WHO Prequalification of Diagnostics Programme
PUBLIC REPORT

Product: Alere Determine™ HIV-1/2
Number: PQDx 0033-013-00

Abstract

Alere Determine™ HIV-1/2 with product codes 7D2342, 7D2343 and 7D2343SET manufactured by Alere Medical Co. Ltd., 357 Matsuhidai Matsudo-shi, Chiba-ken 270-2214, Japan, rest of the world regulatory version (non CE-marked regulatory version) was accepted for the WHO list of prequalified diagnostics and was listed on 25 November 2011. This public report was amended on 16 June 2016, and then on 12 July 2016.

Intended use:
Alere Determine® HIV-1/2 is an in vitro, visually read, qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2 in human serum, plasma or whole blood. The test is intended as an aid to detect antibodies to HIV-1/HIV-2 from infected individuals.

Assay principle:
Alere Determine HIV-1/2 is an immunochromatographic test for the qualitative detection of antibodies to HIV-1 and HIV-2. Sample is added to the sample pad. As the sample migrates through the conjugate pad, it reconstitutes and mixes with the selenium colloid-antigen conjugate. This mixture continues to migrate through the solid phase to the immobilized recombinant antigens and synthetic peptides at the patient window site.

If antibodies to HIV-1 and/or HIV-2 are present in the sample, the antibodies bind to the antigen-selenium colloid and to the antigen at the patient window, forming a red line at the patient window site. If antibodies to HIV-1 and/or HIV-2 are absent, the antigen-selenium colloid flows past the patient window, and no red line is formed at the patient window site. To ensure assay validity, a procedural control bar is incorporated in the assay device.

A negative result with Determine HIV-1/2 does not exclude the possibility of infection with HIV. A false negative result can occur in the following circumstances:
- low levels of antibody (e.g., early seroconversion specimens) are below the detection limit of the test
- infection with a variant of the virus that is less detectable by the Determine HIV-1/2 assay configuration
- HIV antibodies in the patient that do not react with specific antigens utilized in the assay configuration
- specimen handling conditions which result in loss of HIV antibody multivalency
• For these reasons care should be taken in interpreting negative results. Other clinical data (e.g., symptoms or risk factors) should be used in conjunction with the test results.

Positive specimens should be retested using another method and the results should be evaluated in light of the overall clinical evaluation before a diagnosis is made.

Test kit contents:

<table>
<thead>
<tr>
<th>Component</th>
<th>20 tests (7D2342)</th>
<th>100 tests (7D2343)</th>
<th>100 tests (7D2343SET)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test cards</td>
<td>2 10-test cards</td>
<td>10 10-test cards</td>
<td>10 10-test cards</td>
</tr>
<tr>
<td>Chase buffer</td>
<td>N/A</td>
<td>N/A</td>
<td>1 bottle/2.5ml</td>
</tr>
<tr>
<td>EDTA capillary tubes</td>
<td>N/A</td>
<td>N/A</td>
<td>100</td>
</tr>
<tr>
<td>Blood lancets</td>
<td>N/A</td>
<td>N/A</td>
<td>100</td>
</tr>
</tbody>
</table>

Items required but not provided within test kit:

<table>
<thead>
<tr>
<th>Consumables</th>
<th>Product codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chase buffer (1 bottle/2.5ml)</td>
<td>7D2243</td>
</tr>
<tr>
<td>EDTA capillary tubes (100 units)</td>
<td>7D2222</td>
</tr>
<tr>
<td>Blood lancets (100 units)</td>
<td>7D2233</td>
</tr>
</tbody>
</table>

Storage:
The test kit should be stored at 2-30 °C.

Shelf-life upon manufacture:
18 months.

Summary of prequalification status for Alere Determine™ HIV-1/2

<table>
<thead>
<tr>
<th>Initial acceptance</th>
<th>Date</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>PQ amended</td>
<td>16 June 2016, 12 July 2016</td>
<td>listed</td>
</tr>
<tr>
<td>Status on PQ list</td>
<td>25 November 2011</td>
<td>listed</td>
</tr>
<tr>
<td>Dossier assessment</td>
<td>22 November 2011</td>
<td>MR</td>
</tr>
<tr>
<td>Inspection status</td>
<td>24 October 2011</td>
<td>MR</td>
</tr>
<tr>
<td>Laboratory evaluation</td>
<td>11 November 2011</td>
<td>MR</td>
</tr>
</tbody>
</table>

MR: Meets Requirements
NA: Not Applicable
Prioritization for prequalification
Based on the established criteria, Alere Determine™ HIV-1/2 was given priority for WHO prequalification.

