REF OD376

VISITECT® CD4 Advanced Disease

Rapid test for the estimation of CD4+ T cells in human whole blood.
Store at 2-30°C. DO NOT FREEZE.
For professional use only.

IVD CE

INTENDED USE

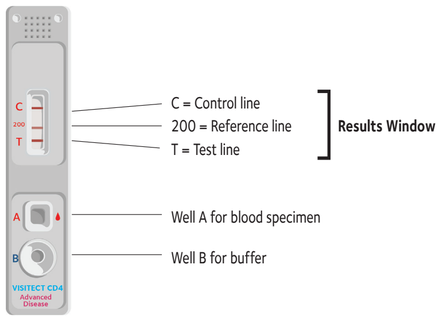
The VISITECT® CD4 Advanced Disease Rapid Test is a manually operated semi-quantitative assay for the estimation of CD4 protein on the surface of CD4+ T cells in human whole blood (capillary or EDTA venous) to indicate whether the level is above or below 200 cells/µL within pre-diagnosed HIV patients.
The VISITECT® CD4 Advanced Disease *in vitro* diagnostic test is for use as an aid in the management of patients with advanced HIV disease (patients with CD4 count below 200 cells/µL). This visually read test is designed to be used at the point-of-care and therefore has utility in decentralised diagnostic settings.
VISITECT® CD4 Advanced Disease is for professional use only.
VISITECT® CD4 Advanced Disease is not intended for individuals <5 years of age.
VISITECT® CD4 Advanced Disease is not intended for use in the determination of HIV status.
VISITECT® CD4 Advanced Disease is not intended for self-testing.

INTRODUCTION

The CD4+ T cell count has made a critical contribution to assessing the immune and clinical status of HIV patients over the last 35 years.[1]
Although the annual number of people dying of AIDS-related causes has reduced, this decline has stalled in recent years due to the challenges of advanced HIV disease, defined by WHO as <200 CD4+ T cells/µL or clinical stage III and IV disease.[2] Patients presenting with advanced HIV disease are at high risk of opportunistic infection and death, the risk increases with decreasing CD4 cell counts.
The role of CD4 cell counts has been re-assessed.[3] Current WHO guidelines for the management of advanced HIV disease recommend a package of care be offered to those presenting with advanced HIV disease depending on age and CD4 cell counts.[2] A HIV patient who has advanced disease requires additional testing and prophylaxis or treatment for opportunistic infections in order to safely initiate ART and decrease risk of death.[4]
The VISITECT® CD4 Advanced Disease *in vitro* diagnostic test is a rapid, instrument-free test, that provides actionable results at the point-of-care. The test provides an estimation of CD4 protein levels associated with T cells and indicates whether the patients' CD4+ T cell count is above or below 200 cells/µL and so HIV disease status.

PRINCIPLE OF THE TEST

The VISITECT® CD4 Advanced Disease Rapid Test is an immunochromatographic assay that estimates full length CD4 protein associated with CD4+ T cells in human whole blood, and is directly correlated with CD4+ T cell levels.
A capture monoclonal antibody (MAb) specific for the cytoplasmic domain of CD4 is applied as a line on the nitrocellulose membrane. Whole blood is added directly to the VISITECT® CD4 Advanced Disease Rapid Test where red blood cells and monocytes are retained in the blood collection pad and following the addition of buffer, other white blood cells (including CD4+ T cells) migrate to a reaction area where cell lysis occurs, resulting in the release of full-length CD4 for capture in the test strip. Colloidal gold-labeled MAb conjugate against CD4 binds the captured CD4 and forms a test line. These complexes are visualised as a pink/purple line. A reference line (200 line) is included to allow estimation of CD4 levels by comparison to a set cut-off (equivalent to the signal level generated by specimens containing 200 CD4+ T cells/µL). The 200 line and control line must be present for the assay result to be valid. The control line in the test device is not a specimen addition control.
The VISITECT® CD4 Advanced Disease test device has a results window where lines will appear.
The ***Control line***, located in the **results window marked "C"**.
The ***Reference line***, located in the **results window marked "200"** exhibits an intensity approximately equal to that seen with a specimen containing 200 CD4+ T cells/µL.
The ***Test line***, located in the **results window marked "T"** exhibits an intensity that correlates to the number of CD4+ T cells in the specimen.
The test result is interpreted by comparing the intensity of the Test (T) line with the Reference (200) line. If the **Test (T) line** has **equal or weaker intensity** than the Reference (200) line, the test result is **"Below Reference"** (**≤200 CD4+ T cells/µL**).
If the **Test (T) line** has **stronger intensity** than the Reference (200) line, the test result is **"Above Reference"** (**>200 CD4+ T cells/µL**).



