also unaffected when the hematocrit was altered ranging from 20% to 60% and when icteric and lipemic samples were tested.

**POL Studies**

Three physicians' offices were used to conduct an evaluation of the Infectious Mononucleosis Test Device. Personnel with various educational backgrounds performed the testing. Each physician's office tested a randomly coded panel of samples consisting of negative (15), low positive (15), moderate positive (15) and invalid (15) for three days. The results obtained had a >99% correlation with the expected results.

**Non-Laboratory User Study**

A total of 77 untrained, inexperienced, non-laboratory participants were enrolled at three separate locations to demonstrate that they could follow the product instructions and perform the Infectious Mononucleosis Test Device (Whole Blood) and obtain results similar to those obtained by trained laboratory technicians. Each participant received four blinded spiked whole blood samples: one negative, one invalid, one low positive and one medium positive.

Study participants were instructed to follow the Instructional Insert and Procedure Card instructions to test the provided samples and record their test results. No other instruction or training was given. Upon completion of the test, participants filled out a brief questionnaire regarding the test procedure and ease of use of the labeling. The following results were obtained:

| Site | Low Positive | Medium Positive | Negative | Invalid | Total Correct |
|---|---|---|---|---|---|
| A | 23/27=85% (66-96%)* | 25/27=93% (76-99%)* | 27/27>99% (87-100%)* | 27/27>99% (87-100%)* | 102/108=94% (88-98%)* |
| B | 25/27=93% (76-99%)* | 25/27=93% (76-99%)* | 27/27>99% (87-100%)* | 27/27>99% (87-100%)* | 104/108=96% (91-99%)* |
| C | 23/23>99% (85-100%)* | 23/23>99% (85-100%)* | 23/23>99% (85-100%)* | 23/23>99% (85-100%)* | 92/ 92>99% (96-100%)* |

*Denotes 95% Confidence Interval

## IX. References


1. *Pediatr Clin North Am.* 1997 Dec; 44(6):1541-56
2. Omori, M. *2002 Mononucleosis.* http://www.emedicine.com/EMERG/topic319.htm
3. Linde, A. 1996, *Scand J Infect Dis Suppl*. 100:83-8
4. Papesch, M. & Watkins, R. *2001 Clin. Otolaryngol*. 26, 3-8
5. *CDC National Center for infectious Dis*eases: EBV & IM: www.cdc.gov/ncidod/diseases/ebv.htm
6. ProAdvantage® by NDC Infectious Mononucleosis Test Device Package Insert

## Test Procedure Review

| Supervisor | Date Reviewed | Supervisor | Date Reviewed |
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