Product dossier assessment
Alere Medical Co. Ltd. submitted a product dossier for Alere Determine™ HIV-1/2 as per the “Instructions for compilation of a product dossier” (PQDx_018 v1). The information submitted in the product dossier was reviewed by WHO staff and external experts (assessors) appointed by WHO.

Commitments for prequalification:
1. analytical performance studies
2. clinical performance studies
3. stability studies
4. a new version of the instructions for use.

WHO will follow-up on implementation of these commitments at the next re-inspection.

Based on the product dossier screening and assessment findings, the product dossier for Alere Determine™ HIV-1/2 meets WHO prequalification requirements.

Manufacturing site inspection
A comprehensive inspection was performed at the site of manufacture of Alere Determine™ HIV-1/2 manufactured by Alere Medical Co. Ltd., at 357 Matsuhidai Matsudo-shi, Chiba-ken 270-2214, Japan on 11 to 15 May 2015. The inspection procedure is described in “Information for manufacturers on WHO prequalification inspection procedures for the sites of manufacture of diagnostics” (PQDx_014 v1).

The inspection found that Alere Medical Co. Ltd. had an established quality management system and manufacturing practices in place that should ensure the manufacture of a product of consistent quality. The manufacturer’s responses to the nonconformities found at the time of the inspection were accepted on 13 April 2016.

Commitments for prequalification:
1. Alere Medical Co. Ltd. will continue to review Risk Analysis and Risk Management for accuracy of assessment of risk, attributed to specific components of the product, and the mitigation of such risk, and to ensure ongoing due consideration of end users in resource limited and environmentally challenging regions to which the product is distributed.
2. Alere Medical Co. Ltd. will inform the WHO of changes made subsequent to the site inspection, such as change in location of site of manufacture of major components.

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1 Previous inspection took place on 28 September to 1 October 2010
of the test, or other changes to the manufacturing process that may affect the quality of the product.

Based on the site inspection and corrective action plan review, the quality management system for Alere Determine™ HIV-1/2 meets WHO prequalification requirements.

Laboratory evaluation

Alere Determine™ HIV-1/2 was evaluated by WHO in the third quarter of 2011 at the Institute of Tropical Medicine, Belgium – a WHO Collaborating Centre for HIV/AIDS Diagnostics and Laboratory Support. The laboratory evaluation was conducted according to the “WHO Protocol for the laboratory evaluation of HIV serology assays” (PQDx_030 V1.0), and drew the following conclusions:

Alere Determine™ HIV-1/2 is an immunochromatographic rapid diagnostic test for the detection of antibodies to HIV-1/2 in human serum, plasma, and whole blood. A volume of 50µl of serum, plasma or venous/capillary whole blood is required to perform the test procedure. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities. Reading of the results are performed visually i.e. subjective reading.

In this limited performance evaluation using a panel of 1079 biological specimens, we observed an initial (sensitivity (95% CI) of 100% (99.1% - 100%) and an initial specificity (95% CI) of 97.87% (96.4% - 98.8%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.1% - 100%) and the final specificity (95% CI) was 98.93% (97.8% - 99.6%) compared to the reference assays. In this study, 0.3% of the overall results were recorded as indeterminate. Results were interpreted independently by three technicians; the inter-reader variability was 1.4%. The invalid rate was 0.3% for initial testing and 0.1% for repeat testing.

Change notification

In 2015, Alere Medical Co. Ltd., notified WHO of a change related to addition of a product code for a configuration that included all accessories and reagents required to conduct the test procedure. This notification of change was assessed and product was found to meet WHO prequalification requirements.