CONTENTS OF THE VISITECT® CD4 ADVANCED DISEASE KIT

Materials provided:

- 25 foil pouches containing: one test device and one desiccant sachet
- 1 bottle with 7mL buffer containing 0.05% sodium azide
- 25 sampling devices
- 25 sterile retractable lancets
- 25 alcohol swabs
- 1 job aid for venous blood
- 1 job aid for capillary blood
- 1 instructions for use

Materials required, but not provided:

- New pair of disposable gloves
- Timer
- Pen
- Sharps/biohazard bin
- Dry gauze or tissue
- Precision pipette capable of delivering 30µL plus disposable tips (venous blood only)
- EDTA blood collection tube (venous blood only)
- Plaster

KIT STORAGE

The kit will perform within specification until the stated expiry date when stored at 2-30°C out of direct sunlight. Do not use the test device or buffer beyond the date of expiration. Do not freeze.

QUALITY CONTROL

The VISITECT® CD4 Advanced Disease test device contains an internal control which should exhibit a pink/purple coloured line independent of the Test (T) and Reference (200) lines. The Control (C) line must be present for the assay result to be valid. The Control (C) line in the test device is not a specimen addition control. There is no quality control standard available, however it is recommended that a specimen greater than 200 CD4+ T cells/µL (characterised by flow cytometry) is run and three pink/purple lines are visible. It is recommended that such a control is run on a regular basis according to local guidelines.

SPECIMEN COLLECTION AND TEST PROCEDURE

This assay is designed to be used only with peripheral whole blood collected by venepuncture into EDTA tubes or by finger-prick. **Capillary** or **venous blood** is transferred directly into Well A of the device. Read carefully the limitations, warnings and safety and handling precautions within these instructions for use. Long term kit storage is 2-30°C. Assay components must be run at 15-35°C. Place the test device on a horizontal surface.

Preparing for the test

1. Allow the test kit to come to operating temperature (15-35°C) before use. Check expiry on foil pouch and kit components are within date.
2. When you are ready to perform the test, tear open the foil pouch and remove materials. (VISITECT® CD4 Advanced Disease test devices should not be used more than 30 minutes after removal from the foil pouch.) Ensure a desiccant is present and discard. If no desiccant is present discard test device and use another test device. Dispose of all packaging in a general waste bin.
3. Write the patient's name or patient identifier on the test device.
4. Put on the disposable gloves. Use new gloves for each patient.

Specimen collection

5. Proceed to capillary or venous blood sampling, depending on blood collection type.

Capillary Blood Specimen

i. Take a supplied retractable lancet. ⚠ Check the cap seal is not broken before use. Ask the patient which is their non-dominant hand and clean the side of the finger with the alcohol swab where the prick will be performed. Allow the finger to air dry, twist off lancet cap and pierce the skin of the fingertip to the side of the ball of the finger. Dispose of the retractable lancet into the sharps/biohazard bin immediately.
ii. Wipe away the first drop of blood with a piece of dry gauze or tissue and dispose in the sharps/biohazard bin.
iii. Take a supplied sampling device. Gently squeeze the finger until a full drop of blood develops. DO NOT squeeze the finger too hard. Hold the sampling device provided horizontally and touch the tip of the sampling device to the blood specimen. Capillary action will draw blood to the black line (30µL). Do not squeeze the bulb to draw blood into the tube. Use immediately.

EDTA Venous Blood

i. Collect a venous specimen of blood using established techniques. Prepare the precision pipette volume to 30µL and attach a disposable tip.
ii. Mix the EDTA blood specimen by gentle inversion at least 8 times and ensure fully mixed. Open the EDTA blood tube.
iii. Press the plunger button of the pipette to the first stop. Immerse the disposable tip vertically into the EDTA tube. Smoothly release plunger button, drawing the blood into the disposable tip.

Test procedure

6. Touch the centre of **Well A** lightly and squeeze the bulb of the sampling device/depress the pipette plunger gently to ensure the full 30µL specimen is released into **Well A**.
7. Discard the sampling device/disposable tip into a sharps/biohazard bin.
8. Wait for **3 minutes**.
9. Hold the buffer bottle **vertically 1cm above Well A**. Add **1 drop** of buffer to **Well A** where the blood has been added.
10. Wait for **17 minutes**.
11. Hold the buffer bottle **vertically 1cm above Well B**. Carefully add **3 drops** of buffer to **Well B** allowing each drop to absorb into the well before adding the next drop.
12. Wait for **20 minutes**. After the test is complete, interpret the results within **5 minutes.**

INTERPRETATION OF RESULTS

13. Refer to examples of results on reverse.
The Control (C) line and Reference (200) line must be present when reading the test results for the test to be valid. Results are interpreted visually by comparing the colour intensity of the Test (T) line with the Reference (200) line.

Line Intensity	Interpretation of the test result
Test (T) line EQUAL to Reference (200) line	BELOW REFERENCE
Test (T) line MISSING	BELOW REFERENCE
Test (T) line LIGHTER than Reference (200) line	BELOW REFERENCE
Test (T) line DARKER than Reference (200) line	ABOVE REFERENCE
Reference (200) line MISSING	INVALID, REPEAT THE TEST
Control (C) line MISSING	INVALID, REPEAT THE TEST

14. Dispose of test device and gloves in a sharps/biohazard bin.

LIMITATIONS

- VISITECT® CD4 Advanced Disease is not intended for individuals less than 5 years of age.
- EDTA blood specimens must not be used more than 24 hours post collection when stored at 2-30°C.
- The presence of the Control (C) line only means that flow of the test has occurred. It does not guarantee that:
  i. the correct specimen has been used
  ii. the specimen has been applied correctly
  iii. the specimen and test have been correctly stored
  iv. the test procedure was followed correctly
- There is no re-use protocol for this product.
- VISITECT® CD4 Advanced Disease test devices should not be used more than 30 minutes after removal from the foil pouch.

WARNINGS

- Read the instructions carefully before performing the test. Failure to follow the instructions may lead to inaccurate test results.
- Use of any other buffer or fluid except the buffer supplied with the kit will invalidate the results.
- Do not use the kit beyond the expiry date.
- Do not use if any kit components are damaged.
- ⚠ Check the lancet cap seal is not broken before use.
- Do not use if the product has been exposed to excessive heat or humidity.
- Check for the presence of a desiccant immediately after opening the pouch. If no desiccant is present, do not use the test device and discard as appropriate.
- The test device, alcohol swab, lancet and sampling device are each intended for single use only.
- For finger-prick specimens, the use of any other sampling device except the sampling device supplied with the kit will invalidate the results.
- The use of specimens other than capillary or EDTA whole blood specimens have not been validated in this test.
- Clinical decisions should not be made solely on the findings of one test. When making an interpretation of the test all clinical data should be taken into consideration.
- Do not touch the test strip within the test device with your fingers.
- Do not use haemolysed, lipemic, coagulated or frozen bloods.
- No other anticoagulants other than EDTA can be used as they may give incorrect results.