In 2016, Alere Medical Co. Ltd., notified WHO of a change related to shelf life. This notification of change was assessed and product was found to meet WHO prequalification requirements.
Labelling

1. Labels
2. Instructions for use
1. Labels

**Alere Determine™ HIV-1/2**

**EN**
For In Vitro Diagnostic Use.
Alere Determine™ HIV-1/2 is a visual read, qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2.
7D2243 Chase buffer is required for whole blood testing.

**Kit contains:**
* 2 HIV-1/2 recombinant antigen and synthetic peptide coated test cards.

**ES**
Para uso en diagnóstico in vitro.
Alere Determine™ HIV-1/2 es un inmunoanálisis cualitativo de lectura visual para la detección de anticuerpos anti-VIH-1/2.
7D2243 Se requiere buffer de detección para todas las pruebas por sangre.

**FR**
Pour diagnostic in vitro.
Alere Determine™ HIV-1/2 est un dosage immunologique qualitatif, à lecture visuelle, pour la détection des anticorps dirigés contre la VIH-1 et la VIH-2.
La solution tampon de migration 7D2243 est nécessaire pour tester les échantillons de sang total.

**PT**
Para utilização no diagnóstico in Vitro.
Alere Determine™ HIV-1/2 é um imunoensaio qualitativo de leitura visual para a deteção de anticorpos contra o HIV-1 e o HIV-2.
7D2243 É necessário o tampão de detecção para realizar análises em sangue total.

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**Alere Determine™ HIV-1/2**

**EN**
For In Vitro Diagnostic Use.
Alere Determine™ HIV-1/2 is a visual read, qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2.
7D2243 Chase buffer is required for whole blood testing.

**Kit contains:**
* 10 HIV-1/2 recombinant antigen and synthetic peptide coated test cards.

**ES**
Para uso en diagnóstico in vitro.
Alere Determine™ HIV-1/2 es un inmunoanálisis cualitativo de lectura visual para la detección de anticuerpos anti-VIH-1/2.
7D2243 Se requiere buffer de detección para todas las pruebas por sangre.

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7D2243 É necessário o tampão de detecção para realizar análises em sangue total.
EDTA Capillary Tubes

EN EDTA Capillary Tubes are to be used in the fingerstick collection of whole blood specimens for use in Determine™ format products. Refer to the assay-specific package insert for full procedure. Bring to room temperature before opening the cap.

ES Los tubos de capilares con EDTA se utilizan en la obtención mediante punción dactilar de muestras de sangre total para productos de formato Determine™. Consulte el folleto de instrucciones específico del ensayo para obtener información acerca de todo el procedimiento. Deben estar a temperatura ambiente antes de abrir la tapa.

FR Les tubes capillaires EDTA sont utilisés pour recueillir des échantillons de sang total par piqûre du doigt pour les produits au format Determine™. Se reporter à la notice d’emballage spécifique au test pour la procédure complète. Amenez à température ambiante avant d’ouvrir le bouchon.

PT Os tubos capilares EDTA devem ser utilizados na coleta por picada no dedo de amostras de sangue total para utilização nos produtos do formato Determine™. Consulte o folheto informativo específico do ensaio quanto ao procedimento completo. Coloque à temperatura ambiente antes de abrir a tampa.

CAUTION: Glass capillaries may be damaged during transportation or when in use. Handle with care in order to avoid injury when removing from the packaging as well as during use and during disposal. Store in a cool, dry location. Do not refrigerate.

Advice Line Telephone number
Europe & Middle East: + (44) 161 483 9032
Asia Pacific: + (61) 7 3363 7711
Africa, Russia & CIS: + (972) 8 9429 683
Latin America: + (57) 2 6618 797

Store at 2-30°C
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241203/R6

Produced by:
Drummond Scientific Co.
Broomall, PA USA 19008
For: Alere Medical Co., Ltd.

Exp. Lot
2. Instructions for use
EN

Key to syningthediseases:

- Catey Category number
- Contaon suflce to dislodge
- Keyply to syning

This package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Incorrect or improper results cannot be guaranteed if there are deviations from the instructions in this package insert.

NAME AND PRODUCT USE

The Alere Determine™ HIV-1/2 is an in vitro, visually read, qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2 in human serum, plasma or whole blood. The test is intended as an aid to detect antibodies to HIV-1/2 in persons with indeterminate results.