SAFETY AND HANDLING PRECAUTIONS

- Safety Precautions
  i. Handle all specimens as potentially infectious.
  ii. Wear gloves and protective clothing while handling specimens and running the test.
  iii. Do not smoke, eat or drink while handling specimens or performing the test procedure.
  iv. Apply standard biosafety precautions for handling and disposal of potentially infective material. Dispose of all packaging in a general waste bin.
  v. Avoid splashing and aerosol formation.
  vi. Clean up spills thoroughly using an appropriate disinfectant.
- Handling Precautions
  i. Do not use if any kit components are damaged.
  ii. Do not use if the desiccant package is missing or damaged. Discard device and use a new test.
  iii. The test device, alcohol swab, lancet and sampling device are each intended for single use only.
  iv. Do not use kit components beyond the expiry date printed on the label. Always check expiry date prior to testing.
  v. Adequate lighting is required to read a test result.
  vi. All reagents and used test device should be treated as potential biohazards in use and disposal. Final disposal must be in accordance with local legislation. Do not ingest.
  vii. VISITECT® CD4 Advanced Disease buffer contains 0.05% sodium azide as a preservative which may be hazardous to health if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.

PERFORMANCE CHARACTERISTICS

Performance Evaluation Data

All performance evaluations were carried out by hospital clinic sites.
Sensitivity: specimens ≤200 cells/µL correctly identified against Flow Cytometry (95% confidence intervals)
Specificity: specimens >200 cells/µL correctly identified against Flow Cytometry (95% confidence intervals)

VISITECT® Batch 1

VISITECT® CD4 Advanced Disease performance evaluation with venous blood performed in India (n=245).

Sensitivity (44/51)	**86.3%** (73.7% - 94.3%)
Specificity (180/194)	**92.8%** (88.2% - 96.0%)

Category (cells/µL)	≤100	101-200	201-350	351-500	>500
Correctly classified	100%	63%	75%	98%	100%

VISITECT® Batch 2

VISITECT® CD4 Advanced Disease performance evaluation with capillary blood performed in India (n=144).

Sensitivity (25/29)	**86.2%** (68.3% - 96.1%)
Specificity (109/115)	**94.8%** (89.0% - 98.1%)

Category (cells/µL)	≤100	101-200	201-350	351-500	>500
Correctly classified	100%	81%	74%	100%	100%

VISITECT® Batch 3

VISITECT® CD4 Advanced Disease performance evaluation with capillary blood performed in Zimbabwe (n=145).

Sensitivity (25/27)	**92.6%** (75.7% - 99.1%)
Specificity (107/118)	**89.8%** (82.9% - 94.6%)

Category (cells/µL)	≤100	101-200	201-350	351-500	>500
Correctly classified	100%	80%	67%	100%	94%

Other external test results

VISITECT® CD4 Advanced Disease test performance at several clinical sites in the UK, Zimbabwe and India with 1232 venous blood specimens demonstrated a sensitivity of 92% (88.0%-95.1%) and a specificity of 89.5% (87.4%-91.4%)

Category (cells/µL)	≤100	101-200	201-350	351-500	>500
Correctly classified	97%	87%	60%	92%	99%

Repeatability

Within run repeatability of the VISITECT® CD4 Advanced Disease test was determined by running ten replicates with an above and below reference specimens on one batch of devices by a single operator. All results were identified correctly 100% of the time.

Reproducibility

Within run reproducibility of the VISITECT® CD4 Advanced Disease test was determined by running three replicates with an above and below reference specimens on one batch by three operators in three separate locations.
Between batch reproducibility of the VISITECT® CD4 Advanced Disease test was determined by running ten replicates with an above and a below reference specimens on three batches of test devices. All results were identified 100% of the time.

Interfering Substances

No interference in the performance of the VISITECT® CD4 Advanced Disease was evident when above and below reference blood specimens were spiked with the following endogenous interferents: Bilirubin (conjugated) up to 30µmol/L, Bilirubin (Unconjugated) up to 48µmol/L, Total Protein up to 120mg/mL, Lipids up to 37mmol/L, Rheumatoid Factor up to 100IU/mL and Haemoglobin at 2g/L. Additionally, no interference was observed with Biotin at 50ng/mL, Soluble CD4 at 12ng/mL, Human Anti-Mouse Antibody at 300ng/mL and Monocytes up to 1000cells/µL.

SYMBOL LEGEND

The following symbols may have been used within the labelling of this product.

CE	This product fulfils the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices.	Harmful	
LOT	Batch code	IVD	*In vitro* diagnostic medical device
	Biological risks		Keep dry
REF	Catalogue number		Keep away from sunlight
	Caution		Manufacturer
	Consult instructions for use	SN	Serial number
Σ	Contains sufficient for "n" tests	STERILE R	Sterilised using irradiation
	Date of manufacture		Temperature limit
	Do not re-use		Use-by date

REFERENCES

1. D Barnett et al. CD4 immunophenotyping in HIV infection. Nat Rev Microbiol. 2008; 6: S7-S15.
2. World Health Organization. Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy. Geneva, Switzerland: WHO, 2017.
3. N Ford et al. The evolving role of CD4 cell counts in HIV care. Curr Opin HIV AIDS. 2017;12: 123-128.
4. N Ford et al. Managing Advanced HIV Disease in a Public Health Approach. Clin Infect Dis. 2018; 66: (S2): S106-S110.

8376 V6 JULY 2020
OMEGA DIAGNOSTICS LTD.
Omega House
Hillfoots Business Village
Alva FK12 5DQ
Scotland, United Kingdom
+44 (0)1259 763030
odl@omegadiagnostics.co.uk
www.omegadiagnostics.com
AN ISO 9001 AND ISO 13485 CERTIFIED COMPANY

MATERIALS PROVIDED

TEST DEVICE AND DESICCANT

SAMPLING DEVICE **(FOR CAPILLARY BLOOD COLLECTION ONLY)**

BOTTLE CONTAINING BUFFER

ALCOHOL SWAB

STERILE RETRACTABLE LANCET

MATERIALS REQUIRED, BUT NOT PROVIDED

DISPOSABLE GLOVES

TIMER

PEN

SHARPS/ BIOHAZARD BIN

DRY GAUZE OR TISSUE

PRECISION PIPETTE CAPABLE OF DELIVERING 30µL PLUS DISPOSABLE TIPS **(VENOUS BLOOD ONLY)**

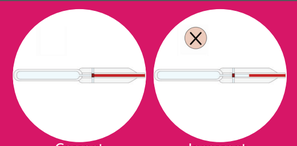
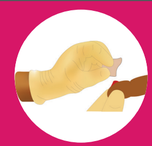
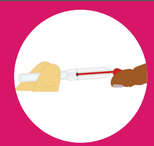
EDTA BLOOD COLLECTION TUBE **(VENOUS BLOOD ONLY)**

PLASTER

COLLECT ALL THE REQUIRED MATERIALS BEFORE STARTING THE TEST. READ INSTRUCTIONS CAREFULLY

Do's and Don'ts

DO NOT RE-USE THE TEST

BUFFER BOTTLE	SAMPLING DEVICE	FINGER WIPE	BLOOD DRAW
 Correct Incorrect	 Correct Incorrect	 Do not wipe first drop of blood with alcohol swab but with a piece of clean dry gauze or tissue	 Do not squeeze bulb of sampling device to draw the blood

PREPARING FOR THE TEST

1 Check expiry on foil pouch, and that kit components are within date and are at operating temperature (15–35°C) before use.

2

Tear open foil pouch and remove materials.

Discard desiccant sachet.

Dispose of all packaging in a general waste bin.

3 Write patient's identifier on device.

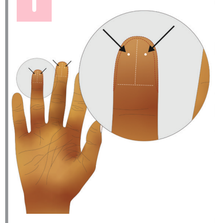
4 Put on a new pair of disposable gloves.

SPECIMEN COLLECTION

5 Proceed to capillary or venous blood sampling, depending on blood collection type.

CAPILLARY

i

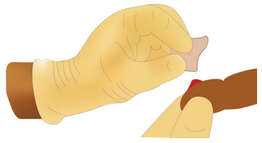


Ask patient which is their non-dominant hand, clean side of finger with alcohol swab where prick will be performed.

Allow finger to air dry, twist off lancet cap and pierce skin of fingertip to the side of the ball of the finger.