SUMMARY AND EXPLANATION OF THE TEST

AIDS (Acquired Immunodeficiency Syndrome) is characterized by changes in the population of T cell (lymphocytes). In an infected individual, the virus causes depletion of helper T cells, which leaves the immune system susceptible to opportunistic infections and some malignancies. The virus that causes AIDS exists in two related types known as HIV-1 and HIV-2.

The presence of the AIDS virus elicits the production of specific antibodies to either HIV-1 or HIV-2.

BIOLICAL PRINCIPLES OF THE PROCEDURE

Alere Determine™ HIV-1/2 is an immunochromatographic test for the qualitative detection of antibodies to HIV-1 and HIV-2.

Samples are added to the sample pool. As the sample migrates through the conjugate pad, it collects antibodies and antigens from the sample on a filter paper. The antigen-antibody immune complex that forms during the migration through the test strip is detected using a visual readout system. If antibodies to HIV-1 and/or HIV-2 are present in the sample, the antigen-antibody complex binds to the antigen-antibody on the test strip and changes the color of the test strip. If antibodies to HIV-1 and/or HIV-2 are absent, the antigen-antibody complex does not change the color of the test strip.

CONTENTS

Alere Determine™ HIV-1/2 Natural Format Assay: 10 Tests (001304) or 100 Tests (001311)

- Alere Determine™ HIV-1/2 Test Card: 2 cards or 10 cards (10 tests/card), HIV-1 reactive antibody and synthetic peptide coated.

ACCESSORIES (required but not provided)

- One package White Blood cells
- One bottle 0.9% ehae Ce (500mL) prepared in phosho buffer: Preservative: Antiseptic Agents.

White Blood Cell (Minimum) required

- EDTA Caviity Tube (10mL)

Materials Required But Not Provided

Disposable gloves, firming device.
Monopropnestus capable of delivering 200 uL (other than Becton Dickinson).
Alcohols and, guitar pad, Leucor (for phlebotomists).

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use.

CAUTIONS

Appropriate laboratory practice should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

- Wear gloves.
- Do not ingest by mouth.
- Do not eat, drink, smoke, apply cosmetic, or handle contact lenses in areas where these materials are prohibited.
- Clean and decontaminate all tools of specimens and reagents using a suitable disinfectant, such as 0.5% chlorhexidine.
- Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local regulations.

LIMITATIONS

The Alere Determine™ HIV-1/2 Test Card and Chaste Buffer must be stored at 2-8°C until expiration date. Kit components are stable until expiration date when handled and stored as directed. Do not use kit components beyond expiration date. Immediately discard all unused tests in the foil pouch containing the desiccant by pressing seal from end to end as close.

SPECIAL COLLECTION

Serum, Plasma, and Whole Blood Collection by Venipuncture.

Human serum, plasma, and whole blood collected by venipuncture should be collected aseptically in vacuum tubes (heparinized).

NOTE: For whole blood and plasma specimens, EDTA collection tubes must be used.

White Blood Collection by Phentolamine®

Obtain collection is heparinized specimens, place on EDTA capillary tubes on a clean dry surface.

1. Choose the finger of the middle, ring, or index finger by checking the least painful site and reducing the chance of the finger. Warm the hand as needed until warm; most hands vary in temperature.

2. Clean finger with alcohol to air dry. Prepare the hand grip.

3. Use a blood lactate for each person. Place the lactate on the thumb of the right. Simple the lactate on the thumb of the right. Simple the lactate on the thumb of the right.

4. Place the finger in a horizontal position.

5. Hold the finger by the edge of the finger and apply gentle, intermittent pressure to the base of the puncture site. Squeeze the blood for 0.5 seconds. If no blood is visible, repeat.

6. EDTA Caviity Tube (10mL) will be used, fill the tube with blood between the 2 marked lines (50mL).

SPECIAL STORAGE

Serum and plasma specimens should be stored at 2-8°C if the test is to be run within 7 days of collection. If testing is delayed more than 7 days, the specimen should be frozen (-20°C or colder).

Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 7 days of collection.

Whole blood collected by phentolamine should be tested immediately.

TEST PROCEDURE

The eluted number of test units from the 10-test card can be done by bending and having all the test units.