Dispose of the retractable lancet into a sharps/biohazard bin immediately.

ii Wipe away first drop of blood with piece of dry gauze or tissue, dispose of in sharps/biohazard bin.



iii Gently squeeze the finger until a full drop of blood develops.

Hold sampling device horizontally and touch the tip to the blood specimen. Capillary action will draw blood to the black line (30µL). Do not squeeze the bulb to draw blood into the tube. Use immediately.

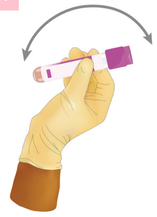
EDTA VENOUS BLOOD

i

Collect venous specimen of blood using established techniques.

Prepare precision pipette volume to 30µL and attach disposable tip.

ii



Mix the EDTA blood specimen by gentle inversion at least 8 times and ensure fully mixed.

Open the EDTA blood tube.

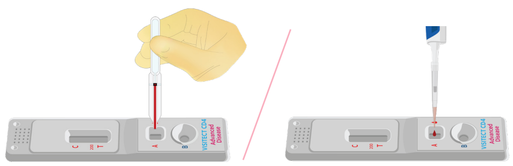
iii

Press the plunger button of the pipette to the first stop.

Immerse the disposable tip vertically into the EDTA tube. Smoothly release plunger button, drawing the blood into the disposable tip.

TEST PROCEDURE

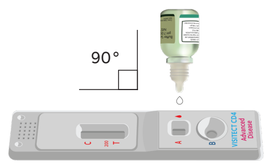
6 Touch the centre of **Well A** lightly and squeeze the bulb/depress the plunger gently to ensure the full 30µL specimen is released into **Well A**.



7 Discard the sampling device/ disposable tip into a sharps/ biohazard bin.

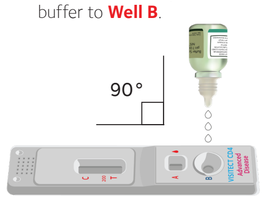
8 Wait for **3 MINUTES**.

9 Hold the buffer bottle vertically 1cm above **Well A**. Add 1 drop of buffer to **Well A**.



10 Wait for **17 MINUTES**.

11 Hold the buffer bottle vertically 1cm above **Well B**. Add 3 drops of buffer to **Well B**.

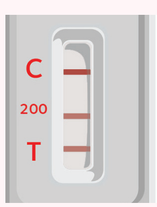


12 Wait for **20 MINUTES**.

Interpret the results within **5 MINUTES**.

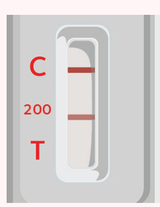
INTERPRETATION OF RESULTS

13 The Control (C) line and the Reference (200) line must be present when reading the test results for the test to be valid. Results are interpreted visually by comparing the colour intensity of the Test (T) line with the Reference (200) line.



Test (T) line EQUAL INTENSITY to Reference (200) line
CD4 count equal to or below 200 cells/µL

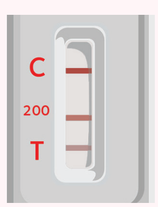
Test result is **BELOW REFERENCE**



Test (T) line MISSING

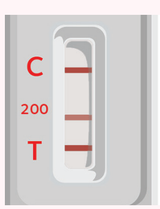
CD4 count below 200 cells/µL

Test result is **BELOW REFERENCE**



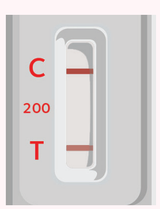
Test (T) line LIGHTER than Reference (200) line
CD4 count below 200 cells/µL

Test result is **BELOW REFERENCE**



Test (T) DARKER than Reference (200) line
CD4 count above 200 cells/µL

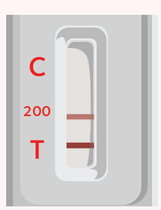
Test result is **ABOVE REFERENCE**



Reference (200) line MISSING

Test result is **INVALID**

Repeat the test



Control (C) line MISSING

Test result is **INVALID**

Repeat the test

14 Dispose of the test device and gloves in a sharps/biohazard bin.

Ordering Information

Part number: OD376

Description: VISITECT CD4 Advanced Disease

Tests per kit: 25

Sample type: Whole blood

CE-marked: Yes

Omega Diagnostics

Omega House, Hillfoots Business Village,
Alva, FK12 5DQ, Scotland, United Kingdom

+44 (0) 1259 763 030
odl@omegadx.cm
www.omegadx.com

CE

A subsidiary of Omega Diagnostics Group PLC
AN ISO 9001 AND ISO 13485 CERTIFIED COMPANY

14376 V2 DECEMBER 2021

Burnet Institute
Medical Research. Practical Action.