TEST PROCEDURE

The eluted number of test units from the 10-test card can be done by bending and having all the test units.

NOTES

- Removal of the test units should start from the first site of the test unit to preserve the last number on the test unit and thus the test unit on the left side of the test card. The assay should be performed within 10 minutes after removing the remaining test unit from each test unit.

- The test units should be removed from each test unit.

- For serum or plasma samples:
  - Add 50 mL of serum or plasma sample to the sample pad treated with the amine symbol.
  - After 10 minutes, add one drop of Chaste buffer to the sample pad treated with the amine symbol.

- For whole blood samples:
  - Add 50 mL of serum or plasma sample to the sample pad treated with the amine symbol.
  - After 10 minutes, add one drop of Chaste buffer to the sample pad treated with the amine symbol.

- Place one drop of each reagent to the sample pad treated with the amine symbol.

- After 10 minutes, add one drop of Chaste buffer to the sample pad treated with the amine symbol.
QUALITY CONTROL
To ensure assay validity, a procedural control is incorporated in the device and is labeled "Control." If the control does not react or react falsely, the test result is invalid and the sample should be retested.

INTERPRETATION OF RESULTS
POSITIVE (Thin Bar)
Red bars appear in both the control window (labeled "Control") and the patient window (labeled "Patient") of the strip. Any visible red bar in the patient window should be interpreted as positive.

NEGATIVE (None)
One red bar appears in the control window of the strip (labeled "Control"), and no red bar appears in the patient window of the strip (labeled "Patient").

INVALID (Narrow Bar)
If there is no red bar in the control window of the strip, and even if a red bar appears in the patient window of the strip, the result is invalid and should be repeated.

NOTES:
1. The test result is positive even if the patient bar appears lighter or darker than the control bar.
2. The control may exhibit a weak intensity for some patient samples, particularly those with high HIV.
3. Upon appearance of a narrow bar in the control window, no matter what frond test, the result is considered invalid.
4. If an invalid test result occurs repeatedly, or for technical assistance, contact your local distributor or call Technical Support.

LIMITATIONS OF THE PROCEDURE
1. The *Aureo Determine™ HIV-1/2 Test* is designed to detect antibodies to HIV-1 and HIV-2 in human sera, plasma, and whole blood. Other body fluids or pooled specimens may not give accurate results.
2. The intensity of the patient bar does not necessarily correlate to the titre of antibody in the specimen.
3. A negative result with *Aureo Determine™ HIV-1/2* does not exclude the possibility of infection with HIV. A false negative result can occur in the following circumstances:
   - Low levels of antibody (e.g., early seroconversion specimens) are below the detection limit of the test.
   - Infection with a variant of the virus that is not detectable by the *Aureo Determine™ HIV-1/2* assay configuration.
   - Antibodies in the patient that do not react with specific antigens utilized in the assay configuration.
   - Specimen handling conditions which result in loss of HIV antibody multivalency.
4. For these reasons care should be taken in interpreting negative results. Other clinical data (e.g., symptoms or risk factors) should be used in conjunction with the test results.
5. Positive specimens should be released using another method and the results should be evaluated in light of the overall clinical evaluation before a diagnosis is made.
6. Whole blood or plasma specimens containing anticoagulants other than EDTA may give incorrect results.
7. Nevirapine- or efavirenz-resistant HIV-infected patients may carry maternal antibodies to HIV for up to around eighteen months, which may not necessarily indicate the true infection status of the neonate.

PERFORMANCE CHARACTERISTICS
SPECIFICITY
A total of 1015 serum and plasma specimens from Asia, West Africa, and North America were tested by *Aureo Determine™ HIV-1/2* and were commercially available test (Table I).