VISITECT® CD4 ADVANCED DISEASE

Supporting the identification of advanced disease in people living with HIV

Informing decisions
Improving health

Omega Diagnostics

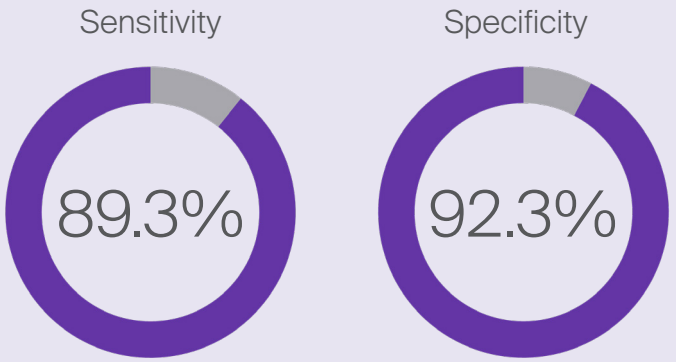
VISITECT® CD4 Advanced Disease supports the identification of advanced disease in people living with HIV

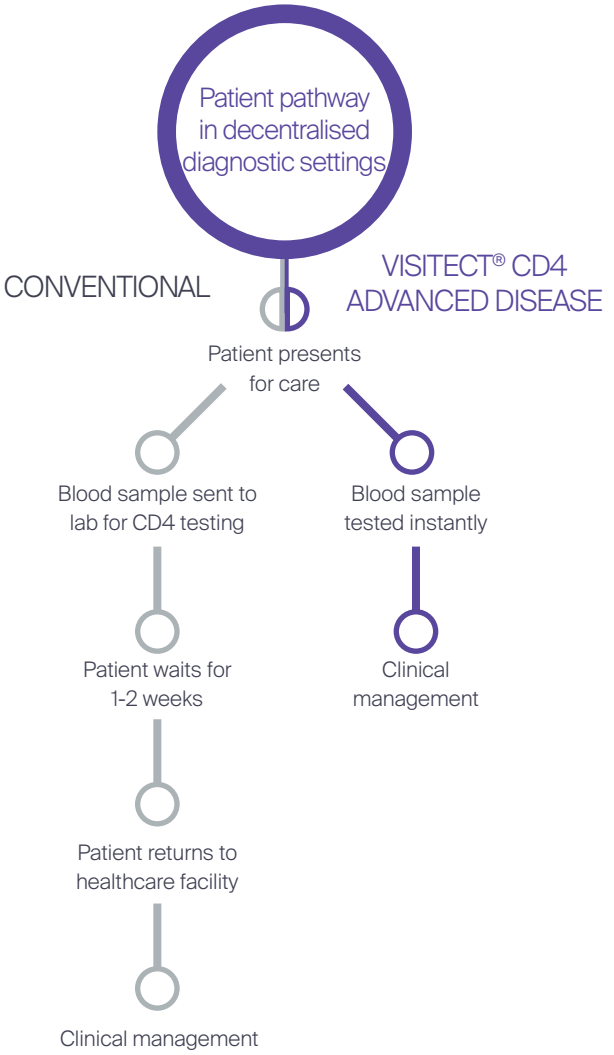
VISITECT® CD4 Advanced Disease is a unique, instrument-free, rapid and disposable CD4 test.