<table>
<thead>
<tr>
<th>Specitivity of <em>Aureo Determine™ HIV-1/2</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
</tr>
<tr>
<td>Number of Specimens Tested</td>
</tr>
<tr>
<td>Seemagative Sera</td>
</tr>
<tr>
<td>Plasma</td>
</tr>
<tr>
<td>Pregnant Females</td>
</tr>
<tr>
<td>West African</td>
</tr>
<tr>
<td>Disease Statuses Other than HIV and Potentially Interfering Substances</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

**One specimen from a pregnant female and an HIV positive patient were positive by both *Aureo Determine™ HIV-1/2* and the commercially available test. Both specimens confirmed positive by HIV-1 Western blot.**

***45% specimens were from North America, 1080 specimens were from Asia, and 49 specimens were from Africa.***

***The reference method of a commercially available test is used for purity assessment.***

A total of 3660 sera and plasma specimens from North America, Asia, and Africa were tested by *Aureo Determine™ HIV-1/2* and commercially available tests (Table II). The specimens from North America, Asia, and Africa of 2119 specimens from Africa referred to as “West Africa” in Table II were included in Table I. Discordant specimens were confirmed negative by either Western blot or HIV-1 PCR assays.

<table>
<thead>
<tr>
<th>A Comparison of <em>Aureo Determine™ HIV-1/2</em> Specificity by Geographical Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
</tr>
<tr>
<td>Number of Specimens Tested</td>
</tr>
<tr>
<td>North America</td>
</tr>
<tr>
<td>Asia</td>
</tr>
<tr>
<td>Africa</td>
</tr>
</tbody>
</table>

The reference method of a commercially available test is used for purity assessment, enzyme immunoassay and chemiluminescent immunoassay.
**Determine™ Chase Buffer**

**Key to symbols used/Používané symboly/Symbolförklaring/Erläuterung der verwendeten Symbole/Примечание:**

- **Symbol:** Indicates use of chase buffer in vitro.
- **Symbol:** Indicates use of chase buffer in vivo.
- **Symbol:** Indicates use of chase buffer in vitro.
- **Symbol:** Indicates use of chase buffer in vivo.

**Contents**

- **1 Bottle** (2.5 mL) Chase Buffer prepared in phosphate buffer.
- **Preservatives:** Antimicrobial Agents.

**Storage Instruction**

Recap and store the chase buffer at 2-30°C to avoid evaporation or spillage.

**Advice Line**

For further information, please contact your distributor, or call Alere Technical Specialists:

- **Africa, Russia & CIS:** Tel: +7 9 9429 683
  Email: ARCCISproductsupport@alere.com
- **Asia Pacific:** Tel: +61 7 3383 7711
  Email: APproductsupport@alere.com
- **Europe & Middle East:** Tel: +44 161 483 9032
  Email: EMEEuropeproductsupport@alere.com
- **Latin America:** Tel: +57 2 661 8797
  Email: LAAmericaproductsupport@alere.com

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**CZ**

**Název a použití**

Chase buffer je určen pro použití v produkty ladění Determine™.

**Informační Linka**

Pro další informace se obraťte na svého distributora nebo na Alere Technického specialistu:

- **Africa, Rusko a Spolkové státy:** Tel: +7 9 9429 683
  Email: ARCCISproductsupport@alere.com
- **Asie a Tichý oceán:** Tel: +61 7 3383 7711
  Email: APproductsupport@alere.com
- **Evropa a Střední Východ:** Tel: +44 161 483 9032
  Email: EMEEuropeproductsupport@alere.com
- **Latinská Amerika:** Tel: +57 2 661 8797
  Email: LAAmericaproductsupport@alere.com

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**DE**

**Produktbezeichnung und Verwendungszweck**


**Inhalt**

1 Flasche Chase Buffer (2.5 mL)

**Lagerungsvorschriften**

Verpacken Sie den Chase Buffer wieder und lagern Sie ihn bei 2-30°C. Um Verdunstung oder Verschmutzung zu vermeiden.

**Infotelefon**

Weitere Informationen erhalten Sie von Ihrem Vertreiber oder vom technischen Kundendienst von Alere:

- **Afrika, Russland & CIS:** Tel: +7 9 9429 683
  Email: ARCCISproductsupport@alere.com
- **Asien/ Pazifische Inseln:** Tel: +61 7 3383 7711
  Email: APproductsupport@alere.com
- **Europa & Mittelmeerraum:** Tel: +44 161 483 9032
  Email: EMEEuropeproductsupport@alere.com
- **Lateinamerika:** Tel: +57 2 661 8797
  Email: LAAmericaproductsupport@alere.com