CD4 remains the best measurement of a patient's immune and clinical status, identifying those at risk of opportunistic infections (OI), and supporting diagnostic decision-making, particularly for patients living with advanced HIV disease.[1]

VISITECT® CD4 Advanced Disease is a rapid, semi-quantitative lateral flow assay for the estimation of CD4 protein on the surface of CD4+ T cells in human whole blood that indicates whether the level is above or below 200 cells/µL. It can be used in decentralised settings at the point-of-care or primary healthcare level.

Performance data with capillary samples[2]





VISITECT® CD4 Advanced Disease benefits people living with HIV and healthcare providers

Accelerate clinical disease management

Faster decision-making, reduce burden on healthcare workers

Reduce patient loss to follow-up

Improve patient retention

Test anywhere, anytime

Convenient, disposable and read by eye

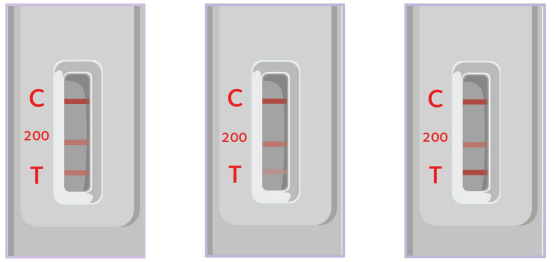
Reduce costs

Zero investment in equipment, no sample transport required

Improve patient outcomes

Patients with advanced HIV disease targeted for OI investigations earlier

Test Interpretation



References

1. N Ford et al. The evolving role of CD4 cell counts in HIV care. Curr Opin HIV AIDS. 2017; 12: 123-128
2. VISITECT® CD4 Advanced Disease performance compared to flow cytometry in two studies conducted in India (n=144) and Zimbabwe (n=145) using finger-prick blood. 95% Confidence Intervals.

EC Declaration of Conformity (Directive 98/79/EC)

Manufacturer Omega Diagnostics Ltd., Omega House, Hillfoots Business Village, Alva, Clackmannanshire, FK12 5DQ, Scotland, United Kingdom

Manufacturer Identification Code: 0000000024

Competent Authority: Medicines and Healthcare Products Regulatory Agency, Competent Authority GB / CA 01

European Authorised Representative: EMERGO EUROPE, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands

Product Details: See EC Declaration of Conformity List (attached)

Classification: General IVD (others)

Conformity Assessment Route: Annex III IVDD

We hereby declare the devices named in the EC Declaration of Conformity List (see attached) comply with the requirements of DIRECTIVE 98/79/EC, on in vitro diagnostic medical devices.

Standards Applied: EN ISO 9001:2015, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN 13612:2002 EN 23640:2015 and EN 13641:2002.

Signed: 

Name: Angela Robertson
Position: Group Regulatory Affairs Director
Place: Omega Diagnostics Ltd., Omega House, Hillfoots Business Village, Alva, Clackmannanshire, FK12 5DQ, Scotland, United Kingdom
Date: 19 March 2021

EC Declaration of Conformity List

GMDN Classification	Description	Product Product Code - Test Size
63165	CD4 cell marker IVD, kit, immunochromatographic test (ICT), rapid	VISITECT® CD4 Rapid Test OD296 - 25 Tests OD296N - 25 Tests OD296R - 25 Tests VISITECT® CD4 Advanced Disease Rapid Test OD376 - 25 Tests OD376N – 25 Tests
64956	SARS-CoV-2 immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, immunochromatographic test (ICT), rapid	VISITECT® COVID-19 IgM/IgA/IgG OD910 - 25 Tests
64787	SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid	VISITECT® COVID-19 Antigen OD930 – 25 Tests

Lloyd's Register

Current issue date:	3 November 2020	Original approval:
Expiry date:	31 October 2023	ISO 13485 - 25 January 2017
Certificate identity number:	10303971	

Certificate of Approval

This is to certify that the Management System of:

Omega Diagnostics Limited

Omega House, Hillfoots Business Village, Alva, FK12 5DQ, United Kingdom

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number: ISO 13485 – 00007203

The scope of this approval is applicable to:
Design, manufacture, contract manufacturing, marketing and sale of in vitro diagnostic test kits and reagents.

David Derrick

Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001